ISO GUIDE 25 LABORATORY ACCREDITATION FOR PGI LABORATORIES - AN EXPERIENCE

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ABSTRACT

The Philippine Geothermal Laboratories at Tiwi and Mak-Ban successfully qualified for accreditation under the ISO/IEC Guide 25: 1990 on August 3, 1998. The two field laboratories were awarded separate accreditation for sampling and analysis of water, steam and gas. All the samplers and chemists from both laboratories were accredited as approving signatories for sampling and chemical tests, respectively. This quest for quality in the laboratories is part of PGI's overall commitment to excellence.

The requirements of the ISO/IEC Guide 25: 1990 include a full documentation of the laboratory quality management system. In compliance, the laboratories established a Quality Manual, a General Procedures and Work Instructions Manual, and a Laboratory Procedures and Work Instructions Manual covering the rules and regulations of the laboratories, general procedures and work instructions and analytical and sampling procedures and work instructions. Internal quality audits were conducted and preventive and corrective actions were implemented to sustain the quality system.

The Laboratory Quality Management Team spearheaded the efforts for accreditation and with the full support of management, total commitment, dedication, and teamwork from all the staff, PGI became the 14th company in the Bureau of Product Standards' roster of ISO Guide 25 accredited laboratories.

1.0 INTRODUCTION

The Tiwi and Mak-Ban Laboratories are an integral part of Philippine Geothermal, Inc. (PGI), a wholly owned subsidiary of UNOCAL Corporation which supplies steam to National Power Corporation (NPC). The laboratories provide the sampling and analytical requirements of each field. Each laboratory is supervised by a Laboratory Supervisor who reports directly to the Asset Manager. The Laboratory Operations Coordinator oversees the technical and quality assurance functions of both laboratories.

In an effort to further improve the service to our internal clients and produce timely, accurate and precise analytical and sampling results, PGI laboratories applied for accreditation **fiom** the Bureau of Product Standards (BPS) under the ISO Guide 25. The laboratories embarked on this venture with the following expectations in mind:

- Enhanced reliability of data
  This refers to comparability of data between different laboratories and within a single laboratory, between different analysts.
- Reduced waste due to repeated testing and incorrect conclusions
  Acceptable precision and accuracy achieved at first analysis. "Doing things right the first time".
- Simplification of communication
  Everyone understands how data were generated.
- Increased efficiency and ease of instrument maintenance
  Performance documented, PM scheduled and done, recurring problems reduced.

- International recognition of proficiency in testing.
- Improved awareness of health, safety and environmental concerns.
- Continuous improvement of operations through interactions at all levels
  The clients, analysts and chemists are involved through information and feedback.

On August 3,1998 the two PGI laboratories earned the distinction of becoming the fourteenth company as well as the first in geothermal industry to be accredited under the ISO/IEC Guide 25: 1990 for sampling and analysis of geothermal fluids. All the chemists, analysts and samplers were granted as approving signatory status to the tests performed. This is proof of the laboratories' commitment to take an active role in the pursuit of excellence and continuous learning and improvement not only in PGI but also in the geothermal industry.

2.0 PHASE I: APPRAISAL AND PLANNING

PGI Laboratories began preparation for accreditation in the first quarter of 1997. On February, 1997, the ISO 25 Steering Committee was created as an ad hoc working team whose goal was to establish a quality system based on the ISO/IEC Guide 25: 1990 requirements. The team evaluated and assessed the laboratories' standing in terms of accreditation requirements and worked on the following:

- Reviewed all procedures, records and logbooks and recommend additions and changes to documentation and practice
- Training needs and personnel records to be developed
- Equipment maintenance/calibration and status documents
- Management support and involvement
- Determine gaps between ISO 25 standards and current practice
- Determine how to close gaps, e.g. additional documentation and procedures
- Develop timeline fur eliminating variances between procedures and practices and achieve compliance.
- Develop Gantt chart for implementation.

The team is composed of the Laboratory Operations Coordinator who chairs the committee, the Laboratory Supervisors, and the appointees - the Quality Administrators, the Lead Auditors, the Training Officer and the Document Officer. These are the key personnel involved in the establishment of the Laboratory Quality System.

On April 1997, the laboratory staff started attending training courses for ISO/IEC Guide 25: 1990. Based on the thirteen (13) elements of the ISO/IEC Guide 25: 1990, the ISO 25 Steering Committee laid out the plans on how to fulfill the requirements of the guide.

