1.0 Purpose

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

2.0 Scope

This procedure covers audit planning, execution of audit, and reporting of all types of audits as listed below as well as the suspension, withdrawal, and reduction process:

- Stage 1 audit.
- Stage 2 audit.
- Follow up audit.
- Surveillance audit.
- Transfer audit.

3.0 Responsibility

3.1 The Quality Manager is responsible for planning the audit and ensuring the audit reports are received timeously by the office and review of the audit reports. As well as the review of any documentation surrounding the need for suspension, reduction, or withdrawal of a certificate to a client.

3.2 **Audit Team Leaders/ Auditors are** responsible for the execution of audits preparation of an audit and submitting the audit reports and non-conformances.

4.0 Description of Activity

4.1 Introduction

The objective is to provide consistent service delivery norms. Audit Team leaders are auditors responsible for ensuring the objectives of their assigned audits are fully met. The various activities needed to be carried out are –

- **Stage 1 Audit.**
- **Stage 2 Audit.**
- **Follow-up Audit.**
- **Surveillance Audit.**
- **Triennial Audit.**
- **Special Visit**

4.2 Audit Visits

4.2.1 The purpose of the audit visits is to provide reasonable assurance that the auditee organisation quality management system conforms to the requirements of the standard being 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 organisation activities.

The Quality Manager or their designee is responsible for the selection of the audit team, using Auditor Qualification Summary. Unless required for technical reasons and logistics, care shall be taken to ensure that the same auditor does not visit the client for 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 the Quality Manager. The Quality Manager shall review the same and take the necessary decision, which may include replacing the person with another auditor.

4.2.2 The team leader leads the audit following the referenced instructions. A set of updated documents about the previous client audit, i.e. the client details, open non-conformances, surveillance plan, and comments from prior visits as applicable, is provided to every audit team. Activities include the opening meeting with the auditee organisation, team briefings, audit interviews, non-conformance issuance, auditee organisation briefings, and the closing meeting with the auditee organisation. The team leader issues an audit report reflecting the recommendations concerning registration based on the team findings.

If non-conformances are 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 requirements not having been followed, the auditor will communicate their findings to the team leader who in turn will notify the auditee organisations management of the violation. The auditor will further investigate the same and check as to why the auditee organisations management has failed to detect and address the issue. When, after proper investigation, the auditee organisation management system has shortcomings/ the infringement of the applicable standard is established, a major/minor non-conformance as appropriate will be raised. Follow-up visits are made to verify that major non-conformance (s) are effectively remedied before registration is granted. In the case of legal/statutory/regulatory requirements by the auditee organisation, the following policy shall apply:

In the event of the auditee organisation conducting a valuation of the legal requirement, the auditee organisation, as part of the rules and regulations of Zolabix (Pty) Ltd Certification, will inform Zolabix (Pty) Ltd on its own pro-actively and voluntarily. This proactive information communicated by the auditee organisation is not to be confined to onsite-audit activities but applies to the entire registration period which the auditee organisation is entitled to by way of Zolabix (Pty) Ltd certification. In case of observations of legal requirements that are observed during a Registration Audit (Stage 2 Audit or Surveillance Audit, the Zolabix (Pty)Ltd audit team will notify the auditee organisation management of the observation. Further, the audit team will conduct a proper investigation on the issue and check as to why the auditee

organisation management system has failed to detect and address the same. Based on the investigations of the audit team, if it is so established that the management system has shortcomings/ and infringement of the applicable standard is observed, a major or minor non-conformance note will be issued.

Additionally, the auditee organisation must ensue and provide evidence to that to Zolabix (Pty) Ltd that the appropriate authorities have been notified of the violation of legal requirements as per the prescribed procedure instituted by the relevant authorities.

During the audit, the audit shall be so planned that 60% of the time is spent on auditing critical processes.

4.3 Stage 1 Audit

Stage 1 Audit is a part of the registration process and not an optional activity.

