MOTIVA Lab	**Issue Date:** 02 Mar 2013	**SP-003**

Internal Audit and Management Review Procedure

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1.0 SCOPE AND FIELD OF APPLICATION

1.1 This procedure covers the all MOTIVA Lab audit, inspection and management review activities within the Americas Region and relates primarily to health and safety inspections and quality audits and reviews. It includes internal audits, inspections, audits of clients, suppliers and subcontractors.

1.2 The aim of audits within MOTIVA Lab is to determine the level of implementation and effectiveness of the MOTIVA Lab management system and whether the system allows for improvement. The aim of inspections within MOTIVA Lab is to determine the existence of any conditions which may adversely affect the health, welfare and safety of MOTIVA Lab staff and whether or not MOTIVA health and safety requirements have been appropriately implemented.

1.3 Audits and inspections have different foci.

- Audits are to be considered collegial activities between colleagues to enhance MOTIVA Lab conformance to requirements. This process is about the discussion.
- Inspections are to be considered examinations of existing and potential conditions and processes which will affect the safety of staff and visitors. This process involves enforcement.

1.4 The aim of management reviews is for top management to determine whether the MOTIVA Lab management system is helping to facilitate the attainment of the objectives defined in the MOTIVA Lab HSEQ Policy Manual.

2.0 NORMATIVE REFERENCES

- Pol-001: MOTIVA Lab Corporate Quality Manual
- ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
- SP-001: MOTIVA Lab Continual Improvement Procedure.

3.0 TERMS AND DEFINITIONS

3.1 Contained in Pol-001: MOTIVA Lab 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.

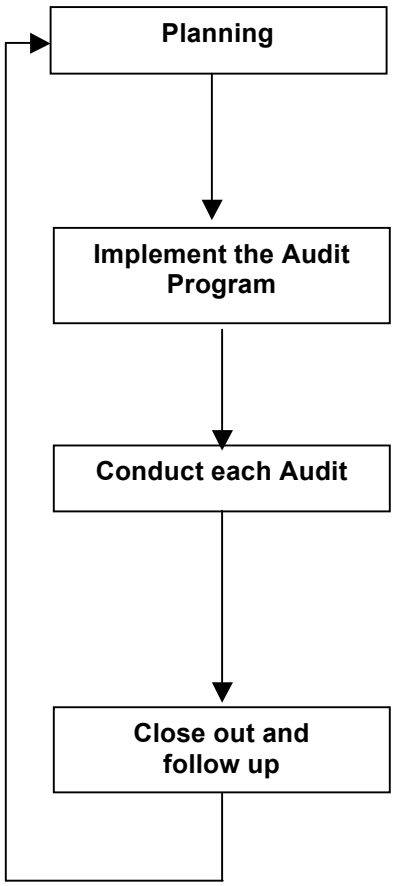
4.2 Identification of health and safety conditions and responses to health and safety events are covered in this procedure.

5.0 PROCEDURE

5.1 General

5.1.1 The general process for the conduct of audits, inspections and management review within MOTIVA Lab is shown below.

5.1.2 The cyclical nature of this process also allows each MOTIVA Lab section to implement changes based on past performance. In other words, the effectiveness of this process can be measured.



- Based on the needs of the management system, previous audits/inspections, frequency, scope, resources, etc.
- Audits established by the General Manager and the HSEQ team
- Inspections established by MOTIVA Lab policy and the JHSC
- Audit and inspection programs agreed by all participants

- Plan for each individual audit / inspection occurrence
- Allocate resources and establish timings, scope, objectives for each audit / inspection
- Each individual audit / inspection agreed by all participants, auditees, and inspectors/auditors.

- Document review (System Audit), checklists prepared, timings for each audit / inspection activity established beforehand and agreed
- Onsite audit (Conformance Audit) or inspection (Workplace Inspection)
- Opening meeting (if needed)
- Areas audited / inspected as agreed
- Findings agreed and written
- Report presented to onsite representatives during closing meeting

- Auditee action – remediation followed by corrective/preventive action as required.
- Formal close out of findings
- Follow-up as required, including any further audits or inspections.

5.2 Audit and Inspection Planning and Requirements

5.2.1 Internal Audit Planning Requirements

5.2.1.1 All MOTIVA Lab sections are audited such that all components of the MOTIVA Lab management system in each section are audited at least once per year. The internal audit results from the previous calendar year are reviewed prior to formulating the new audit program to ensure that any outstanding audits are accounted for in the revised audit program.

5.2.1.2 The MOTIVA Lab internal audit effort is coordinated by the HSEQ Manager and approved by local top management.

5.2.1.3 A copy of the audit program specific to each section is maintained by the HSEQ Manager and the manager of the section being audited.

