CHAPTER TWENTY-FOUR

Quality Control

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1 INTRODUCTION

The philosophy of quality control in industrial hygiene must reflect the professional goal of the industrial hygiene program, health protection through prevention of occupational diseases. Quality control's contribution to the real value of the industrial hygiene program is measured in terms of its contribution to the performance, cost, or schedule of the program. Quality control is then an extension of the role of management and assures effective management of the industrial hygiene program. Incorporation of the quality control plan into the management of an industrial program will trigger timely, consistent actions, and will provide evidence of the industrial hygiene program's effectiveness not only internally but externally. The outside parties may include facility management, the workers being protected, evaluation and accreditation groups, and regulatory agencies.

Quality control in industrial hygiene is analogous to quality control for plant processes. The industrial hygiene program itself is the embodiment of the principles and practices of quality control. The identification, evaluation, and control of health hazards, the triad of industrial hygiene, is the quality control approach or philosophy. A plant process produces certain occupational exposures to the workers from the noise, heat, dust, gases, and vapors, and so on, being produced by the process. These exposures can be considered as defects in a perfect production process. The perfect process would be so engineered that the loss of energy, the formation of by-products or contaminants, and the wear or breakdown of equipment would not occur. We must, however, deal with reality. The industrial hygiene engineer contributes to the design of optimum, if not perfect, plant processes. The monitoring program validates the effectiveness of the process design and control techniques. It detects the impending or recent failure of these control measures. The cause of the "out-of-control" situation is

determined, and corrective action is taken to put the plant operation back into control—that is, no unacceptable occupational exposures. Monitoring is resumed. The level of monitoring is proportional to the magnitude and frequency of problems or "out-of-control" situations. According to Hagan, a good ground rule to follow might be: "Let the level of detail be equal to the value of preventing problems" (1).

This chapter provides guidance needed by the formulators of the industrial hygiene program for incorporating efficient quality control practices. These practices will assure timely and consistent actions to achieve the program's goal. The material is presented as an overall plan or system. The order of presentation follows the sequence that the industrial hygiene program would use to consider and install the various elements of the system. Initial consideration must be given to the scope and application of quality control in the industrial hygiene program. The program management section includes such elements as objectives and policies, organization, planning, operating procedures, chain of custody, records, corrective actions, training, and costs. The section on equipment, standards, and facilities covers the areas of sampling equipment, direct reading instruments, analytical instruments, calibration, preventive maintenance, reagents and reference standards, control of purchases, and facilities. The laboratory analysis control section is analogous to process quality control and deals with sample identification and control, intralaboratory control, and interlaboratory testing. The area of sample handling, storage, and delivery is considered in light of the logistical needs of the industrial hygiene program. The section on statistical quality control presents aspects of control charts, data validation, data analysis techniques, and the use of sampling plans. The final section discusses the third element of management responsibility, that is, evaluation in the context of a quality control program audit.

2 SCOPE OF THE QUALITY CONTROL PROGRAM

2.1 Program Elements

The elements of an industrial hygiene quality control program include (1) statement of objective, (2) policy statements, (3) organization, (4) quality planning, (5) standard operating procedures, (6) chain-of-custody procedures, (7) recordkeeping, (8) corrective acction, (9) quality training, (10) quality costs, (11) document control, (12) calibration, (13) preventive maintenance, (14) reagent and reference standards, (15) procurement control, (16) sample identification and control, (17) laboratory analysis and control, (18) intra- and interlaboratory testing programs, (19) sample handling, storage, and delivery, (20) statistical quality control, (21) data validation, and (22) system audits.

Most of these program elements are already operational in a more or less adequate and documented system. Evaluation of the degree of conformity of the program's operations to program needs is the key to fulfilling the program's responsibility.

2.2 Application of Program Elements

The application of program elements to the industrial hygiene program must be accomplished in consonance with the program's operational needs and resources. A systematic approach to program evaluation and development is an investment whose payoff is the reduction of embarrassments (serious errors in reported results and recommendations). In a more positive tone, the quality control aspects of the industrial hygiene program contributes value in achieving the performance, cost, and schedule commitments of the program. A principal aspect of performance relates to the professional quality rather than quantity of results and decisions of the industrial hygiene program.