4.3.1 Objectives of Stage 1 Audit

During 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 a review of the available evidence. This evidence may take many forms, and some cases need not be documented.

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, (resources, time allocations) by review of the clients status and understanding regarding the standards w.r.t objectives and operations of the management system, site activities, identification of applicable legislation and licenses are matching with site and activities of the auditee organisation, discussion with clients 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 discussion 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 locations of the client, and related statutory and regulatory aspects and compliance, e.g. quality, environment, legal aspects of the client's operation, and associated risks.

- To review the allocation of resources for a stage 2 audit and agree with the client on the details of the stage 2 audit.

- To provide a focus for planning and 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 audit and management system substantiates that the client is ready for the stage 2 audit.

For companies requiring transferring from another certification body

- If the company has an accredited certificate by another body, then the auditors need only carry out a partial Document Review from the Zolabix (Pty) Ltd offices.

- If the company has a non-accredited certificate, then the Zolabix (Pty) Ltd standard procedures must apply in full.

4.3.2 Stage 1 audit is intended to:

- Assess that the auditee has a document management system, which is compliant with the applied standard.

- Ensure that the EMS includes an adequate process for the identification of environmental aspects, impacts, and determination of their significance.

- Ensure that the system includes a procedure for the identification of applicable regulatory requirements and that all the required environmental licenses, permits, and approval are in place.

- Ensure that the management system is designed to achieve defined policy, objectives, and targets.

- Establish that internal audits conform to the requirements of the respective standard and that the internal audits are effective and relied upon. Seeding evidence for competence, experience, training, and independence of internal auditors; auditing procedure & methodology; reference & standards; resources availability; organisation & planning of audits; checks & reports; timeliness & effectiveness of corrective action and management of audit follow-up.
- Establish that management reviews are conducted and cover continuing suitability, adequacy, and effectiveness of the management system.
- Establish that relevant communication from customer / 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 organisation business activities.
- Confirm the auditee organisation readiness for stage 2 audit.
- Obtain information about the auditee organisation 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 organisation.
    - Applicable statutory requirements and Licenses.
    - Technology expertise necessary.

- Prepare a detailed program including audit trails for upcoming Stage 2 audit.
- Review the adequacy of audit time for stage 2 audit. Increase the time duration if required based on the findings of the audit; complexity/volume of processes; variation found from the data provided by the client in the F025 questionnaire.

4.3.3 When carrying out a review, the auditor shall note his/her finding in the Stage 1 audit report and record this against the relevant topic if such fails to satisfy the requirement of the standard. 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 part of the Stage 1 audit and include at least the following:

- Documentation including procedures with links to related requirements of the respective standard. If the client has integrated systems (QMS, OHSMS), the documentation shall be reviewed with regard to interfaces with other systems.
- The documentation must have been issued and would normally have been in place for a minimum of three months.
- Description of the organisation and its on-site processes
- Environmental aspects impact and determination of significant aspects (for Ems).
- Means and system for realizing continual improvement.
- An overview of applicable regulations and agreements with authorities.
- An internal audit program identified nonconformities and records
- Records of incidents, breaches of regulation, and relevant correspondence and EMS-related communication with the action taken

- Records for management review.
- Details of identified nonconformities and corrective action taken in the past 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 Stage 2 Audit may be delegated to the other audit team members. The process of the Stage 1 audit can be briefly described as follows:

1) The Quality Manager advises the concerned auditor/team leader of the assignment.
2) The team leader prepares the audit schedule and contacts the client normally a week before the planned audit date. The audit schedule contains the auditors' names. Auditors' background details are provided to the client upon request.
3) An opening meeting is held to put the auditee organisation at ease, advise them of the objectives of the document review, and obtain the auditee organisations cooperation.
4) Generally, only one person is required to perform the Stage1 audit, but where a team is used, or an auditor under training is present, then a team briefing may be necessary.
5) To prepare the detailed program of the audit, a tour of the facility to provide familiarisation with the auditee's organisation is essential.
6) The main objective is to review the auditee's organisations readiness concerning the points listed above. Documents are reviewed only to the level necessary to establish compliance with the relevant standard. A record of document reviews is made.
7) The auditor shall review for any discrepancy in any information provided in the questionnaire and contract review. This shall be reviewed by the Managing Director and may result in changes in man-days assigned for the contract.
8) An auditee debrief meeting is held to discuss the audit findings and obtain further information necessary to decide on further action.

