MOTIVA Lab	**Issue Date:** 02 Mar 2013	**SP-004**

Document Control and Control of Records

Issue No: 02	**Author:** I. A. M. Quality, Quality Manager	**Approved:** I. B. Boss, General Manager

1.0 Introduction

1.1 The General Manager approves the MOTIVA Lab Quality Manual and delegates the authority for the approval of Quality System documents in accordance with the list contained in this instruction. With the exception of marketing materials, they will either be dated or contain a document revision number. Draft materials will be so identified, and will be designated with the term “Draft” included in the revision number.

1.2 Only those personnel listed in the Master Document List as approving authorities may approve MOTIVA Lab quality system documents. As well, these same authorities are responsible for ensuring that all documents within their purview are reviewed periodically.

1.3 For each approved official document, only one computer copy (plus back up) is the official electronic version. This most recent version is retained in the “MOTIVA Lab Master Documents” directory on the MOTIVA Lab Server. Controlled versions of MOTIVA Lab documents are held in each of the Quality System Binders in the MOTIVA Lab Quality Library.

1.4 MOTIVA Lab generates records in support of its operations. Once generated, records are normally retained in a file appropriate to record. Records are managed in accordance with the needs of the business and the section or area that generated them and is responsible for their retention and use.

1.5 This procedure outlines the approach to be used by MOTIVA Lab in the control of its documents and records.

2.0 Scope

2.1 All documents and records created for use within the Association are controlled and covered by this procedure.

3.0 Definition of “Document” and “Record”

3.1 The term “document” as used in this procedure means and includes virtually all of the policies and procedures received and/or produced by MOTIVA Lab, including policies, procedures, laws, regulations, standards, and instructions, held by MOTIVA Lab, regardless of their source or authorship. For legal purposes, the term “document” is also deemed to include all aspects of “records” defined below.

3.2 The term “record” as used in this procedure means and includes virtually all the records received and/or produced by MOTIVA Lab, including paper records (whether handwritten or printed materials), sound recordings, videotape, films, photographs, charts, graphs, books of account, e-mail and all data and information in electronic form. Thus, items that may not be considered important, such as interoffice emails, desktop calendars and printed memoranda, are records that are considered important under this procedure.

3.3 In other words, all records are part of this document control procedure, although their treatment may differ slightly from documents that are not records.

4.0 The MOTIVA Lab Master Document List (MDL)

4.1 The Master Document List (MDL) is an Excel spreadsheet and is maintained by the Quality Manager. It contains the effective date of revision of all MOTIVA Lab documents. It also contains the names of documents relevant to MOTIVA Lab programs, the authors of these documents, their approving authority, a unique document code number for each document and the current revision number and date of each document. The documents related to each specific aspect of MOTIVA Lab operations and programs are kept in binders in the Quality Library of the MOTIVA Lab office.

4.2 The MDL contains the appointments of MOTIVA Lab staff authorised to review and approve MOTIVA Lab Quality System documents.

Binder Code	Title
AD	Administrative Procedures Manual
F	Forms Binder
Pol	Corporate Policy Binder
S	Standards and External Documents
SP	System Procedures Binder
TP	Technical Procedures Binder

4.3 The controlled copy of the MDL is held in the MOTIVA Lab Quality Library and is amended, from time to time, by persons authorised to revise Quality System documents.

4.4 The Master Document List contains a column to allow document authors and approving authorities to indicate, by their signature, that they have reviewed a document for content and applicability.

4.5 The MDL also contains a column to indicate when documents are due for review.

5.0 Annual Review of MOTIVA Lab Documents

5.1 All documents must be reviewed for content and applicability at least once per calendar year. The Master Document List contains a column to allow document authors and approving authorities to indicate, by their signature, that they have reviewed a document for content and applicability.

5.2 Review of all documents controlled by MOTIVA Lab shall take place during the beginning of the calendar year, between January and March, so that the task is completed by 1 March, in time for the internal audit.

5.3 As external documents do not have document authors assigned, their annual review is the responsibility of the assigned approving authority.

