MOTIVA CAB	**Issue Date:** 02 Mar 2013	**SP-001**

Continual Improvement Procedure

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1.0 SCOPE AND FIELD OF APPLICATION

1.1 This procedure covers the whole of MOTIVA continual improvement activities including management of Quality deviations (potential or actual) and health and safety incidents and conditions (potential and actual) from identification through resolution to follow up. This procedure does not cover feedback, including complaints as these aspects of the MOTIVA Quality management system are covered under SP006: Canvassing Clients, Complaints and Feedback, and Client Service.

1.2 The procedure has been prepared to ensure a consistent approach to continual improvement, to ensure that that investigations and root cause analysis is thorough and effective in all instances. It is also designed to ensure that informed, targeted corrective actions are selected and implemented with a view to eliminating such deviations.

1.3 Consideration of appropriate preventive actions, from the identification of potential difficulties, is important to eliminate the first-time occurrence of undesirable conditions or events. This same process can be used to pro-actively enhance processes.

1.4 The aim of continual improvement within MOTIVA is to provide a safe working environment and to produce only technically valid results.

2.0 NORMATIVE REFERENCES

- MOTIVA Corporate Quality Manual
- ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
- MOTIVA Documentation

3.0 TERMS AND DEFINITIONS

3.1 Contained in: MOTIVA Corporate Quality Manual

4.0 HEALTH AND SAFETY

4.1 All processes, procedures and environments affected by this procedure include considerations for health and safety.

4.2 Identification of health and safety conditions and responses to health and safety events are covered in this procedure.