9) The findings are collated, and an audit report is prepared for handing over at the closing meeting. Based on the findings. A recommendation is made to proceed/defer/ cancel the registration. The auditor shall explain the reason for considering the documentation or system unsatisfactory. In the case of many or larger issues, the stage 1 audit may need to be carried out again. This shall be discussed with the auditee, and a suitable date will be decided. This may require working out an amendment to the contract.

10) The visit ends with a closing meeting where the points agreed with the auditee organisation are confirmed. The Scope of Registration for the audit is confirmed. The audit report is handed to the auditee organisation and a copy is forwarded to the head office for review and processing. The reports will also include the audit program detailing expected times and duration for an audit of each activity.

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

12) The Stage 2 audit shall be conducted within three months of a stage 1 audit. Any further delay shall require a stage 1 audit to be carried out again. There is no restriction on minimum time duration; however, the general practice is at least seven days depending on the findings of the stage 1 audit and client's readiness.

4.3.5 Nonconformity and sentencing of major and minor non-conformances – QMS.

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

4.3.5.1 During an audit a minor non-conformity shall be deemed present with any activity that 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 minor (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, where there is a complete failure to fulfill 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 serious cumulative numbers of minor non-conformities are found overall, or when there is a complete lack of system control. Several non-conformities may be grouped as one major non-conformity.

4.3.5.3 If all non-conformities have been rectified within three 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 Managing Director. If on a follow-up visit, it is found that the major non-conformities have not been satisfactorily addressed, then another visit is to be made within two weeks. If this fails, then a full re-audit must take place. All visits will be charged at the standard rate, and the client shall be invoiced. The Quality Manager will confirm the time and auditors for the closeout visit and will advise the Managing Director about the invoicing.

4.3.5.4 In all cases of "follow-up", the auditor must complete a continuation sheet indicating the areas covered. Head the sheet "Closeout Visit". Any small points not fully closed out may be re-raised as minor discrepancies at the discretion of the Lead Auditor. After a "follow-up" visit, the audit report will be completed again by the auditor. Clients whose systems are rejected on initial audits and are accepted on the "follow-up" partial audit, may have surveillance visits set at one extra to that stated on the Contract Review for the first year of registration. This decision will be at the discretion of the Lead Auditor and is based on the severity of the major non-conformances. The time (half-day minimum) for the "follow-up" partial re-audit is indicated by the Lead Auditor on the audit report, along with the suggested re-audit date.

4.4 Stage 2 Audit

The objective of the Stage 2 audit is as follows:

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

b) To confirm that the management system of the auditee organisation conforms to all the requirements of the current version of the respective standard (s), normative documents, and achieving the organisation's policies and objectives.

c) To evaluate compliance with the applicable legal and regulatory requirements

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

- Assess that the auditee organisation quality management system has been implemented and objective evidence is available to demonstrate its practical 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.

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 and other requirements.
- Inconsistencies between the organisational policy, objectives, and targets and its procedure to achieve them or the results of their application. The stage 2 audit team shall appreciate that it is for the organisation to define how its policy commitment to continual improvement and customer satisfaction is achieved and to develop processes for achieving/measuring performance.
- Auditee's procedure and application for investigation/development of opportunities for improvement and programs for improvement.
- Operational control to maintain consistent performance and compliance with procedures.
- Performance monitoring, measuring, reporting, and reviewing against the legislative requirements, objectives, and targets.