5.4 The Master Document List record posted on the Quality Library contains a column (Needs Review?) that compares the date of last review with the date of printing of the record. Whenever there is more than one-year difference between the two dates, a “Yes” appears in this column. Document authors are to periodically examine the MDL record to determine if any of their documents require review.

6.0 External Documents

6.1 Many documents that are used by MOTIVA Lab are created outside of MOTIVA Lab. An example of this type of document is ISO/IEC 17011, one of the standards that contain the requirements used as the basis of the MOTIVA Lab Quality System.

6.2 External documents may be controlled within the MOTIVA Lab document control structure by their inclusion on the Master Documents List. They are normally retained in one of the “S” (standards) binders of the MOTIVA Lab document structure.

6.3 Any MOTIVA Lab staff member or MOTIVA Lab official may request that MOTIVA Lab adopt and control a copy of an external document. When a copy of that document is added to one of the “S” binders and an entry is made in the Master Documents List, it is considered a controlled document. Responsibilities for the use of external documents is allocated to the person named as the approving authority within the Master Documents List.

7.0 Creating or Revising Quality System Documents

7.1 Creation and Revision Processes

7.1.1 The only reliable paper copies of MOTIVA Lab Quality System documents are the copies held in the Quality System binders in the MOTIVA Lab Quality Library. These documents, and the registered versions of the Quality Manual are treated as "controlled" documents.

7.1.2 Document authors submit proposed Quality System documentation to a potential document approval authority for approval. In discussion with the appropriate manager and Quality Manager, an appropriate person will

become the approval authority for the document. They shall be listed in the Master Document List. Document authors are also listed in this same table.

7.1.3 Only those personnel listed in the Master Document List as approving authorities may approve MOTIVA Lab quality system documents. As well, these same approving authorities are responsible for ensuring that all documents within their purview are reviewed periodically.

7.1.4 A revision to any part of a Quality System document is a revision of the whole document. Revisions to MOTIVA Lab Quality System documents are normally "highlighted" to indicate the actual changes in wording. Alternatively, when the revision involves only deleting text, the deleted text may be shown with "strikethrough." Highlighting added text and striking through deleted text may, or may not include, minor editorial changes. Document authors and approving authorities are cautioned to ensure that any text that provides noteworthy changes should be clearly identified to ensure clarity and understanding. How much highlighting and/or strikethrough is required, is left to the document authors and approving authorities.

7.1.5 The only "official" versions of MOTIVA Lab Quality System documents that are in electronic format are those in the Master Documents directory on the MOTIVA Lab Server. The version of a document produced following any revision will carry the electronic signature of the revision but is applied to the whole document.

7.1.6 The document authors or approving authorities are the only persons who can make revisions to their Quality System documentation but a revision to Quality System documents may come from anyone. Proposed revisions are forwarded via email to the document author listed in the Master Document List as well as cc'd to the Quality Staff. The use of "post-it" notes to add information or "white out" to remove or modify information is not permitted.

7.2 Publishing MOTIVA Lab documents on the MOTIVA Lab Website

7.2.1 If a document is to be posted to the MOTIVA Lab website that is not currently posted, the approval authority is to specify this and state where on the website the document is to be posted. The MDL record entry is to show the asterisk that denotes a publicly available document posted to the MOTIVA Lab website. The Quality Staff will then mark the document in the appropriate directory with a red label to indicate it is a web document.

7.2.2 For documents requiring revision on the website, this same approach is used, for the most part. An e-mail to the Quality Staff, informing them of the change to the document and a note that the document is to update one currently on the website.

7.2.3 Once a document has been approved and placed in the appropriate binder in the MOTIVA Lab Quality Library, the document author or approving authority shall indicate, in the Master Document List that is also in the Library, that the document has been revised. This indication shall take the form of a handwritten amendment to the revision number of the document, the date of its revision and the initials of the person making the amendment.

7.3 Effective Dates of Revisions

7.3.1 The Master Document List (MDL) contains the effective date of revision of all MOTIVA Lab documents. This list is an Excel spreadsheet and is maintained by the Quality Manager. The controlled copy of this document is held in the MOTIVA Lab Quality Library and is amended, from time to time, by persons authorised to revise Quality System documents.

