

## QUALITY ASSURANCE MANUAL

## 1. Introduction

This manual contains a description of the Quality Assurance Program of Phoenix Chemical Laboratory, Inc., as required by the relevant sections of 10CFR50 App. B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants, and as detailed in ANSI N45.2-1971, Quality Assurance Program Requirements for Nuclear Power Plants. Phoenix Chemical Laboratory, Inc., is an analytical and consulting laboratory engaged in providing services to its clients among whom many include operators of nuclear power plants and other organizations which provide supplies and services to such institutions.

The principal activities of Phoenix Chemical Laboratory, Inc., lie in analysis, research and development in the fields of fuel and lubricant technology, work oils, coatings and adhesives, gas analysis, solvent analysis, environmental science (air and water) and industrial hygiene and safety. Phoenix Chemical Laboratory, Inc., is capable of performing a wide variety of Standard Tests as specified by the American Society for Testing and Materials, various agencies of the Department of Defense, the General Services Administration and other private and governmental bodies that promulgate such standards. In addition, Phoenix Chemical Laboratory, Inc., has the capability of performing custom analysis, research and development. Phoenix Chemical Laboratory, Inc., specializes in projects of an investigatory or problem-solving nature.

The work of Phoenix Chemical Laboratory, Inc., is supported by a modern chemical and instrumental Laboratory. Among the techniques which are available to serve its clients are gas-liquid and gas-solid partition chromatography, both isothermal and temperature programmed, with thermal conductivity, electron capture, hydrogen flame and flame photometric detection, computer assisted infrared microspectroscopy; ultraviolet spectroscopy; photomicroscopy with bright-field, dark-field, phase contrast, and epi-illumination; atomic absorption spectroscopy for trace metal analysis including flame photometric and flameless techniques; and emission spectrographic analysis.

With this background of the activities of Phoenix Chemical Laboratory, Inc., it will be understood that only some of the Quality Assurance requirements of the above referenced Regulations and Standards are applicable to the operations of this Corporation.

## 2. Quality Assurance Program and Corporate Organization

The nature of the services performed by Phoenix Chemical Laboratory, Inc., have been described in par. 1 above. The overwhelming majority of those services which are related to activities directly or indirectly associated with nuclear power plants are performed in accordance with Standards published annually by the American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA (ASTM). Occasionally services are performed in accordance with the requirements of various Federal, Military and/or Industrial Standards and Specifications. Copies of all relevant Standards and Specifications are maintained by Phoenix Chemical Laboratory, Inc., and are at all times available to its personnel for their use. Since changes in ASTM Standards occur frequently, printed notices of such changes are posted in a central location so that all concerned persons may be aware of such changes as they occur.

Phoenix Chemical Laboratory, Inc., has a horizontal table of organization. All professional employees and technicians report directly to the Technical Director, Dr. Arthur A. Krawetz, who has the combined responsibility for direction of technical activities including Quality Assurance and such corporate activities which may devolve to him as Chief Executive Officer of Phoenix Chemical Laboratory, Inc. Appendix I contains the curriculum vitae of Dr. Arthur A. Krawetz. These duties include indoctrination of new employees in the practices of Phoenix Chemical Laboratory, Inc., supervision of the training of personnel in operation of equipment or performance of analytical and/or physical measurements, assurance that complete documentation and record-keeping of laboratory operations is maintained and that performance of analytical and physical measurements are conducted in the manner required by whatever regulations and/or specifications against which laboratory specimens are examined during the normal and everyday course of the activities of Phoenix Chemical Laboratory, Inc. The latter activity includes necessary calibration, control and monitoring functions which comprise the regular activities of Phoenix Chemical Laboratory, Inc., and which are defined and controlled by the several ASTM, Federal, Military, Industrial and/or other governmental regulations, codes, specifications, laws and ordinances which may be related to any analytical program required for the examination of a particular sample or group of samples.

### 3. Sample and Document Control

Client instructions in the form of correspondence, telephone messages, purchase orders and blanket orders are maintained in pending files until samples or other specimens are received for analysis. Upon receipt of such samples or specimens all relevant documentation is collected, placed with the subject samples or specimens and held to be entered into the laboratory record system.