- Internal auditing, identification/evaluation of non-conformities and completion of effective corrective action.
- Management review and management responsibility for the quality management system.
- Interfaces and links between policy, aspects and impacts, objectives and targets, responsibilities, programs and procedures, performance data, internal audit, and management review.
- Seeking evidence for competence, experience, training, and independence of internal auditors; auditing procedure & methodology; reference & standards; resource availability; organisation & planning of audits; checks & reports; timelines & effectiveness of corrective action and management of audit follow-up.
- Staff awareness of standard requirements.

4.4.3 Process Steps for Stage 2 Audits

1) The Quality Manager or designee 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. On receiving the audit schedule from the Quality Manage, the TL discuss the logistics and audit plan with the auditee organisation. TL prepares the audit plan and contacts the client, usually a week before the planned audit date, and the same is agreed upon before the audit. In case of any changes required by the client, the same is captured as part of the Incident Report and the necessary action taken. In case of any changes in the audit plan during the audit, the same is captured as part of the audit report. Auditor background details are provided to the client upon request.
2) During the audit planning, specific guidelines and audit trails are used to identify critical processes. At least 60% of audit time shall be used for critical auditing processes.
3) Where the assignment is complex, (multi-site, has specific technical requirements, and /or utilises 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 the stage 2 audit, details of the audit and schedule is obtained from the auditee organisation cooperation.

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

6) Changes to the auditee organisation documentation since the previous visit is reviewed, and outstanding non-conformance (s) are followed up. The auditee organisation's quality management system is assessed according to the schedule and audit trails identified during the stage 1 audit. Documents reviewed, personnel interviewed, and other pertinent data is recorded in the auditor's notepad. Non-conformances are raised after the 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 of non-conformance are not reflected as observations and vice versa. The recording of observations will strictly be confined to areas of improvement only.

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

8) On the final day of the audit, the team discussed the overall performance during the audit, review the stage 1 report, and prepare the audit report (F32). The team's decision to approve or defer registration is recorded in the report. A program for the next visit is also prepared (follow-up visit/surveillance plan) An organisation can be recommended only if no major non-conformances are found. In case of a major non-conformance, a complete/limited audit is necessary, and the audit time requirement is estimated by the auditor in discussion with the Managing Director. The audit schedule for the special audit is detailed and agreed upon with the client.

9) The visit ends with a Closing Meeting where the recorded findings and team recommendations are formally presented to the auditee

organisation and any follow-up action is agreed upon. The auditee submits the corrective action plan for all non-conformances issued. During the Closing Meeting, the Team Leader informs the client to submit the evidence of Corrective Action to be taken for review and closure of any Minor non-conformances identified. In the case of major non-conformances identified, the client is informed whether an additional full audit or an additional limited audit is necessary depending on the impact of the major non-conformances identified.

10) The report (F32) is submitted to the Managing Director and Account Executive for processing. The Managing Director and the Account Executive will review the report, whereby the Managing Director will submit the same to the auditee organisation. The program for the next visit and auditors' notes is set out in the report. Stage 2 audit reports issued are also returned to the Managing Director and Account Executive. The audit- trails are private notes strictly for the use of the auditor to carry out the audit, and the team leader shall ensure that they are never given to the Auditee Organisation.

11) The report is submitted only after satisfactory verification of corrective actions taken for the non-conformance (s). The client shall submit evidence of corrective action taken within three months of the audit. Failure to satisfy closure shall result in a complete re-audit.

4.5 Follow-up Audit (FA)

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

4.5.2 The team leader will plan and determine the type of follow-up that is required. An off-site follow-up may be conducted when the corrective action can be objectively evaluated based on documented evidence sent to Zolabix (Pty) Ltd by the auditee organisation. If the follow-up audit is not performed within three

months of the Stage 2 audit, a partition re-audit must be performed (the time required shall be about 50% of the Stage 2 audit). A completed re-audit will be carried out if the follow-up audit is not performed within six months.