5.2.1.4 The internal audit program is established at the beginning of the audit cycle and is regularly reviewed by HSEQ staff throughout the year to address any delays or problems in a timely manner. General Managers/Facility Managers/section Head(s) are informed of the outcome of these reviews and assist in overcoming obstacles to the implementation of the audit program.

5.2.1.5 MOTIVA Lab sections that perform pharmaceutical testing are also subject to facility and process audits (often referred to as self inspections) at least annually as per a predefined schedule. Good Laboratory Practice

(GLP) compliant facilities are also required to schedule study and critical phase audits dependant on the nature of the studies being performed. GLP and Good Manufacturing Practice (GMP) compliant facilities have local procedures in place which detail the scheduling, conduct and reporting of facility inspections, process, study and critical phase audits.

5.2.2 Inspection Planning Requirements

5.2.2.1 Inspections are conducted as per the following inspection schedule and cover the whole of MOTIVA Lab areas and applicable processes at least three times per year.

- Joint Health & Safety Committee (JHSC) – Monthly (designated section)
- Managers – Monthly (their own section)
- General Manager – Quarterly (whole facility)

5.2.2.2 The MOTIVA Lab inspection effort is coordinated by the JHSC and notified to the HSEQ Manager and top management.

5.2.3 Selection of Auditors and Inspectors

5.2.3.1 Audits are performed by trained, competent auditors in all instances. Internal and external auditors are appointed on the basis of their training, experience and knowledge of technical and/or quality matters as appropriate. Records of training and competence are maintained on file for review by clients, appropriate regulatory authorities and accreditation bodies. In addition to the aforementioned, all internal auditors have a sound understanding of the MOTIVA Lab management system and the accreditation requirements with which the business complies.

5.2.3.2 Inspectors are selected by the JHSC, and are trained and qualified for workplace inspection by the mandatory courses approved by the Ministry of Labour (Canadian province) or the State or Federal OSHA (USA).

5.2.3.3 A list of approved auditors and inspectors is maintained by the HSEQ staff and the JHSC maintains a duplicate list of inspectors.

5.2.3.4 Specific information relating to each auditor's and inspector's training, experience and knowledge are retained within the individual's training records.

5.3 Implementing Audit and Inspection Programs

5.3.1 MOTIVA Lab Approach in the Conduct of Audits and Inspections

5.3.1.1 Internal audits and inspections are the most comprehensive tools used within MOTIVA Lab to determine the suitability of the MOTIVA Lab management systems. They provide the best possible picture of the state of MOTIVA Lab management systems and their implementation.

5.3.1.2 HSEQ staff plan, coordinate, and implement the processes of audit and assist the JHSC in doing the same for inspections within MOTIVA Lab. They track the results of these activities on behalf of senior management. The owners of the areas and systems being examined, however, are the people and management teams that work in them. The owners are the beneficiaries of the effort – and they are also the providers of solutions within their parts of the MOTIVA Lab management system.

5.3.1.3 It is important for auditors and inspectors to appreciate that internal audits and inspections are to provide information and evidence to the owners of the processes and areas under examination. Neither process is to develop a list of deficiencies or to simply "help" the staff working in a particular area.

5.3.1.4 The information provided by audits and inspections is to be used by the section or department concerned to examine the issues and processes identified by the audit or inspection that are within their purview for their own benefit and the benefit of their operations.

5.3.1.5 Inspection information is also used in support of demonstrated conformance to regulatory health and safety requirements and will be reported to interested parties who are authorised by top management to receive it.

5.3.2 Planning for each Audit or Inspection

5.3.2.1 Each audit and inspection is preceded by an examination of the documents that cover the process or procedure being audited or the area being inspected.

5.3.2.2 Timings and other logistic details are agreed between the auditor / inspector and the senior person responsible for the process or procedure being audited or the area being inspected.

5.3.2.3 Checklists for audits are developed prior to the actual audit and will vary depending on the purpose and type of audit. Checklists enable the auditor to focus on the audit and to provide a clear and transparent line of examination to allow for a determination of the conformance of the process under investigation. Checklists may also act as a prompt during the audit and serve as an effective, consolidated repository of information gathered during the audit.

5.3.2.4 Checklists for inspections are based on the Workplace Inspection Form

5.3.3 General Conduct of Audits and Inspections

5.3.3.1 Auditors and inspectors are provided access to all documents, records and areas under examination and the people that work in those areas or in the processes under examination.

5.3.3.2 Audit and inspection notes are recorded the activity and are traceable back to the auditor / inspector and the date on which they were made. They may also be appended to the audit / inspection report. These notes may be captured on checklists and controlled forms or may be in the form of hand-written notes on uncontrolled copies of the methods, procedures or processes subject to audit, or of diagrams that may form part of a Workplace Inspection.