Entry of sample or specimen into the laboratory record system includes the following steps:

- (a) Each sample is assigned a unique laboratory number which is, in fact, a date code which indicates the date of receipt of the sample. Thus the 21st sample received on January 2, 1987, would be assigned the following number 7 1 2 21.
- (b) A label is placed on each sample with the assigned laboratory number.
- (c) A three-part form is completed for each sample or set of samples which contains the client's name and address, purchase order number, telephone number, reporting and billing instructions, the sample laboratory numbers and instructions relative to the analyses to be performed on each sample. This process is reviewed by Dr. Arthur A. Krawetz both before and after the formal completion of the control documents.
- (d) One part of the three-part form is retained in the office for the entry of laboratory results as they become available. Entry of results is performed by Dr. Arthur A. Krawetz. The second part of the form is maintained on a working file for laboratory personnel so that they may determine what tasks need to be done. The third part of the form is a tag which is attached to each sample or group of samples to be analyzed.
- (e) Laboratory results are received in the office as they are completed. At this time they are entered in the office working file. Initial review of results is performed by Dr. Arthur A. Krawetz at this time. Unusual findings are usually checked automatically by each chemist or technician if he feels a problem may exist. Dr. Arthur A. Krawetz may also request a result to be repeated at this stage.
- (f) Upon completion of all test requirements the working file is reviewed by Dr. Arthur A. Krawetz prior to its being typed. This review may reveal the need for further study if inconsistencies or unusual relations between chemical and physical properties are discovered. Necessary calculations are also performed by Dr. Arthur A. Krawetz at this time. If required, a narrative comment is prepared by Dr. Arthur A. Krawetz.
- (g) The working file is then given to a member of the secretarial staff for typing.

- (h) After a typed report has been prepared it is subjected to a final review prior to signature by Dr. Arthur A. Krawetz.
- (i) Fuel samples are retained for 7 days after completion of testing. Lubricant and other non-hazardous samples are retained for 60 days. Hazardous samples are returned to their sender for disposal.
- (j) Original laboratory records are kept in bound notebooks and are retained indefinitely. Correspondence, copies of laboratory reports, purchase orders and invoices are retained for 7 years.
- (k) In the event of the absence of Dr. Arthur A. Krawetz for any reason the sample and document control functions described above are performed by senior staff members, usually in consultation with Dr. Arthur A. Krawetz via telephone. In such cases, however, all documents and reports are segregated and retained until they are reviewed by Dr. Arthur A. Krawetz upon his return.

#### 4. Instructions and Procedures

The basic method of the conveying of instructions and procedures has been described in par. 3 above. However, analytical studies often reveal findings which may have been unexpected at the time those original instructions were given. In such cases, necessary variances in procedures, revised instructions or completely new instructions are developed by Dr. Arthur A. Krawetz in consultation with the laboratory personnel responsible for the studies in question. Problems of this nature are discovered by the chemist performing the analysis as well as by Dr. Arthur A. Krawetz during the several stages of review to which data are subjected prior to the preparation of a test report.

#### 5. Control of Purchased Material, Equipment and Services

Materials and equipment purchased for standard procedures are specified in the written procedures for each test. Chemical reagents and laboratory equipment are purchased to those specifications. The list of purchases is reviewed by Dr. Arthur A. Krawetz prior to the placement of orders. Supplies when received are checked against the original order and the packing slip initialed by the chemist who receives the subject material to signify that the material or equipment is that which was, in fact, ordered. Measuring devices are calibrated upon receipt to determine whether they are acceptable for use or should be returned as being out-of-specification. An annual vendor audit questionnaire will be sent to suppliers of calibration services and equipment. Should sub-contracting of any laboratory services be required the same form will be sent to the sources of these services. The questionnaire is included as Appendix II.