3.0 PHASE II: DESIGN AND DEVELOPMENT

The laboratory encountered problems during the documentation process. The entire staff including the ISO Steering Committee had to cope up with the demands of the clients while preparing the documents. Teamwork and commitment were evident but the burden of working against time trying to finish the documentation, plus putting in extra time for meetings so we could settle differences in opinions before we could proceed with the documentation took its toll on its members. There were times when differences in perception or interpretation of what ISO/IEC Guide 25: 1990 requires resulted in raised voices. What saw us through these times were the affirmations and the confidence management placed in us, but most especially, the overall leadership of our Laboratory Coordinator.

Inspite of the frustrations besetting the team, the ISO 25 Steering Committee was able to come up with a Laboratory Quality System appropriate to the needs of the two laboratories at the Mak-Ban and Tiwi Assets less than a year after we started. The quality system established contains the thirteen (13) elements needed to meet the requirements of ISO/IEC Guide 25: 1990.

3.1 Organization and Management

The Quality Manual includes organizational charts showing the origin and independence of the laboratory. It also contains the requirements such as appointment of deputies, job descriptions, statement of authorized responsibilities and protection of clients' confidential information.

The Laboratory Operations Coordinator serves both as Technical and Quality manager of both laboratories and is of executive status. The Laboratory Supervisors, in their capacity as head of the laboratory, perform administrative and safety management functions and act as the Technical Manager of each laboratory. The Quality Administrators ensure the effective implementation of the Laboratory Quality System. The Document Officer establishes the document and records control system for both laboratories. The Document Controllers acts as the custodian of all the documents in each laboratory.

Committees and ISO implementors were also formed to help implement the requirements of the guide:

The Laboratory Quality Management Team (LQMT)
Formerly called the ISO Steering Committee, it provides the overall direction, ensures that the corporate quality policy is understood, forms the quality organization and structure and designates responsibilities, approves laboratory policies guidelines, procedures and work instructions and holds regular review of the laboratory quality system.

The Internal Quality Audit (IQA) Team
Composed of a lead auditor and four members fiom each laboratory (a total of eight), chosen based on their technical expertise in their field of specialization and training on proper audit procedures. The team conducts a quarterly quality system audit based on ISO/IEC Guide 25: 1990. The lead auditor is also the deputy of the laboratory operations coordinator and is a member of the LQMT.

The Training Team
Composed of a Training Officer and two members fiom each laboratory. The team is responsible for determining the training needs of each position and developing a training program in order to maintain highly qualified and competent staff. The Training Officer is a member of the LQMT.

The Quality Assurance (QA) Team
Composed of a QA Lead and one member from each laboratory. The team is responsible for establishing quality control (QC) checks for all analytical procedures and monitoring implementation of these QC checks, preparing control samples, handling intra- and interlab tests and validation modifications of standard procedure.

The Quality Management Sysiem Implementors
Laboratory staff from each field was assigned specific roles and responsibilities on the following areas of activities:

- Preventive Maintenance and Calibration
- Accommodation and Environment
- Chemical and Supplies Inventory
- Chemical Labeling
- Outside Support and Services

3.2 Quality System, Audit and Review

The documentation of the quality system is structured on four levels:

Level 1 - The Laboratory Quality Manual
Contains the laboratory policy for each area of activity, defines the general requirements, and identifies the responsibilities for the implementation of the policy.

Level 2 - The Procedures and Work Instruction Manual

- The General Procedures and Work Instruction Manual (GPAWIM)
  Describes the administrative responsibilities, procedures and work instructions needed to implement quality activities.

- The Laboratory Procedures and Work Instruction Manual (LPAWIM)
  Describes the detailed tasks, equipment handling and specific methods of sampling and analysis done in the laboratory.

Level 3 - References and Externally Generated Documents

Refer to international guides and standards, standard methods, textbooks, personnel records, internal communication, training modules, catalogues, journals and other documents that are used to support the quality system.

Level 4 - Quality and Technical Records

Provide objective evidence of the extent of the fulfillment of the requirements on laboratory operations. Aside from records pertaining to the technical operations of the laboratory, records of internal quality audit and management reviews are also included.

Internal quality audit is carried out by the IQA team quarterly with subsequent review of audit results. Management reviews are conducted twice a year by LQMT. Corrective and preventive actions on non-compliance noted are implemented.

3.3 Personnel

Records of all staff including the job description, academic and professional qualifications, copies of diploma, training certificates, experiences, training records and training schedule for the year are kept in the laboratory. Only those with the necessary training and proficiency are qualified to carry out analytical and sampling activities.