5.0 PROCEDURE

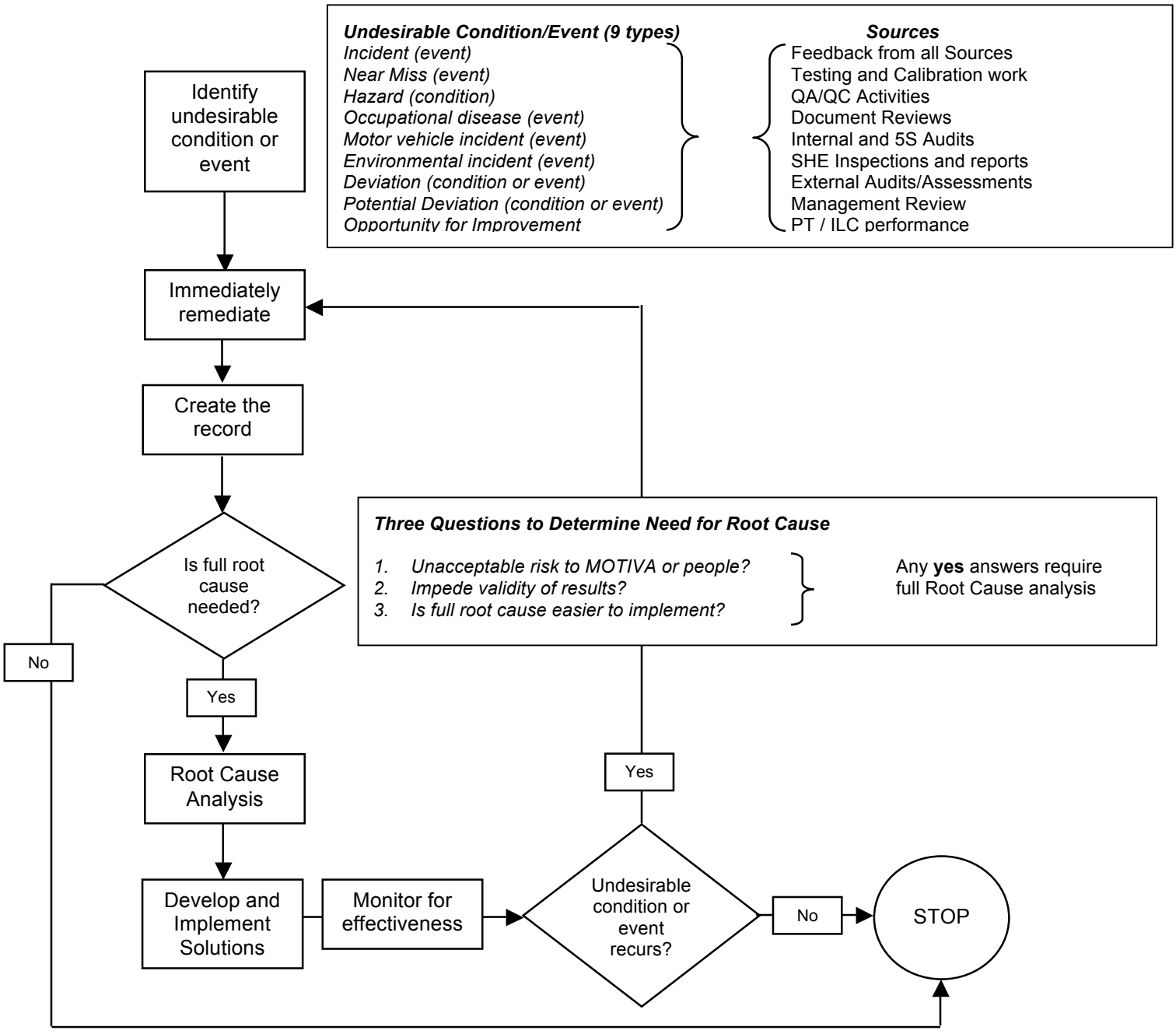
5.1 General

5.1.1 MOTIVA encourages all staff and visitors to identify any and all areas where activities do not conform to requirements (deviation, incident, near miss or hazardous condition) or they may not conform in the future (potential deviation) or where a process can be improved to some benefit (opportunity for improvement).

5.1.2 Tools are provided to allow all MOTIVA personnel and visitors to:

- Identify undesirable conditions or events,
- Remediate undesirable conditions and the impact of undesirable events,
- Determine the impact of these conditions and events on MOTIVA Lab, its people and visitors,
- Identify the root causes of these conditions and events,
- Propose and implement effective solutions,
- Record objective evidence of the entire process, and
- Follow up to determine, where appropriate, the effectiveness of the solutions implemented.

5.1.3 Process flow chart for Continual Improvement.



5.2 Identify the Condition or Event

5.2.1 Deviations (actual or potential), opportunities for improvement, and any health and safety events or conditions may be identified through a number of means. These include all sources such as:

- Testing and calibration work, including sample reception, sample preparation, Quality control and Quality assurance, and the issuance of technically invalid results to a client.
- Internal and 5S audits and Health and Safety Inspections
- Management review activities
- Audits and assessments from outside agencies, including 2nd party (client) audits and 3rd party (accreditation body) assessments.
- Reviews of MOTIVA documents or other documents controlled by the MOTIVA document control system (See SP003: Documentation and Document Control).
- Feedback, both positive and negative received by MOTIVA. See SP006: Feedback to MOTIVA.
- Reports of undesirable conditions including SHE Application reports.

5.2.2 It is important to understand that ANY condition or event encountered that is not exactly as specified (written) is considered to be an undesirable condition or event. All undesirable conditions within MOTIVA are recognised as indications that the management system is not sufficiently supporting the work of the people within the system.

5.2.3 Questionable or Anomalous Results

5.2.3.1 The primary aim of any laboratory Quality system is to support the production of technically valid results. Suspect, questionable or anomalous results are therefore cause for Quality system action, but only if the results are clearly invalid, by their **failure to meet written and specified QC or QA criteria**. As well, any results deemed outliers by their comparison to other equivalent results, such as from QC runs or proficiency testing (PT) programs or inter-laboratory comparison (ILC) programs, are considered deviations.

5.2.3.2 In general, anomalous or apparently incorrect results are considered potential deviations. Statistically, it is possible for results to be generated that appear anomalous to other results obtained from the same batch of samples or material. In such instances, an investigation is performed to ascertain whether the results have occurred as a result of a deviation or due to statistical variation (often termed outliers).

5.2.3.3 The terms “Out-of-Specification (OOS)” and “unexpected result (UR)” refer to results that are outside the parameters expected by a client or other party. Sometimes these are associated with test results which show a product to be somewhat different than was promised by a supplier or on a certificate of conformance. OOS and UR are not necessarily deviating results. While they may not be undesirable conditions or events, it is possible that the investigation of an OOS or UR points to a deviation within the MOTIVA management system or procedures. If a deviation is identified, the remainder of this procedure applies.

5.2.3.4 “Suspect” results or a “suspect population” of results are also deemed to be undesirable conditions requiring examination under this procedure.

5.2.3.5 For laboratories approved by Nadcap a significant out of tolerance event is defined as “an excursion from acceptable operation that corresponds to more than 1.25 times the permitted tolerance.” *AC 7101/1: Nadcap Audit Criteria for Materials Testing Laboratories General Requirements for All Laboratories*

5.2.4 Immediate Remediation for Safety-Related Conditions

5.2.4.1 In certain circumstances, immediate remediation (correction or prevention) is needed to contain the impact of a deviation, potential deviation or a hazard.