## 6. Identification of Purchased Materials

Reagent chemicals are labeled by their manufacturer. Reagents with expiration dates are not used after such dates. If transfer of a chemical to a secondary container, as such, or in the form of a solution or mixture is required, a permanent label is affixed to the secondary container. A complete set of Material Safety Data Sheets is maintained for all reagents used. Measuring devices, such as thermometers, which have serial numbers are identified by those numbers which are kept in a permanent file.

## 7. Inspection and Test Control

Phoenix Chemical Laboratory, Inc. is a member of the ASTM Interlaboratory Exchange Group. In that program samples of various fuels and lubricants are tested by over 400 laboratories. Results are provided in a format which permits statistical evaluation of analytical performance. Phoenix Chemical Laboratory, Inc., is a member of the Great Lakes Regional Sample Exchange Program. In that program, monthly samples are exchanged for the determination of research octane, motor octane, API Gravity, Reid Vapor Pressure, distillation and lead content. A monthly report of the results is circulated to the membership so that each may evaluate his performance on a statistical basis. On an irregular schedule Phoenix Chemical Laboratory, Inc., participates in ASTM round-robin studies to evaluate the precision of various test procedures. Various government agencies and industrial organizations also conduct round-robin test sequences in which Phoenix Chemical Laboratory, Inc., participates. As the Midwest (Chicago) Region contractor for the Defense Fuel Supply Agency, our work with aviation turbine fuels is regularly inspected by DCASMA, O'Hare International Airport, P.O.Box 66911, Chicago, IL 60666-0911. The above are in addition to the control measures described in par. 3 and 4 above.

## 8. Control of Measuring and Test Equipment

Weight is the fundamental measurement in all chemical laboratories. All balances at Phoenix Chemical Laboratory, Inc., are calibrated annually by an approved supplier who supplies a certificate of conformity which is traceable to NIST. Thermometers are calibrated when received and at regular intervals thereafter. Calibration of precision thermometers is by comparison to a platinum resistance thermometer the calibration of which is traceable to NIST. Routine thermometers are calibrated by comparison to precision thermometers. Changes in calibration are detected by determination of ice-points or by a convenient fixed point for those thermometers which do not have an ice-point. A standard thermometer calibrated by the NIST is also available for calibration by comparison. Meters and pyrometers are calibrated by use of precision potentiometers. Thermometers found to be out

of calibration by more than the allowable variation in the relevant Standard are discarded. Thermometer calibration data are kept in a computer data-base which contains archival calibration data as well as the most recent calibrations which include reference to calibration source when secondary standards are employed for comparison purposes. Meters or pyrometers are recalibrated and/or repaired. Flow measurement devices are calibrated regularly by use of a positive displacement flow calibrator. Low flow rates are calibrated by a soap-bubble flow device.

#### 9. Non-Conforming Items

Materials, purchased equipment or supplies which are found to be non-conforming to relevant specifications will be subject to corrective action as described in paragraph 10. If requested by a client Phoenix Chemical Laboratory, Inc., will indicate in its report the conformity or non-conformity of test results to any given specification. Upon request, such findings of non-conformity will be communicated by telephone.

#### 10. Corrective Action

Non-conforming materials, purchased equipment or supplies are returned to the supplier for corrective action. On site equipment which is found to be non-functional is repaired under existing service contracts, returned to its manufacturer for repair or serviced by personnel of Phoenix Chemical Laboratory, Inc., to ensure that proper operational norms are delivered. Any deficiencies discovered by the quality assurance procedures described in par. 3 and 4 are corrected by immediate replication of the suspect test result. Should our review indicate that other results may have been similarly affected, those studies are also replicated. A similar procedure is followed for inquiries made by third parties. However, it is noted that in such cases if the replicate data requested by a third party agree with the original data within published limits of precision, a charge is made for such replication.

#### 11. Quality Assurance Records

All calibration and related quality assurance records are kept indefinitely in the original laboratory notebooks of record and for seven years in the case of round-robin test data. Thermometer calibration records are also kept on disc for ready access by computer.

#### 12. Audits

The audit program as described above is a continuous, on-going program. Phoenix Chemical Laboratory, Inc., will make its facilities and procedures available to external auditors by appointment.