3.4 Accommodation and Environment

Laboratories located in each field are maintained clean, well lighted, cooled and ventilated to facilitate proper performance of testing. There is an effective separation of the wet laboratories, instrument rooms, stock rooms for samples, cylinder pad areas and laboratory waste storage rooms conforming with the requirements of ISO/IEC Guide 25: 1990. Room temperature and humidity are monitored daily. Good housekeeping and safety are practiced. An updated floor plan is available to staff to familiarize them with the location of safety equipment and emergency exits in the laboratory. Access of non-laboratory staff is limited to defined areas.

3.5 Equipment and Reference Materials

The laboratories are furnished with state-of-the-art instruments, equipment and reference materials required for the correct performance of sampling, analysis and calibration. There are policies, procedures and work instructions on instruments' calibration, equipment preventive maintenance (PM), repairs, commissioning and operation. Each piece of equipment bears a code or a unique identification number and this is recorded in an inventory list together with the equipment's calibration or preventive maintenance status. The calibration and PM program is found in the Equipment Calibration and PM Calendar. An equipment use record is kept beside each piece of equipment. Procedures for loaning out or removing equipment from the laboratory for repair are documented.

3.6 Measurement Traceability and Calibration

Policies, procedures and work instructions for calibrations, standardization and use of Reference Standards are documented and implemented. All measurements made in the conduct of testing or calibration within and outside

the laboratory should be traceable to National *or* International **Standards.** If traceability to National **Standards** is not evident **or** *cannot* be demonstrated, the laboratories will provide satisfactory evidence of correlation of results.

The laboratory maintains several reference materials such **as** standard weights, digital flowmeter, thermometer, thermohygrometers, digital gauges, standard or reference chemicals such **as** primary standards, NIST SRM, IC, **AAS** and GC grade **standards,** etc.

3.7 Calibration and Test Methods

All sampling, testing, and calibration methods, instrument operation manuals, standards, instructions and reference **data** are documented and maintained current by the laboratories. Standard methods are adopted from **APHA,** AOAC, IGNS and ASTM. In the absence of any published standard method, **an** alternative **method** is allowed provided it is agreed upon with the client, fully documented and validated prior to use.

All chemicals are properly labeled including its hazard rating. Proper use of computers, statistical techniques, QC checks, validation of test procedures, calibration and receiving, purchase, inventory and storage of chemicals are documented.

3.8 Handling of Calibration and Test Items

All items received by the laboratory for sampling and testing are accompanied by either a Sampling and Analysis Request Form *(SARF) or* a Chain of Custody Record (COC) properly accomplished by the requesting customer *or* the laboratory sampler. The condition of the test item upon receipt is documented either in the SARF *or* COC **and** filed. All samples received are given a Laboratory Reference Number (LRN). Procedures *on* sample **retention,** prioritization, and disposal are implemented.

39 Records

Records such as SARF, COC, Sample Receipt Register (SRR), Raw Data Logbooks, Data Log Sheets and the Final Reports generated in the conduct of tests performed *on* each item are in place **to** facilitate traceability. Records are kept in the laboratory at all times in accessible areas and are readily available for inspection. Quality and personnel records are filed at the office of the Laboratory Supervisor. Procedures on retention and disposal of obsolete records are implemented.

3.10 Certificates and Reports

All Certificates and Test Reports contain the information needed **to** meet the requirements of ISO/IEC Guide **25:** 1990. Policies, procedures and work instructions **for** certificate validity, amendments to reports, results from subcontract laboratories, confidentiality clauses and disclaimers are documented and implemented. Partial or full results which are transmitted through telephone, facsimile or oral preliminary releases are confirmed with final reports.

3.11 Sub-contracting of Calibration or Testing

When the requested test or calibration is beyond the capacity of the Laboratories, Subcontracting such tests or calibration is done. The laboratories maintain a list of laboratories which are accredited or have **met** the requirements of the client and the field laboratories and to which we *can* sub-contract such job. Clients are notified of the sub-contracting activities.

3.12 Outside Support, Services and Supplies

The laboratories procure outside *services* and supplies that are of standard quality **from** PGI's accredited suppliers to **sustain** confidence in the laboratories' calibration, sampling and analytical tests. Purchased supplies *or* procured support and services are **not** used until they have been found to comply with relevant **standards** or

specifications. Procedures for inspection, calibration and verification are documented. The laboratory maintains records of all suppliers.

3.13 Complaints

Procedures for the resolution of complaints received from customers are in place. A 'Complaints Form" is used to document the complaint. Complaints received and the subsequent actions to resolve them are recorded.