7.3.2 The effective date of revision is also published on the cover of MOTIVA Lab documents published for use by others. These dates are not normally repeated in the footer of the document as per the formatting requirements given below.

7.4 Document Formatting Requirements

7.4.1 Any formal reference to a document controlled within the Quality System uses the nomenclature (name) of its entry in the Master Document List. Such reference is to include the full nomenclature of the document: for example, "SP-004 – Document Control and Control of Records." Neither "SP-004" nor "Document Control" are sufficient references to this document.

7.4.2 The following criteria apply to the creation and/or revisions of all MOTIVA Lab Quality System documentation, once these have been approved.

a. Documents circulated for review that have not yet been approved, contain clear and visible indication that they are only "draft" documents.

b. All footers in amended documents are modified and the revision number changed in the footer as per the following example.

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c. Appendix documents, such as Q08, employ *leading zeros* in their alpha-numeric designation, for all documents numbered less than 10.

d. The format for revision numbers follows the approach shown above. The actual numbers used for any revision, provided this approach is followed, are at the discretion of the document approving authorities listed in the Master Document List.

e. The revision numbers are amended on the cover pages.

f. For the preface page of the Quality Manual, the revision number is amended.

g. The page numbering for the introductory section of any large documents, such as the Quality Manual, are amended accordingly.

h. Before printing the final copy of a large document, the table of contents and its corresponding pages are checked for accuracy to the revisions made.

7.5 Formal Approval and Issue

7.5.1 The Approval Authority for each document is to verify that the content and the formatting meet the requirements of this procedure. When they are satisfied that this is so, they are to ensure that the document is submitted to the Transfer directory of the MOTIVA Lab Master Documents directory on the network (MOTIVA Lab Server), and place a copy in the appropriate Quality System Binder in the Quality Library.

7.5.2 Make handwritten amendment to the copy of the MDL found in the MOTIVA Lab Quality Library. Amend the Revision (“Rev”) column, amend the Revision Date (“Rev Date”) column, and if necessary revise the title of the document or appendix as it appears in the list. Initial the changes.

7.5.3 This table shows the specific steps in publishing a change, once it has been authorised:

Person Responsible	Specific Step
Document Author	Amend the appropriate binder in the MOTIVA Lab Quality Library
Document Author	Hand write an amendment to the Master Document List in the same Library
Document Author	Post an electronic version of the authorised document in the Approval Directory of the Master Documents directory on the MOTIVA Lab Server.
Quality Staff	Move the electronic version of the authorised document to the appropriate quality system directory in the Master Documents directory on the MOTIVA Lab Server.
Quality Staff	Notify the IT Manager if the document is a web document.
Quality Staff	Amend the electronic version of the MOTIVA Lab Master Document List, mdl.xls, to reflect the amended revision number of the newly modified document.

7.6 Document Removal, Deletion, and Archiving

7.6.1 Once a document has been created and made part of the MOTIVA Lab Quality System, it is retained by MOTIVA Lab indefinitely. As soon as a new authorised version of an official document has been approved, old versions (both paper and computer) will be destroyed with the exception of one file copy that will be marked “SUPERSEDED” and stored in one of the superseded files, separately from the current version. The date of supersession is handwritten next to the stamp so as to note the actual date of replacement of the superseded document.

7.6.2 Only the approving authority shown in this procedure can remove a document from the MOTIVA Lab Quality System. When a document is removed from the Master Document List table below, the document slot is identified as "deleted" and the document code is not reassigned to any new document. Any copies of the deleted document that exist are gathered and treated as per an old version of a current document. It will be marked "SUPERSEDED" and stored in one of the superseded files retained in the file room. Approving authorities shall ensure that this procedure is followed.

7.6.3 MOTIVA Lab moves documentation and data from the active file storage area to the archive storage site on a yearly basis. Each section and area within MOTIVA Lab decides the criteria for the selection of documentation and data to be moved.