3 QUALITY CONTROL PROGRAM MANAGEMENT

Several areas or elements of a quality control program are part of the overall management plan. These elements include objectives, policies, organization, planning, operating procedures, chain of custody, recordkeeping, corrective actions, training, and costs.

3.1 Objective

The objective of the quality control function of the industrial hygiene program is to "assure the medical and or scientific reliability of data and subsequent decisions of the program." The subobjectives include the following: (1) the use of rugged method meeting the program's needs, (2) routine determination of the level of performance of the program, (3) making item 2 compatible with item 1, (4) monitoring routine performance to assure long-term adequacy, and (5) validation of performance by comparison with peer groups. The National Institute for Occupational Safety and Health (NIOSH) has published a quantified objective statement for its Industrial Hygiene Analytical Laboratory (2).

3.2 Policies

Quality policies provide the framework of procedures that the industrial hygiene program uses to accomplish the foregoing objective(s). The policies are based on good quality control practices and compliance with applicable regulations, and they will assure the implementation of the quality control program elements just outlined. They may also specify the manner of implementation and frequency of implementing certain procedures such as preventive maintenance, calibration and checking of field and sampling equipment, laboratory internal quality control procedures, and participation in interlaboratory quality control or evaluation programs.

3.3 Organization

The quality control function of the industrial hygiene program must be carried out by both the line supervision and by nonline monitoring of the total effort. This situation is no different from that of the quality control function for the plant or facility or for the total industrial hygiene program itself. The quality control staff function will be a "collateral-duty" or part-time responsibility in most programs. The quality control coordinator should be a designated individual, having defined responsibilities (3). These responsibilities require the authority and organizational freedom to identify and evaluate quality problems and to initiate, recommend, or provide solutions. The job description of the quality control coordinator will include such areas as developing and carrying out quality control programs, monitoring quality control activities of the program, and advising management with respect to the quality aspects of industrial hygiene work.

3.4 Planning

The special controls, methods, equipment, and skills necessary for upcoming work should be identified and provided for in timely fashion. The planning allows for necessary research or development work to provide analytical methods or instrumentation or correlation among these. Compatibility of program's needs with both field and laboratory capabilities is assured.

3.5 Operating Procedures

The operating procedures necessary to the industrial hygiene program include survey protocols, sampling procedures (4) (sampling data sheets), analytical procedures (5–7) (may include sampling), instrumentation calibration and maintenance procedures, and quality control procedures (3) to ensure the validity of the industrial hygiene program's data.

Once such operating procedures are established, they must be communicated to the appropriate staff members. For the smallest of programs, a single volume for each type of adopted operating procedure may suffice. Generally, several sets of operating procedures need to be maintained. The industrial hygiene program manager must institute some means of assuring himself that all personnel are using the current adopted procedures. Each procedure or section should be uniquely identified. The document control system provides for updating by having the program manager issue memos describing adopted changes. Any member of the staff can and should initiate such updates, but they must be adopted and promulgated by the manager to assure consistency and awareness of the entire staff of the changes. Formalized systems (3, 8) can be used. Each section or procedure should contain the following elements: Section No. XX, Revision 0 (for initial issue), date of issue, and page Y or Z. A single page can then be revised, if

appropriate, later. The manager will need to know who has received operating procedures, so that revisions also can be distributed to the staff.

3.6 Chain of Custody

Consideration of chain-of-custody procedures benefits the industrial hygiene program in several ways. If the samples or measurements taken may be part of a court case, the need for chain-of-custody procedures is self-evident. Since such procedures guarantee the integrity of the evidence collected, data developed for standards setting or for regular program work will benefit by such assurances. The manager should consciously assess the "benefits versus risk" of not following a chain-of-custody requirement. The laws or regulations of the state applicable to chain-of-custody should be complied with. A discussion with legal personnel would provide the basic requirements of that state.

1. A general discussion (9) of the chain-of-custody procedure follows. A sample is in your custody if (*a*) it is in your actual physical possession, or (*b*) it is in your view, after being in your physical possession, or (*c*) it was in your possession and you locked it up in a manner that would prevent any tampering.

