

SECTION: LQM 4.1 ORGANIZATION AND MANAGEMENT

EFFECTIVE DATE

10-10-2008

ISSUE DATE: 10-10-2008

ISSUE NO: 1

REVISION DATE: 0

REVISION NO: 0

COPY NO: 2

PAGE 1 OF 5

4.0 MANAGEMENT REQUIREMENTS

4.1 ORGANIZATION AND MANAGEMENT

The Company and laboratory organization charts are documented as in [Exh. 1](#) and [Exh. 2](#) respectively in this LQM. The responsibilities and authorities of personnel who manage, perform and verify works affecting quality are also detailed in this LQM.

The Laboratory Manager is also the Management Representative who has defined authority and responsibility, which includes:

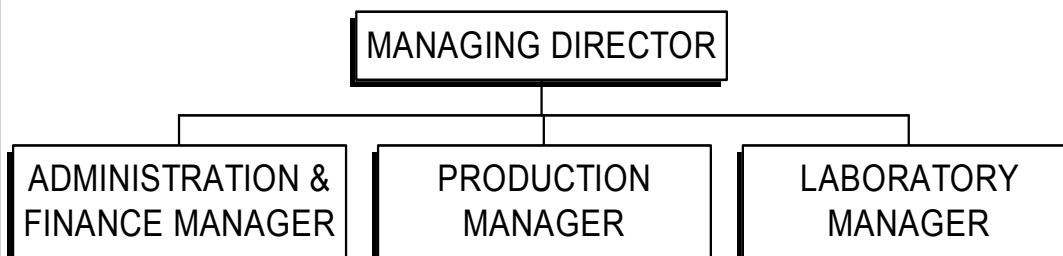
- Ensuring the Laboratory Management System is established, implemented, maintained, **continually improved** and updated in compliance to MS ISO/IEC 17025:2005 at all times,
- Direct access to the top management of the Company (**ABC Group**) on the laboratory policies and quality related matters,
- Ensuring that complete internal quality audits are carried out at least once in seven months.
- Ensuring the laboratory management review meeting is carried out as least once in seven months.
- Reporting on the performance of the Laboratory Management system to the Company management
- Liaising with external parties on issues relating to the **management system**.

4.1.1 Laboratory Organization Structure

The laboratory organization comes under the Quality Control Section. The Quality Control Section is under the responsibility and authority of a Laboratory Manager, who reports directly to the [Managing Director](#).

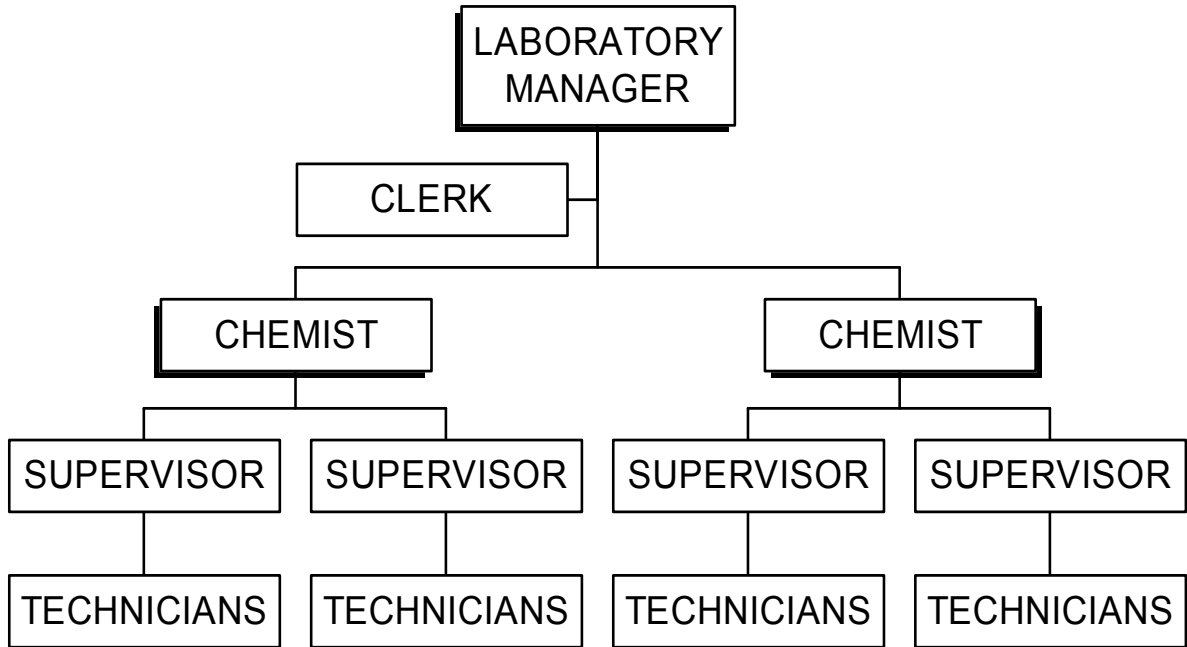
The laboratory consists of [at least 21 personnel](#) who report to the Laboratory Manager.