4.5.3 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 Registration Committee. Quality Manager initiates withdrawal/suspension procedures if the auditee organisation fails to respond to a corrective action request effectively or if the corrective action is not satisfactory. The audit report for the Follow-up audit shall be the same as for the stage 2 audit.

4.6 Surveillance Audit (SA)

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

4.6.1 SA is intended to:

- Assess that the auditee organisation registered quality management system has been maintained.
- Verify that changes to the quality Management system, after the previous visit are following the respective standard and that objective evidence is available to substantiate implementation.
- Reconfirm that the quality management system is appropriate to the auditee organisation's product, process, or service provided, with the capability of managing and improving performance.
- Promote the effectiveness of the quality management system.
- Assess major changes in auditee organisations operations, and the technology that could affect the certification /registration.

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

- Changes to a documented system;

- Legal, regulatory compliance.
- Internal audits.
- Documented control.
- Management responsibility & review.
- Use of certificate and logo.
- Corrective action.
- Achievement of objectives and continual improvement.

- Appeals/complaints/communication from external interested parties.
- Effectiveness of a quality management system to achieve auditee organisation policies, objectives, and targets.
- Progress of the planned activities and continuing operation.
- Follow up on identified non-conformities (internal & certifying body)

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

4.6.3 Process Steps for Surveillance Audit

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

1) The Quality Manager or designated person schedules the audit and informs the Audit team leader (TL). Care is taken that the audit is scheduled within 12-month intervals – the date being the last day of the Certification Audit. A set of necessary documents like client details, earlier audit reports etc. is given to TL. On receiving the audit schedule from the QM, the TL discusses the logistics and audit plan with the auditee organisation.

2) The TL shall review the functions /processes audited in the earlier surveillances before finalising the audit plan. TL shall ensure that all critical processes are audited at least twice and the rest at least once in the three years.

3) Where an assignment is particularly complex (i.e. begins at several different locations, has technology requirements, and or utilises many team members, etc.), it may be beneficial to call a team briefing sometime before the scheduled surveillance date to coordinate the details.

4) An opening meeting is held to advise the auditee organisation of the objectives of the audit, and details of the audit, and schedule and obtain auditee organisation cooperation. An auditee brief may be conducted if the 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 organisation documentation since the previous visit is reviewed, and outstanding non-conformances are followed up. The scope of certification 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 Quality Manager or appointed person for further consideration.

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

7) On the final day of the surveillance, the team discusses the overall auditee organisation performance and determines the recommendation

(registration to continue or follow-up is required). The team prepares the audit report (F32). The team's decision is recorded on the Audit report. Areas to be reviewed at the next visit are also detailed.

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 action is agreed upon. The Record of Findings is handed to the auditee organisation and a copy is forwarded to the Managing Director 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 is covered over three years by surveillance. At each visit compliance, audit registration marks, documentation changes done evidence of improvement will be reviewed.

Any auditee organisation must notify Zolabix (Pty) Ltd in writing of any major changes in the management system and or the scope of activities. The quality Manager decides if the verification of changes can be assessed during the next surveillance audit or if a special visit must be scheduled. The performance of the special visit shall l be similar to the routine surveillance, and the Quality Manager shall be informal with the assigned auditor to audit the required changes in the system.

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 recommendations from the audit team leader during routine surveillance audits provided that any non-conformity or any other situation may lead to withdrawal or 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.

4.6 Recertification (Triennial Audits)

4.7.1 The purpose of the recertification audit is to confirm the continued and effective management system is followed and the continued relevance and applicability of the scope of certification, commitment to enhance and maintain

overall effectiveness and improvement of the management system and whether the operation of a certified client contributes to the achievement of the client's policy and objectives.