8.0 Records Management

8.1 MOTIVA Lab produces records that demonstrate the implementation of quality system policies and procedures. Records are maintained in files as described in the MOTIVA Lab File List (see 7.4.1 below).

8.2 All details regarding the retention of MOTIVA Lab records is contained in **Instruction 001 – Record Retention**.

8.3 Maintenance of Lists

8.3.1 The following lists are maintained by the person named:

List	Person Responsible
Staff	HR
Fixed Assets	FO
MOTIVA Lab File List	Administrative Assistant
Data Processing Equipment	IT Manager
Master Document List	Quality Manager

8.3.2 Any staff member becoming aware of changes necessary to a list should notify the individual responsible for maintaining it. The individual responsible will ensure that all staff receive copies of updated lists, as designated in the "Distribution of Lists", at least quarterly, if changes have occurred.

8.4 Client Files

8.4.1 All correspondence with each client will be retained, including but not limited to:

- Formal contracts;
- All requests and work orders;
- All reports issued to clients:
- All client assessments of MOTIVA Lab;
- All client feedback;
- All client invoices and financial records, and
- All client correspondence

8.5 Personnel Records and Files

8.5.1 Access to personnel files is limited to authorized persons that require access to carry out their duties. In addition, because personnel files may include a variety of personal information, authorized staff should have access only to specific categories of personal information contained in the file.

8.5.2 In order to ensure consistency, fairness and in keeping with the required protection of personal information of staff members, MOTIVA Lab segregates **CONFIDENTIAL** personnel files from **GENERAL** personnel files.

8.5.3 Within the **CONFIDENTIAL** files, the filing system distinguishes *categories* of records held. In this way, access to a specific category is limited to authorized staff. Employees dealing with a particular issue will only be given access to records related to that particular issue.

8.5.4 **CONFIDENTIAL** personnel files shall be maintained by the HR Manager under lock, and access is restricted

to the employee and authorized personnel only. The employee shall not be allowed to remove any document from the file. However, they may obtain copies of the documents. No information contained in the **CONFIDENTIAL** file shall be made available to third parties except as authorized in writing by the employee. In this context, the employees' manager, the HR Manager and the General Manager are not third parties.

8.5.5 The **CONFIDENTIAL** personnel file has the following *categories* of personnel records. Examples are also shown.

CATEGORY	DOCUMENTS
Corporate	Reference checks Letter of offer/appointment Salary and bonus information Group Insurance entitlements Timesheets
Health and medical	WCB claims and related materials LTD claims and related materials Physician documentation Group Insurance documentation Emergency Contact Information
Employment	Formal and informal employee performance evaluations
Labour relations	Disciplinary documentation Legal opinions All labour-related matters

8.5.6 **GENERAL** personnel files shall be maintained by the Financial Administrator.

8.5.7 The **GENERAL** personnel file does not distinguish between categories of information and contain the following types of records:

- Resumes and CVs
- Job Application forms
- Job Descriptions
- Training records
- Qualification records
- Conflict of interest and Confidentiality form

8.6 Record Retention

8.6.1 All details regarding the retention of MOTIVA Lab records is contained in **Instruction 001 – Record Retention**.

8.7 Handwritten Amendments to Records

8.7.1 MOTIVA Lab staff, in the conduct of their duties, may amend records. Changes to records shall be done in permanent marker or ink only – not in pencil. The original record shall be crossed out and legible. The amended entry shall be legible and a person authorised to make the change shall initial the change.

8.8 Generating Electronic Reports from MOTIVA Lab Databases

8.8.1 MOTIVA Lab controls the formats used in electronic records and their resulting reports. Quality system documents that are used to control the format of electronically generated records are retained in the appropriate binders in the Quality Library.

8.8.2 Quality system records, which are generated as "reports" from software, may be reprinted at any time, from the originating software (database). The revision number is not amended as it applies only to the format, which is controlled separately. Revision number changes to these documents will occur only when a change to the document format occurs. The most recent record format, with sample information, will be included in the appropriate Forms Binder.

8.9 Master Document List (MDL)

8.9.1 See 4.0 above.