Chain-of-custody record tags should be prepared before the worksite work and should contain as much information as possible to minimize clerical work by field personnel. The source of each sample should also be written on the container itself, if feasible, prior to the field work. Field log sheets, if used, should also be completed to the extent practicable before arriving at the site.

If more than one person is involved in the survey, all participants should receive a copy of any study plan and should become acquainted with its contents before the survey. A presurvey briefing and a postsurvey debriefing should be held. The debriefing should determine adherence to chain-of-custody procedures.

2. Specific points applicable to the industrial hygiene survey include the following:

a. To the extent achievable, as few people as possible should handle the sample.

b. Standard sampling techniques should be used.

c. The chain-of-custody record should be attached to the sample container at the time the complete sample is collected, and it should contain the following information: sample number, time taken, date taken, source of sample (includes type of sample and name of person or area sampled), preservative, if applicable (e.g., for biological samples), analyses required, name of person taking sample, and names of witnesses. The record should be signed, timed, and dated by the person doing the sampling. The records must be legibly filled out in ballpoint (waterproof ink).

d. Blank samples should also be taken. They will be analyzed by the laboratory to exclude the possibility of sample contamination.

e. A preprinted, bound field data record should be maintained to record field measurements and other pertinent information necessary to refresh the sampler's

memory in the event he later testifies about his work during the evidence-gathering activity. A separate set of field records should be maintained for each survey and stored in a safe place where they can be protected and accounted for at all times. The entries should be signed by the field sampler. The preparation and conservation of the field records during the survey will be the responsibility of the lead industrial hygienist. Once the survey is complete, field records will be retained by the head industrial hygienist, or his designated representative, as a part of the permanent record.

f. The field sampler is responsible for the care and custody of the samples collected until properly dispatched to the receiving laboratory or turned over to an assigned custodian. He must assure that each sample container is in his physical possession or in his view at all times, or is locked in such a place and in such a manner that no one can tamper with it.

g. If colored slides or photographs are taken to substantiate any conclusions of the survey, written documentation on the back of the photo should include the signature of the photographer, time, date, and site location. Photographs of this nature, which may be used as evidence, should also be handled in accordance with chain-of-custody procedures to prevent alteration.

3. Some considerations for transfer of custody and shipment are as follows:

a. When turning over the possession of samples, the transferee must sign, date, and time the chain-of-custody record. If a third person takes custody, he must fill in a second "receipt of sample" record. An additional custody record must be completed by persons who thereafter take "custody." Therefore the number of custodians in the chain should be as small as possible. Additional custody records should be numbered consecutively.

b. The field custodian or sampler has the responsibility of properly packaging and dispatching samples to the laboratory for analysis. The sample identification and sample accountability portions of the chain-of-custody record must be completed, dated, and signed.

c. Samples must be properly packed in shipment containers to avoid breakage. The shipping containers are sealed for shipment to the laboratory.

d. All packages must be accompanied by the "sample identification" and "sample accountability record." A copy of each is mailed directly to the laboratory.

e. If sent by mail, the package is registered with return receipt requested. If sent by common carrier, a bill of lading should be obtained. Receipts from post offices and bills of lading are sent to and retained by the laboratory custodians as part of the permanent chain-of-custody documentation.

f. If samples are delivered to the laboratory when appropriate personnel are not there to receive them, the samples must be locked in a designated area within the laboratory, to prevent tampering. The same person must then return to the laboratory, unlock the samples, and transfer custody to the appropriate custodian.

4. Laboratory operations must be so organized that the principles and practices of

chain-of-custody procedures are observed. Clearly these procedures require the application of the best principles of management and scientific investigations.

a. The laboratory must designate one employee as a "sample custodian," and another as alternate. In addition, the laboratory must set aside a "sample storage security area." This should be a clean, dry, isolated area that can be securely locked from the outside.

b. All samples should be handled by the minimum possible number of persons.

c. All incoming samples are to be received only by the custodian, who will indicate receipt by signing the sample transmittal sheets accompanying the samples and retaining the sheets as permanent records.

d. Immediately upon receipt, the custodian places the sample in the sample storage area, which is locked at all times except when samples are removed or replaced by the custodian. To the maximum extent possible, only the custodian should be permitted in the sample storage area.

e. The custodian must ensure that heat-sensitive or light-sensitive samples, or other sample materials having unusual physical characteristics or requiring special handling, are properly stored and maintained.