A "Customer Survey Questionnaire" is distributed to all the clients for them to evaluate the performance of the laboratories once a year. These are reviewed and evaluated by the Laboratory Supervisor and those which need corrective actions are addressed.

4.0 SYSTEM IMPLEMENTATION

A series of roll-outs, in-house meetings and mini-seminars were conducted by the LQMT to the staff Starting from September, 1997. These covered lectures on ISO/IEC Guide 25: 1990 requirements, Laboratory Quality Policy, explanations of the Laboratory Quality System, the contents of the Laboratory Quality Manual including the explanations of each of the thirteen elements, the ISO Organizational Chart, its lead and their functions, the documentation system, The General Procedures and Work Instruction Manual, and The Analytical Procedures and Work Instruction Manual. Handouts and reading materials were distributed to complement the lectures given. Pre-tests and post-tests were given to staff after each lecture for three reasons:

- As a gauge to determine how much information they gained.
- A gauge to determine how much more they need and how best to give it to them, and
- So that they recognize how important it was for them to learn.

The results of the tests proved that information should be disseminated repeatedly and creatively if we are to succeed in helping them learn and manage the change we are introducing.

A series of one-on-one discussions, bench meetings and self study with periodic tests were conducted by the LQMT and some ISO implementors for and with the lab staff on January, 1998 to reinforce what they already know.

At the outset, there were some who lacked self-confidence in learning new information. Others were hesitant to abide by the new policies. For them, adjustment to the Quality System was sometimes difficult. The old habits and practices were really hard to abandon. Painstakingly, we reminded them daily of the Quality System and its importance not only for the laboratory as a team but also for each one of us. After some time, their sense of ownership kicked in and their commitment to the Quality System developed until finally they realized how valuable this accreditation will be in their jobs.

5.0 AUDIT AND REVIEW

To quantitatively measure the extent of the Quality System implementation, several KPI's were formulated and discussed during Management Reviews:

- Quality policy of Timeliness, Accuracy and Precision
  - ➢ % Analysis Completed (no. of analysis completed vs. no. of analysis requested)
  - ➢ % Analysis Completed on Time

- Operate in accordance with the elements of ISO/IEC Guide 25 and pursue continuous improvements in the laboratory in accordance with world standards.
  - ➢ Number of Management Reviews Conducted on Time

- Number of IQA's Conducted on Time
- % Corrective Actions Implemented

- Maintain a highly qualified and competent laboratory staff that share the company's missions and visions.
  - Number of Training Modules Completed
  - Number of Internal Training Implemented
  - Proficiency Test Ratings
  - Interlab/Intralab Test Ratings

- Require that all laboratory staff familiarize themselves with the quality management documentation and implement the policies and procedures at all times.
  - Number of Non-conformances
  - % of Corrective Actions Implemented

- Ensure the precision and accuracy of test results through implementation of strict quality control.
  - Number of Internal Laboratory Re-runs
  - Number of Client Dictated Re-runs
  - Number of Customer Complaints

- Use properly maintained and calibrated equipment
  - % of Equipment Calibrated on Schedule
  - % of PM Conducted on Schedule

- Execute its functions with high regard for the safety of the workers and the environment.
  - % Substandard Conditions Corrected
  - % Attendance of Laboratory Personnel in Safety Meetings
  - Number of STOP Observations Reported and Corrected

The Internal Quality Audit Team (IQA) did a series of full pre-assessment audits to determine the extent of the implementation of the Quality System, to check that necessary documentation is in place, to verify what procedures are practiced and what are not practiced and to correct all deficiencies found.

On February, 1998, we acquired the services of Certification Internationale to conduct an advisory assessment visit on both field laboratories. We were surprised that inspite of all the internal audits we have undertaken, there are a number of non-conformances that were observed on the implementation of the system we established. After correcting all the non-conformances, we applied for accreditation at the Bureau of Product Standards (BPS) on March, 1998.

The Bureau of Product Standards conducted an on-site audit of both facilities on June, 1998. During the post audit meeting, they announced that both fields have no major non-conformance and that all of the applicants passed as approving signatories of the tests performed.

6.0 CONCLUSION

The Bureau of Product Standards accredited both field laboratories to ISO/IEC Guide 25: 1990 on August 3, 1998 after conducting only one assessment. The accreditation is a result of the dedicatión, teamwork and commitment exhibited by all of the laboratory staff from both field laboratories and by unfailing Management support. It is also the result of the numerous prayers offered for the success of this endeavor. The accreditation is truly one accomplished with DIVINE help.