5.2.4.2 Where a hazard is deemed to exist and threaten the health and safety of persons in an area, the steps to remediate the hazard or remove the persons from that area are taken immediately. The condition is reported to a supervisor or manager as soon as these steps are taken. Remediation may include the stoppage of work

in an area to prevent further injury to persons or damage to property.

5.2.5 Immediate Remediation for Quality-Related Conditions

5.2.5.1 Depending on the perceived risk to the business and to clients, the containment actions for deviating conditions affecting MOTIVA work may include the suspension of work in progress or the need to withhold test and calibration results, inspection results, or proficiency test pieces/results. Such containment actions are required and implemented if the impact of a deviation raises doubts about the integrity or technical validity of work performed or in progress.

5.2.5.2 Laboratory Managers and Supervisors or designates are authorised to stop work where there is evidence to doubt the application or integrity of testing or calibration work. Any applicable work in progress may be suspended pending a complete root cause analysis. In some business units / laboratories, this authority may be delegated to the local Quality Manager in accordance with local procedures. The actions implemented may include:

- suspension of any work in progress,
- withholding results/reports/test pieces until a full investigation has been performed to ascertain the significance of the deviation,
- notifying clients if they have been impacted by the deviation which may include recalling results, reports, or test pieces where the investigation has confirmed them to be suspect or invalid,
- resumption of work when the investigation is complete and targeted corrective actions have been implemented and verified as effective.

5.2.5.3 Where work has been affected, steps are taken to correct the defective work. This may include re-test or re-calibration as appropriate. It may be necessary to recall work from the client to facilitate this.

5.2.6 Impact on Client Work and Client Notification

5.3.5.1 Anomalous results are not reported, included or excluded from a data set without sound technical justification.

5.3.5.2 Whenever investigation reveals that work from any client has been affected, the client(s) must be informed. This is both, common courtesy to the client and good customer relations.

5.3.5.3 Some regulatory and accreditation body requirements oblige MOTIVA to notify clients as soon as any evidence shows a possibility that work done on their behalf may have been affected by a deviation. In these circumstances the laboratory does not wait for the outcome of the detailed investigation. Such requirements exist for the following laboratories:

- all laboratories working under Nuclear Regulatory Agency (NRA) regulations per 10-CFR-21,
- all laboratories operating under the Good Manufacturing Practice (GMP) provisions of the US Food and Drug Administration (FDA) and the Canadian federal Department of Health (Health Canada).

5.3.5.4 MOTIVA notifies affected clients within 5 working days about potential deficiencies in data supplied by the laboratory. Notification is done by the most effective means available and is followed by official notification on MOTIVA stationary. All notification is under the direction of the applicable manager.

5.3.5.5 Where re-test may be called for but is not possible, such as following destructive testing, the client's advice is sought as to whether replacement samples can be obtained or to determine whether another course of action is appropriate. It should be noted that in such cases, there could be significant costs involved, which may have to be borne by MOTIVA.

5.3.6. Resumption of Work

5.3.6.1 Testing may only be resumed following the satisfactory resolution of the relevant deviation or hazardous condition together with the application of any corrective measures deemed necessary.

5.3.6.2 Any suspended testing or calibration work may only be resumed with the permission of the manager, in consultation with appropriate business unit or regional Quality staff.

5.4 Create the Record

5.4.1 Recording Health and Safety Conditions or Events (Incident)

5.4.1.1 All health and safety incidents and conditions are recorded and reported. The forms specified in MOTIVA Incident Investigation Procedure are used.

5.4.1.2 An Incident and Deviation Report is created. It is completed in accordance with the MOTIVA Incident Investigation Procedure.

5.4.1.3 All health and safety initial reporting is completed within 24 hours of the incident being reported. The MOTIVA Health and Safety Manager is apprised of all health and safety incidents.

5.4.2 Recording All other Conditions or Events

5.4.2.1 Irrespective of the source of the undesirable condition or event, a MOTIVA Incident and Deviation report form is created to capture it. Supporting documentation is appended to the deviation report, such as: correspondence with clients or notes of telephone conversations raw data including Quality control results; test reports/results; calibration, maintenance or equipment check results. The required data for each record includes the following:

- unique log / report number,
- reference to the governing specification,
- nature of the event or condition,
- immediate action taken (remediation),
- significance of the condition or incident to determine the necessity of any root cause analysis,
- identified root cause (if needed),
- corrective action or preventive action proposed (if needed)
- implementation of corrective or preventive action or simple remediation (immediate action)
- follow-up action (if needed).