4.7.2 The following steps should be followed with planning a three-year approval visit:

- The planning and extent of the visit follow the accreditation board requirements that were determined at the last surveillance visit. The triennial visit is planned based on the client's performance during the certification period, previous surveillance audit reports, trends in NC raised, complaints received during the period, and corresponding investigations reports, etc.
- Triennial audits may include stage 1 if there is a considerable internal and external change in the QMS, activities, location, and scope of certification.
- During recertification audit planning, OD shall ensure auditor rotation in case the complete cycle is carried out by the same auditors as the Team Leader.
- The triennial audit shall include a review of effectiveness and improvements in the QMS performance.
- The triennial audit is a full audit of the auditee organisation quality management system and generally follows the same process as the Stage 2 Audit.
- Triennial audits and reviews follow the same instructions as those of initial audits. Care should be taken to review of changed scope or activities of the client.

4.7.3 Decisions on renewing the certificate will be made by Zolabix (Pty) Ltd based on the results of the recertification audit (review of the report), review of the certified client's system throughout certification and any complaints received against the certified client over the certification period.

4.7.4 Per ISO/IEC17021-1:2015, the triennial audit, closure of all issues, and certification committee decision need to be completed before the expiry date of

the current certificate. The new certificate shall then be considered as a continuation of certification. The "Certified since" date shall be the initial certification date. (The triennial audit should be completed about two months before certificate expiry). In case of a situation where corrective action is not submitted in time to complete the certification decision, additional surveillance shall be planned for six months (for a 12-month surveillance schedule) or one day is added to the first surveillance (for 6/9 months of surveillance schedule).

4.7.5 Where the activity cannot be completed before certificate expiry, the client shall be considered as a new case and man-days for stage 1 and stage 2 and surveillance audit shall be given. Also, if the surveillances are not done as per schedule, the client shall be considered as a new case.

4.8 Special Purpose Visits

4.8.1 Registered quality management systems must continue to comply with the current version of a specific standard, and any changes to the system must also continue to comply. The cope of registration must continue to be appropriate to the auditee organisation's objectives and appropriate for the auditee organisation products and services. On the other hand, complaints, appeals, requests for change in scope, additional accreditation, audit visits, or surveillance visits may disclose the reasons for undertaking an additional visit.

- If there are grounds for undertaking a special purpose visit, the Managing Director or Quality Manager determines what level of review will be required to maintain or extend registration, including by not limited to routine surveillance, unplanned surveillance, partial re-audit, or full re-audit.

- Before undertaking any visit, which is not under any contractual agreement, the auditee organisation must agree in writing to the new terms.

- The scope of the audit shall be predetermined and shall depend on the reason for the visit. In case of any complaint, appeal, or any information that has resulted in doubt on the effectiveness of the system, the audit of the concerned and other related activity may be carried out.

- Visit/audit report shall be recorded similarly to the initial audit. The report shall also be reviewed for risk to Zolabix (Pty) Ltd Certification committee may also discuss the findings with the audit team.

4.8.2 Extension to scope change in management of clients already registered with Zolabix (Pty) Ltd

- The questionnaire should be completed by the client and returned to Zolabix (Pty) Ltd.
- Contract Review will always be carried out by the Quality Manager or appointed person to determine whether a full or partial Stage 1 is required.
- An off-site Stage 1 must be completed and sent to the Quality Manager or appointed person for review. Under exceptional circumstances, an on-site Stage 1 may be required.
- Under no circumstances must the above visit be carried out at the same time as surveillance unless extra time or an extra auditor has been allocated. However, Stage 1 shall be completed before the on-site audit.

An audit for the above reasons will be carried out in the same way as the initial audit. An Audit Report must be completed in the usual way and submitted to the Certification Committee for approval.

If successful, a new certification will be issued by Zolabix (Pty) Ltd

NOTE: After certification, if the client changes anything that significantly affects the registration, then Zolabix (Pty) Ltd must be informed. Zolabix (Pty) Ltd reserves the right to re-assess.