5.3.3.3 In addition, it may be appropriate to include photographic evidence to support the audit or inspection findings. As for audit notes, these shall be incorporated into or appended to the report provided at the end of the audit or inspection.

5.3.4 Specific Conduct of Inspections

5.3.4.1 A minimum of two workers/supervisors shall be consulted during each workplace inspection. All employees will participate in the inspection of their department by answering any questions the investigator(s) may have.

5.3.4.2 Workplace inspections are conducted during normal working hours utilizing an establish inspection guideline or checklist and deficiencies are recorded on an MOTIVA Lab Inspection Report Form.

5.3.4.3 During inspections, it may become apparent that an area or process poses immediate or potential risk to the health and welfare of people. The following remedial action SHALL be taken by inspectors and area representatives before proceeding any further. Such remediation is classified below by the risk assessed at the time of discovery.

- **Critical** a condition or practice likely to cause permanent disability, loss of life or body part and/or excessive loss of structure, equipment or material.
    - Immediate shutdown, stop work and lock out of equipment is required until the hazard is eliminated. Examples include.
        - Improperly guarded machinery
        - Lifting device deficiency (ie, lifting above load limits, untrained staff operating lifting equipment, expired lifting certificate)
        - Unprotected heights/fall areas
- **High** a condition or practice likely to cause property damage that is disruptive but not excessive or injury/illness leading to modified work duties or short term disability.
    - Immediate short term remediation is required to stop the process or condition until the hazard is eliminated. Examples include.
        - Improperly stored combustibles/flammables
        - Unsafe material handling practices
        - Unsecured compressed gas cylinder
- **Moderate** a condition or practice likely to cause non-disruptive property damage or an injury/illness requiring first aid or medical aid.
    - Immediate short term remediation may be required to stop the process or condition until

permanent corrective action is implemented within 1 week. Examples include.

- Exposed sharp edges/objects
- Inadequate emergency lighting
- Failure to wear basic personal protective equipment (ie gloves and lab coat)

- **Ergonomic** equipment use or workplace design that has caused, or has the potential to cause an ergonomic related injury. Repetitive motion injuries and other ergonomic related injuries can become severe if not appropriately managed and treated in a timely manner. In such cases the following actions must be taken immediately subsequent to the inspection:
  - Inspector must immediately inform the Health, Safety & Environment Manager.
  - The area manager affected must ensure that an ergonomic assessment/consultation is performed within 1 week with the advice and assistance of the HSEQ Manager, following which appropriate corrective actions are implemented as soon as practicable.
  - Examples include:
    - Employee reports losing feeling in fingers when typing for long periods.
    - Constant bending or awkward posture required to complete a regular job task.
    - Tools or other equipment for a job/task is causing employee(s) to work in a strained position.
- **Housekeeping** cluttered, unsightly, or dirty work areas or space.
  - No immediate remediation is required for these conditions. However, permanent corrective actions must be implemented within 1 week (including finding a permanent storage location for clutter if it is not garbage). Examples include:
    - Spills or debris on benches
    - Clutter in front of electrical panels, or emergency equipment.
    - Unused equipment or supplies being stored in working area.

5.3.4.4 If the inspection team does not observe any hazards or other conditions during their inspection, they must identify what was observed as demonstrating conformance and compliance.

5.3.5 Audit and Inspection Reports

5.3.5.1 Audit and inspection reports are provided by the auditor to the senior area representative (area manager, supervisor, GM etc) responsible for the area, process or procedure being examined. They are signed by both parties at the time of issue. Each specific finding is to be recorded on a MOTIVA Lab Incident and Deviation Report form.

5.3.5.2 If the JHSC is using a checklist to conduct an inspection, it must, at a minimum, contain all items on the JHSC Inspection Guideline. If any findings are identified, they must recorded on an MOTIVA Lab Incident and Deviation Report. Both the checklist and any completed form(s) must be sent to the HSEQ Manager.

5.3.5.3 Inspection reports are also submitted to the JHSC for examination during the monthly JHSC meeting.

5.3.5.4 One copy of any audit or inspection report is also provided to the HSEQ Manager. This is to allow HSEQ staff to enter the findings into the local tracking system for deviations and incidents.