5.4.2.2 Each deviation report is specific to a laboratory/business unit or to a central service within the MOTIVA region and contains a sequential report number for each year. The unique reference is quoted on all forms and correspondence relating to the condition or event documented from the time of the creation of the record.

5.4.2.3 Required changes to, for example, methods, procedures, processes, data capture systems, training programmes or other changes to MOTIVA management systems resulting from either remediation or corrective/preventive action is also be detailed on the report or appended to it.

5.4.2.4 Once the deviation has been recorded, an investigator is assigned within the laboratory. The investigation initially determines whether work performed for, and on behalf of, any Clients may have been affected and this information is relayed to the manager concerned. If this is the case then this same procedure is followed for all affected work.

5.5 Determine the need for full Corrective- or Preventive Action

5.5.1. Once undesirable conditions have been identified and classified, recurrence can only be prevented through

corrective action. The same applies to an identified potentially undesirable condition and the prevention of its first-time occurrence through preventive action. Both of these efforts require investigation of the circumstance to determine root cause.

5.5.2. Corrective and preventive action can only succeed when the root cause of the undesirable condition has been identified and eliminated. Determining the necessity of either preventive or corrective action is the first step in implementing either.

The necessity of full corrective or preventive action is established by asking the following three questions:

- **Does the current condition or event present unacceptable risk to the business or a hazard to people, or the environment, or the community?** In other words does a risk analysis of the condition (Risk = Exposure X Severity) demonstrate a level of risk that is not acceptable to MOTIVA or does it present any hazard to the health, welfare and safety of people and the environment?

- **Does the current condition or event impede MOTIVA Lab's ability to produce only technically valid results?** In other words, does the current condition result in technically invalid results, or might it?

- **Is the effort to implement full corrective action less than the effort of continued remediation?**

5.5.3. If any of these questions result in a "Yes", full corrective- or preventive-action is needed, starting with an analysis of root cause. If ALL of these questions result in a "No", no analysis of root cause is needed and simple correction / prevention (even if repeated) remediation is acceptable.

5.5.4. In order to prevent the recurrence of deviations, it is essential to identify the source. This is achieved through effective root cause analysis that enables targeted corrective actions to be assigned and implemented. The actions taken to determine the root cause are detailed below.

5.6 Communications with Clients during Root Cause Analysis

5.6.1. Any investigation caused by the discovery of any undesirable condition, whether current or potential, requiring full corrective (or preventive) action is instigated on the day they are identified (internally or by the client) and concluded in a timely manner as defined by the Business Unit. Each Business Unit is governed by different requirements in this regard.

5.6.2. Communication with clients is important throughout the investigation process. In the event that a client is impacted by a deviation or if a deviation report is raised as a result of a client complaint/query, the General Manager or designate contacts the client, initially by telephone to discuss the situation. A confirmation email is sent on the same day as the telephone conversation, quoting the deviation report reference.

5.7 Root Cause Analysis

5.7.1. Root Cause Analysis consists of the identification of the component part of the MOTIVA management system that failed to support MOTIVA policy, objectives, operational requirements, or the people doing the work. Root causes normally fall into one of the following categories:

- Personnel factors
- Environmental factors
- Quality factors
- Procedural factors
- Organisational factors

5.7.2. The implementation of the 5 Whys technique to problem solving is an effective, simple tool to determine the root cause(s) of a deviation. In practice, the investigator will ask more than 5 Whys or questions in determining the root cause or causes. Analysis of all root causes involves the following progressive steps:

- Determination of the Direct Cause;
- Determination of any Intermediate or Contributing Causes, and
- Determination of the Root or Basic Cause

5.7.5 Determination of the Direct Cause

5.7.5.1 The Direct Cause is determined by asking "why" the deviation or other undesirable circumstance occurred. For example: If a person were to ask why they were late for work, the Direct Cause of not getting to work by the appointed time could be cited.

5.7.5.2 While appearing simplistic, the Direct Cause is that most closely associated with the actual undesirable condition in terms of time. Otherwise, it is possible that subsequent "why" questions to identify Intermediate Causes may skip over an important one.

5.7.6 Determination of the Intermediate or Contributing Causes

5.7.6.1 Intermediate or Contributing Causes are determined by asking "why" each cause occurred from the Direct Cause back through the chain of events to the Root Cause. The chain of events examined in this fashion will normally lead to the Root Cause.

5.7.6.2 Only those Contributing Causes that are within the scope of authority of the laboratory to address are considered. Those Contributing Causes that are outside of the scope of the laboratory may lead to an external Root Cause, but the laboratory cannot address it effectively and its identification will not produce any useful resolution of the issues.