f. Only the custodian can distribute samples to personnel who are to perform tests. The custodian must enter into a permanent logbook the laboratory sample number, time and date, and the name of the recipient.

g. The analyst will record in his laboratory notebook or worksheet the name of the person from whom the sample was received, whether it was sealed, identifying information describing the sample (by origin and sample identification number), the procedures performed, and the results of the testing. The notes should be signed and dated by the person performing the tests and retained as a permanent record in the laboratory. In the event that the person who performed the tests is not available as a witness at time of trial, the laboratory may be able to introduce the notes in evidence under the Federal Business Records Act.

h. To the extent possible, standard methods of laboratory analyses are to be used. If laboratory personnel deviate from standard procedures, they should be prepared to justify their decision during cross-examination.

i. Laboratory personnel are responsible for the care and custody of the sample once it is handed over to them and should be prepared to testify that the sample was in their possession and view, or securely locked up, at all times from the moment it was received from the custodian until the tests were run.

j. Once the sample testing is completed, the unused portion of the sample, together with all identifying tags and laboratory records, should be returned to the custodian, who will make the appropriate entries in his log. The returned, tagged sample will be retained in the sample room until it is required for trial. Stripcharts and other documentation of work are also turned over to the custodian.

k. Samples, tags, and laboratory records of tests may be destroyed only on the order of the laboratory director, who first confers with his legal adviser to make certain that

the information is no longer required or that the samples have deteriorated. Several industrial hygiene analytical laboratories currently have a 5-year record retention time.

3.7 Recordkeeping

Records are considered to be a principal form of objective evidence of the operation and effectiveness of the quality control system. Any laboratory needs a system of records to establish and maintain control over the samples received for analysis. An ultimate system would certainly provide confirmation that chain-of-custody requirements have been met. The previous section indicates the nature of such requisite records. Any laboratory also needs administrative records. Since these are not unique to industrial hygiene or to a laboratory operation, however, they are not discussed further.

Quality control records are an integral part of an effective and economical quality control program. The records provide the assurance that calibrations, "blind sampling," recycled sampling, and similar procedures have been carried out in accordance with the laboratory's plan. The records of the day-to-day system and instrumental quality control checks document routine control and the initiation of necessary corrective actions. Control charts for instrument performance and check samples perform an efficient and economical recordkeeping function. As each instrumental check is made, for instance, the result should be posted immediately on the control chart near or on the instrument itself. The analyst has access to the record without difficulty and can make an instantaneous decision about the action to be taken. If the chart shows a pattern of expected variability, no action is necessary. If a real trend is developing or an out-of-control point is plotted, corrective action is initiated. This achievement of real-time decision making is hard to match, even with the more sophisticated computer systems.

The test of the quality control records system is analogous to a certified public accountant's audit of a company's financial statement and its bookkeeping system. A knowledgeable quality control person should be able to audit the records system and come to the same conclusion given by the laboratory personnel about the "state of quality control." An affidavit analogous to that appearing with the annual financial report attesting to the validity of the laboratory's claim about its real state of quality control represents the ultimate compliment to the records system.

3.8 Corrective Actions

Problems are bound to occur with any analytical system. For example, components of the system wear out. When a problem or defect begins to affect the performance of the analytical system, corrective action should be initiated. For major problems, management must initiate the corrective action plan and assure that all affected individuals cooperate in a well-planned program. In many instances, the analyst can detect erratic behavior or changed response level, either based on experience or from out-of-control points on a control chart. The analyst should check the operational parameters likely to

cause such "nonroutine" response. Contamination, which will cause the blank or baseline to shift, is not likely to be evident in the higher level standards. The small change in concentration or instrumental response value will be lost in the normal variability at the higher levels. Calibration-type problems will cause a constant percentage shift in concentration or instrumental response that will be evident in higher level standards but lost in the normal variability of the blank or baseline determination. Seeking out the case of a problem and correcting it requires analytical or technical expertise rather than statistical knowledge. One of the advantages of the analyst or instrument operator being the principal in the bench level quality control program is that he or she on many occasions can initiate corrective actions before problems become major.