4.8.3 A special visit may be carried out on request for additional accreditation. The client may request additional accreditation at any time before the certification audit or during the three years. In case the requested audit is before the stage 2 audit, the request shall be reviewed by the Quality Manager and verified if the client's activities are within Zolabix (Pty) Ltd's scope of accreditation. Stage 2 audit is carried out as described above. I the request is within three years; an additional visit may be required to verify compliance. The commercials shall communicate with the client. The visit may be merged with planned surveillance. Additional accreditation shall be effected only after successful completion of the audit. The certification shall be accordingly amended; however, the expiry date shall be the same. Fees may be charged towards additional accreditation and new certificate issues.

4.8.4 Short Notice audits for clients register with Zolabix (Pty) Ltd

These audits are necessary to investigate any complaints, changes in management systems, and follow-up on suspended clients. Requirements of short notice audits are informed to the client at the time of contract finalisation through F27 Client Agreement.

Special care will be taken in assigning the audit team for short-notice audits.

4.9 Transfer

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

4.9.2 Pre-transfer review

- Carry out the standard 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 certificate activities are compatible with that of Zolabix (Pty) Ltd.
- Try to establish the reason for the client wanting to transfer.
- Check that all the sites that the client wants to transfer 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. A certificate that has been suspended or withdrawn is 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 based on this review procedure).
- Check the status in their current certificate cycle, i.e., are we to take over the surveillance program or are they due for a triennial re-audit, etc. If the

triennial is due, carry out a full triennial audit, including planning and site visits. Any extension to scope will result in visits.

- Requests 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 Zolabix (Pty) Ltd with evidence of corrective action taken for Zolabix (Pty) Ltd 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 program of surveillance visits/triennials is to be adopted from the previous certification body if applicable. The appendix Document is signed by the Chairman of the Certification Committee, Chief Executive, and Technical Expert (if applicable) to the authorised issue of the certificate.

Note: if, because of the review, some of the criteria are not met, then a site audit will be required to give confidence to certifying by Zolabix (Pty) Ltd

4.10 Opening and Closing Meetings

4.10.1 The opening and closing meetings are a critical part of the audit process. Opening meetings ensure that all parties understand what is going to happen and how best they can cooperate and coordinate their efforts. The closing meeting ensures that all parties understand the relevance of the findings, what they need to do, and what happens next. The meeting agenda contains several 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 covered in the instruction, as appropriate and applicable to the situation.

		OPEN	CLOSE

A	Thank the client for selecting Zolabix (Pty) Ltd. Mutual introduction of auditors and auditee	•	
B	Thank the auditee for hospitality. Thank the guides for their support.		•
C	Circulate attendance sheet	•	•
D	State and confirm the contracted scope for certification and objectives of the audit.	•	
E	State that the Team Leader represents the Audit Team. Determine auditee representatives and guides	•	
F	Confirm the audit plan and verify that there are no conflicts with the plan. Reconfirm the time and location for the closing meeting. Make necessary amendments on request	•	
G	Explain the terms of non-conformance (major & minor) and observation	•	•
H	Communicate the policy of notification by auditee for legal/statutory violation	•	•
I	Request sufficient sets of documentation, suitable room, and office support	•	
J	Explain auditors' responsibility to comply with the code of conduct and confidentiality	•	•
K	Explain the audits are sampling exercises, and other issues that may exist. Refer to the need for ongoing internal audit and ongoing surveillance. The audit does not guarantee to identify all areas of non-conformance	•	•
L	Request advice on safety requirements and availability of safety equipment	•	
M	Explaining the findings. Highlight strength. State non-conformances and observations. Explain the expectation of corrective action for non-conformances, including how lack of corrective action will impact on registration.		•