EXH. 1: ORGANIZATION CHART OF ABC INDUSTRIAL SDN BHD



<i>Approved by:</i>	<i>Management Representative:</i>	<i>Prepared by:</i>
<i>Managing Director</i>	<i>This document is the property of ABC Laboratory Sdn. Bhd.</i>	<i>Laboratory Manager</i>

EXH. 2: LABORATORY ORGANIZATION CHART



(Note: Personal names of all personnel are found in the Appendix G at the back of this manual.)

4.1.2 Management Responsibilities and Authorities

4.1.2.1 Laboratory Manager

The Laboratory Manager is the Head of the Laboratory and also the appointed Laboratory Management Representative (MR). He reports directly to the Managing Director. He has overall responsibility and authority for the laboratory, including:

- i) Being the recognized signatory for the laboratory test certificates
- ii) Ensuring the management system of the laboratory is implemented, maintained and updated
- iii) Ensuring the management review meeting is carried out at least once in seven months
- iv) Ensuring complete internal quality audit is carry out at least once in seven months
- v) Ensuring all laboratory management and other personnel are free from any undue internal and external pressures or influences that may affect the quality of their work
- vi) Ensuring client's confidential information and proprietary rights including electronic storage and transmission of results are protected with proper policies and procedures
- vii) Ensuring avoidance of any activity that would diminish confidence in the laboratory's competence, impartiality, judgement or operational integrity
- viii) Ensuring the laboratory organization structure is defined, organized and managed within the Company organization, relating between quality management, technical operations and support services
- ix) Ensuring adequate supervision and resources are provided to enable the laboratory to function competently and reliably, including to trainees and contract staff
- x) Ensuring all personnel's responsibility, authority and inter-relationships are properly defined in order to manage, perform or verify work affecting the quality of the tests
- xi) Ensuring technical operations are properly managed to give accurate and reliable results
- xii) Ensuring the appointment of MR for the laboratory
- xiii) Ensuring all key management positions are deputized in their absence
- xiv) Ensuring its personnel shall be aware of the relevance and importance of their activities, which contribute to the achievement of the objectives of the management system.
- xv) Ensuring appropriate communication processes have been established for monitoring the effectiveness of the management system and the operations.

4.1.2.2 Chemist

The Chemist reports directly to the Laboratory Manager. He is responsible for the operational activities in the laboratory to ensure all testing and services are smoothly carried out in accordance with the established management system. His responsibility and authority includes as follows:

- i) Deputize for the Laboratory Manager in his absence unless otherwise arranged
- ii) Sign (where qualified) for test certificates
- iii) Sign (where qualified) for the test reports
- iv) Assist the Laboratory Manager in the management and administration of the laboratory
- v) Assist the Laboratory Manager in all the quality activities, including the management system implementation, maintenance and updating where applicable and on request
- vi) Participate in the management review meeting
- vii) Supervise the laboratory technical and quality operations
- viii) Involve in the internal quality audits of the laboratory
- ix) Responsible to ensure all laboratory equipment are within calibration, maintained and checked to provide valid and accurate measurement all the time