5.3.6 Internal Audit Report Requirements

5.3.6.1 As a minimum, MOTIVA Lab internal audit and inspection reports contain the following:

- Report number
- Dates of the audit or inspection
- Identification of areas / procedures audited
- Audit or inspection scope and objectives
- List of documents reviewed
- Auditor or inspector name and signature
- Auditor or inspector conclusions
- Auditor or inspector recommendations

- List of findings

5.3.6.2 Each finding, as a minimum, includes the following:

- Date of finding
- Classification of finding (deviation, incident, opportunity for improvement, etc)
- Reference to the specification that governs the condition observed
- Description of the observation
- Citation of the evidence (interview, observation, document review or review of a record) that links the observation to the specification

5.3.6.3 The MOTIVA Lab Incident and Deviation Report form is to be used for the purpose of documenting internal audit and inspection findings. This form allows for the continued tracking of the identified issue (finding) through all phases to completion and follow-up.

5.3.7 Close out and Follow up

5.3.7.1 The close out and follow up of all internal audit findings follows the processes given in SP-001: Continual Improvement.

5.3.7.2 The close out and follow up of all workplace inspection findings follows the process given in the Workplace Inspection Standard.

5.3.7.3 In accordance with SP-001: Continual Improvement, the HSEQ staff track the development and implementation of actions in response to internal audit findings and workplace inspections. The JHSC also tracks the development and implementation of actions in response to Workplace Inspection findings. Logs are maintained to assist in tracking issues.

5.3.7.4 Follow up and close out activities are recorded on the appropriate form and logs and may reference the internal audit or Workplace Inspection details that initiated the finding.

5.4 Management Review of MOTIVA Lab Management System

5.4.1 The review of a laboratory management system can be exercised in a number of ways. Monitoring the performance of a management system is normally exercised through formal reviews of processes and procedures and by meetings that bring all concerned parties together. Within MOTIVA Lab there are three types of meetings:

- management system meetings for all issues;
- JHSC meetings for health and safety issues, and
- annual management review committee meetings.

5.4.2 Minutes are produced for all quality meetings. The minutes clearly identify any actions resulting from the meeting. Experience indicates that any actions resulting from quality meetings are most likely potential deviations and/or opportunities for improvement. These may be addressed as given in SP-001: Continual Improvement.

5.4.3 Laboratory Management System Meetings

5.4.3.1 The area HSEQ coordinator conducts area quality meetings. These meetings are to deal with issues on a periodic basis and examine a portion of the issues facing that section or area over the course of a year.

5.4.3.2 Section or area quality meetings are normally held on a quarterly basis.

5.4.4 MOTIVA Joint Health And Safety Committee Meetings

5.4.4.1 The MOTIVA Joint Health and Safety Committee is established with a mandate to monitor and advise on the state of health and safety within MOTIVA Lab. It has direct access to the General Manager and is authorised, under law, to report to the Ministry of Labour, any breach of the Occupational Health and Safety Act. The HSEQ Manager, or a member of HSEQ staff act as Secretary to the JHSC and volunteers from across MOTIVA Lab are encouraged to participate. The Chair of the JHSC is elected by the members.

5.4.4.2 JHSC meets once per month and publishes minutes of such meetings. Minutes are reviewed by the General Manager and signed off subsequent to their publication.

5.4.5 Annual Management Review Committee Meetings

5.4.5.1 Annual Management Review meetings are conducted under the control of and the chairmanship of top management. The management review committee (MRC) consists of the following persons:

- Top management (GM);
- Line managers
- Functional managers/representatives (HSEQ, Finance, HR, IT, Marketing, Purchasing);
- Other persons at the discretion of the chairman of the meeting

5.4.5.2 The HSEQ Manager prepares the agenda, gathers and delivers all the HSEQ reports required, and acts as secretary to the group. The agenda is normally as follows:

- follow-up actions from earlier management reviews
- the results of internal and external audits, inspections, and assessments from all parties;
- summaries of feedback from interested parties, including any analysis of complaints;
- summaries of appeals (for inspection bodies accredited to ISO/IEC 17020 only);
- reports from operational management;
- summaries of proficiency testing or inter-laboratory comparison performance;
- trends in quality and corrective / preventive action;
- trends in safety and corrective / preventive action;
- changes that could affect the management system, including the volume of work, and
- fulfilment of goals and objectives.

5.4.5.3 Top management, based on the information provided during the MRC, formally decides on the continuing suitability of the MOTIVA Lab management system and any changes necessary. This decision is focussed on the ability of the MOTIVA Lab management system to support the attainment of organisational objectives.

5.4.5.4 Where the MOTIVA Lab management system is perceived to support the attainment of these objectives, there may not be any reason to effect management system change. Where the MOTIVA Lab management system may not adequately support the attainment of organisational objectives, top management may require the modification of either the management system or organisational objectives. The actions arising from the MRC form part of the minutes of the MRC.

5.4.5.5 Actions arising from MRC are treated as detailed in SP-001: Continual Improvement. These are the tools used to effect change in MOTIVA Lab management systems. MRC normally produce opportunities for improvement and potential deviations.