N	State conclusion and recommendation of audit tea. Explain that the team can only make a recommendation. Explain the concept of the Certification Committee. Explain that the appeals process exists and is available on request.		•
O	Obtain an auditee organisation signature on the audit report. Request the auditee to state the corrective action plan. Explain the auditee's responsibility for submission of evidence for non-conformances identified. Request for safekeeping of audit reports.		•
P	INVITE QUESTIONS	•	•

4.11 Multi-site audit (QMS only)

4.11.1 This procedure only applies in certain circumstances, e.g. distribution companies, recruitment companies, etc. and it is the responsibility of the Contract Review process and the person planning the audit to determine its use. The program is particularly suited to those organisations:

- Engage in distribution, having several strategically placed geographic distribution centres, or
- Operating a multi-outlet wholesale business, or
- Performing simple, repetitive processing at several different sites.

4.11.2 The program may be applied to the whole of the organisation 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 expertise. Ensure that the program caters to a representative sample of the activities undertaken. Follow work instructions WI 08.

It is usual to audit the company Head Office and a sample of sites if all sites are working with the same management system and if activities on each site are the same.

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 program 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 program 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 usually be treated as an extension of scope. They must be added to the rolling program, increasing the amount of surveillance time, and cost as appropriate.

4.11.4 With large, multi-site companies it is usual to appoint a Project Leader who will be responsible for ongoing liaison with the client, arranging dates for surveillances, coordinating the rolling program, 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 a rolling program.

It is not necessary to raise opening and closing meetings for every site visited, but a schedule is to be available for each auditor.

4.12 Sampling plan and auditing time.

4.12.1 As such, there is no statistical or mathematical formula to establish the right number of samples to be taken during the 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.

4.12.2 The auditor needs to perform interviews and check records and evidence during the interview. The number of samples to be taken depends on the complexity of the process being audited and the quality of the information received from the auditee during the interview. It is also essential that the auditor maintains the schedule outlined in the audit plan. The auditor needs to feel comfortable that the samples and the objective evidence seen are representatives, to draw appropriate conclusions regarding the implemented QMS.

5.0 Suspension of Certification

5.1 Identification of Grounds for Suspension

- Persistent failure to comply with the standard requirements, refusal to allow required audits, client-requested suspension, or other significant issues identified.
- Review and Decision.
- An independent review team assesses the situation and decides on the suspension. The team should be different from those involved in regular audits to ensure impartiality.
- Notification to Client: Formally notify the client of the suspension decision, grounds for suspension, actions required to lift the suspension, and the timeframe for resolution (not exceeding six months).

6.0 Withdrawal or Reduction of Certification Scope

6.1 Failure to Resolve Suspension Causes

- If the organization fails to resolve the issues leading to suspension within the specified timeframe, initiate a review for potential withdrawal or scope reduction.
- Client Notification: Notify the client formally of the decision, including the reasons for withdrawal or scope reduction and any actions the organization can take to re-apply or appeal the decision.

7.0 Reinstatement Process

7.1 Resolution of Issues and Re-evaluation

- Upon resolution of the issues that led to suspension or withdrawal, the organization can request a re-evaluation.
- Conduct a reassessment audit to verify the implementation of required corrective actions (Stage 1 and Stage 2).
- QM to review the reinstatement audit reports and to be reviewed by the impartiality committee.

8.0 Formats

8.1 F30 – Audit Notification

8.2 F31 – Stage 1 Audit report

8.3 F32 – Stage 2 Audit report

8.4 F27 - Quotation Format

8.5 F28 - Contract Review Checklist

8.6 F29 - Change to Contract

8.7 QP01 Procedures for control of documents

8.8 QP02 Procedures for corrective action

9. Enclosures Nil

10. Formats / Exhibits

10.1 F23 Incident Report

10.2 F24 Incident Log

11. RECORD OF AMENDMENTS

RECORD OF CHANGES, REVISIONS AND CANCELLATIONS		
DATE	NATURE / DETAIL IN CHANGE	REV NUM:
13.05.2024	Document review	Rev: 03