<i>Approved by:</i>	<i>Management Representative:</i>	<i>Prepared by:</i>
<i>Managing Director</i>	<i>This document is the property of ABC Laboratory Sdn. Bhd.</i>	<i>Laboratory Manager</i>

SECTION: LQM 4.1 ORGANIZATION AND MANAGEMENT**EFFECTIVE
DATE****10-10-2008**

ISSUE DATE: 10-10-2008

ISSUE NO: 1

REVISION DATE: 0

REVISION NO: 0

COPY NO: 2

PAGE 4 OF 5

- x) Responsible to ensure regular improvement and innovations in the environment and test activities to provide better efficiency, proficiency, accuracy and reliability
- xi) Responsible to ensure agreed targets are met, implementing corrective and preventive actions on daily test results where necessary.
- xii) Conduct and coordinate sampling and analysis activities where necessary
- xiii) Coordinate the inter-related quality activities between the laboratory and the Company where required
- xiv) Undertake additional tasks that may be requested by the Laboratory Manager or his superiors where relevant

4.1.2.3 Supervisor

The Supervisor directly reports to the Chemist. He is responsible to carry out and coordinate the operational activities in the laboratory, including:

- i) Deputize for the Chemist on assigned roles in his absence unless otherwise arranged
- ii) Responsible for the coordination and distribution of daily tasks and duties to all technicians
- iii) Responsible for maintenance of laboratory equipment
- iv) Responsible for on-the-job training and reporting of all technicians
- v) Responsible for analysis and testing where relevant
- vi) Responsible for maintenance of equipment, housekeeping, safety and health in the laboratory, including the safe handling of chemicals and samples
- vii) Responsible to ensure test results are duly calculated and recorded accordingly
- viii) Responsible to inform superiors immediately any abnormality or nonconformance in the laboratory and associated areas
- ix) Responsible to requisite spare parts for equipment and chemical stocks well in advance
- x) Responsible for proper use and provision of safety gears to technicians
- xi) Maintain all equipment in good and valid conditions (calibration) to provide accurate measurements and records
- xii) Responsible to ensure test methods and equipment are properly utilized and followed by technicians
- xiii) Responsible to ensure the proper preparation of standard materials for calibration
- xiv) Undertake additional tasks that may be requested by the Chemist or his superiors where relevant

4.1.2.4 Technician

He reports directly to the Supervisor. He is responsible to carry out the daily testing and services required of the laboratory, including:

- i) Perform the daily tests and checking of the samples to maintain the quality to meet set targets
- ii) Obtain samples for tests
- iii) Report promptly test results to all relevant departments
- iv) Maintain good housekeeping, safety and health in the laboratory at all times
- v) Follow all regulations, instructions, environmental and safety rules of the laboratory and the Company
- vi) Assist less experienced laboratory personnel in problem solving and overcoming difficulties in their daily operations
- vii) Perform other duties such as chemical analysis works and special tasks whenever necessary (under supervision)
- viii) Record all raw data and test results on relevant log sheets
- ix) Report any abnormalities or nonconformance immediately to superiors
- x) Troubleshoot and assist in problems arising in the systems and any other equipment
- xi) Undertake additional tasks that may be requested by the Supervisor or his superiors where relevant

Approved by:

Management Representative:

Prepared by:

*Managing Director**This document is the property of ABC Laboratory Sdn. Bhd.**Laboratory Manager*

SECTION: LQM 4.1 ORGANIZATION AND MANAGEMENT**EFFECTIVE
DATE****10-10-2008**

ISSUE DATE: 10-10-2008

ISSUE NO: 1

REVISION DATE: 0

REVISION NO: 0

COPY NO: 2

PAGE 5 OF 5

4.1.2.5 Clerk

He reports directly to the Laboratory Manager and Chemist. He is responsible to carry out the daily administrative and office activities, including:

- i) Data entry and preparation of test certificates/reports
- ii) Filing, distribution and records
- iii) Control of office copy of the laboratory quality manual and laboratory quality procedure (for reference)
- iv) Any other quality related activities assigned by the Laboratory Manager and/or Chemist from time to time

*Approved by:**Managing Director**Management Representative:**This document is the property of ABC Laboratory Sdn. Bhd.**Prepared by:**Laboratory Manager*