5.7.7 Determination of the Root Cause

5.7.7.1 Root causes are what caused the problem, not just the symptoms. For example, a headache may be caused by any number of health- or behaviour-related causes even though it occurs on waking up in the morning. Blaming the headache on having to get up misses the significant effect of the activities of the previous evening. In another example, shivering due to feeling cold may not be caused by exposure. It may be caused by a cold or the flu. Shivering is just a symptom – the cause is the sickness.

5.7.7.2 All Root Causes within the MOTIVA management system fall into one of the following categories. The existence of a Root Cause in one of these categories is indication that this part of the MOTIVA management system is missing something that would have prevented the undesirable condition that initiated the investigation.

- Personnel Factors dealing with the demonstrated skills and knowledge of the persons involved.
- Environmental Factors dealing with the physical plant, facilities, and equipment.
- Quality Factors including Quality control and Quality assurance.
- Procedural Factors including the basis and validity for the work being executed, and
- Organisational Factors that include communications and supporting processes.

5.7.7.3 Root Causes based on Personnel Factors

- Insufficient physical capacity
- Insufficient intellectual capacity (may require a professional determination)
- Physical or physiological stress
- Emotional or psychological stress (may require a professional determination)
- Insufficient individual skill
- Insufficient individual knowledge
- Lack of care and attention (may require HR intervention)

5.7.7.4 Root Causes based on Physical Environmental Factors

- Inadequate physical plant and/or facilities
- Inappropriate environment
- Inadequate tools and/or equipment
- Inappropriate materials and/or supplies
- Inadequate maintenance for plant, facility, tools and equipment
- Excessive wear and tear on plant, facilities, tools and equipment

5.7.7.5 Root Causes based on Quality Factors

- Inadequate Quality control
- Inadequate Quality assurance
- Inadequate Quality system

5.7.7.6 Root Causes based on Procedural Factors

- Use of inappropriate procedures
- Lack of development of specifications and procedures
- Lack of implementation of procedures
- Use of inappropriate vendors, personnel, supplies

5.7.7.7 Root Causes based on Organisational Culture

- Insufficient communications
- Inappropriate or misunderstood direction

5.7.7.8 International Quality and safety system literature show that the most common missing pieces of a management system have to do with procedures, Quality controls, and knowledge of requirements.

5.8 Develop the Solutions to Implement

5.8.1 Once the root cause has been identified the next step in the process is to examine potential solutions. The only potential solutions considered are those that address actual root cause and prevent recurrence of the undesirable condition – or its first time occurrence when considering potential deviations or hazardous conditions.

5.8.2 Solutions are normally developed such that they meet the needs of ALL persons affected by the undesirable condition.

5.8.3 Developed solutions are noted on the form used to record the process.

5.8.4 Solutions may require the approval of the local Quality staff and/or Manager. Such requirements are specified in local procedures.

5.9 Implement the Selected Corrective or Preventive Action

5.9.1 The selected solution is implemented as either corrective or preventive action.

5.9.2 Corrective and preventive action(s) are assigned and implemented as soon as the solution has been selected. Implementation is noted on the form used to track the process.

5.9.3 The local Quality representative tracks assignment of this work. Implementation is done by those responsible for the process being modified by the solution

5.9.4 The local Quality representative collects the form following implementation and assigns a date for follow up.

5.10 Monitoring Corrective/Preventive Action for Effectiveness

5.10.1 Only corrective or preventive actions implemented following root cause analysis are monitored for effectiveness.

5.10.2 Remediation (in the form of correction or prevention) does not require follow up. The risk analysis conducted at the beginning of the process has deemed the undesirable condition to be of such insignificance as to not require monitoring beyond an initial record. If corrective or preventive action has been implemented, follow up is normally required.

5.10.3 Whatever the decision regarding follow up, it is recorded in a manner linked to the original record.

5.10.4 Follow up is normally accomplished by examining the condition, through records, at some future date, to determine if the corrective or preventive action selected and implemented actually addressed the root cause determined and prevented recurrence (or first time occurrence in the case of preventive action) of the non-conforming condition.

5.10.5 If the condition has not arisen (again or for the first time) then the solution implemented is appropriate.

5.10.6 If the condition has arisen again, remediation is undertaken and the whole process is taken up from that point. Note that recurrence is evidence that the correct root cause may not have been determined or the appropriate solution selected to address the root cause. Commencing with the remediation step, corrective or preventive action is restarted.

5.11 Equivalent to Internal Audit

5.11.1 Once any portion of the MOTIVA management system has undergone significant review and/or modification caused by corrective or preventive action, that section of the management system is deemed to have been audited. See the MOTIVA Internal Audit and Management Review Procedure.