When there are significant (out-of-control) differences between the observed and expected results on quality control test samples, notification should be sent to the analyst. The analyst should investigate, determine the cause of difference, if possible, take necessary corrective action, and report results to the laboratory management. If the required corrective action is beyond the responsibility and authority of the analyst (e.g., in the case of an incompatibility between the sampling and analytical procedures) the appropriate level of laboratory management must decide what type of corrective action is necessary and ensure its implementation.

As the time increases between the "out-of-control" incident and its investigation, the probability of the analyst finding the cause rapidly decreases. In some cases, the original sample may have been discarded already, or the reagents changed, or the instrument reprogrammed for another analysis. In these cases, the quality control system rather than the analyst must be faulted for what will usually be a futile effort to determine an appropriate corrective action.

3.9 Training

The personnel of the industrial hygiene program must have sufficient training and/or experience to develop the necessary attitudes, knowledge, and skills to proficiently perform their job functions. In most cases, on-the-job or "buddy-system" training is the principal mechanism used to develop new capabilities in the staff. More formal programs should be used to supplement the baseline training as appropriate. There are a number of training resources available to the industrial hygiene program (10, 11). The effectiveness of the training should be evaluated by the program management. The person trained should be able to perform the new function completely and accurately. Performance measures should relate to the degree of proficiency of the staff already performing the function. Values for precision and recovery for an analytical procedure are relatively easy to develop and provide an objective measure of performance. Other functions are more difficult to quantify. In some cases the performance test is the skill with which the staff person can perform the given function—for example, organizing and conducting a plant survey independently.

The quality control function of the industrial hygiene program can perform the func-

tion of auditing the effectiveness of the training program. It is self-evident that personnel charged with the responsibility for the quality control function must also acquire the appropriate training to develop and implement the quality control system.

3.10 Costs

The industrial hygiene program allocates financial and personnel resources among the various elements of the quality control system. These elements can be grouped into four categories. Prevention costs involve elements associated with planning, implementing, and maintaining the quality control program itself—for example, objectives, policies, organization, planning, operating procedures, chain-of-custody procedures, recordkeeping, training, equipment calibration, preventive maintenance, reference standards, control of purchases, and facilities.

Appraisal costs are those entailed in efforts to evaluate and maintain the quality performance levels of the industrial hygiene program. The elements included in appraisal consist of sample identification and control, intralaboratory quality control testing, interlaboratory proficiency testing programs (including accreditation program costs), control charts, data analysis, and data validation. The reports generated on the effectiveness of the quality control system are also included in appraisal costs.

Internal failure costs are the costs to the industrial hygiene program attributable to defective materials, reagents, instruments, sampling, and/or analytical procedures, which cause data to be discarded and repeated or lost. Corrective actions to determine and correct these problems are included in internal failure costs. The costs of having to resurvey a plant, including the travel and personnel time costs, would also be included if the survey had been done by the industrial hygiene program. If the resurvey is to be done by an outside group, the cost would belong to the next category as an external failure cost.

Also included in the external failure costs category are those associated with investigating complaints from defective data that have already been reported. The repetition of procedures or effort spent in validating or revalidating procedures because of reported defective data also constitutes an external failure cost. The costs to other programs or departments may be considerable when defective data are reported. Should the defective data be discovered during an enforcement proceeding, the indirect costs will greatly outweigh the direct costs to plant or agency management. The loss of credibility to the industrial hygiene program cannot be calculated in terms of dollars but may include the very existence of the industrial hygiene program.

The value of categorizing costs is to allow and encourage a programmed and budgetary apportionment of these costs. As the costs can be concentrated in the prevention category, the total costs will decrease. The cost effectiveness of the quality control system and of the industrial hygiene program itself will also improve. In his book *Total Quality Control,* A. V. Feigenbaum provides a comprehensive framework for quality control costs allocations.

4 EQUIPMENT, STANDARDS, AND FACILITIES

4.1 Sampling Equipment

The variability or error associated with sampling equipment is considerable. In a collaborative test on the sampling and analysis of solvents using personal sampling pumps, charcoal adsorption tubes, carbon disulfide elution, and gas chromatographic analysis, the sampling equipment error was of the same order of magnitude as the analytical errors; the relative standard deviation ranged from 5 to 14 percent (12). This error or variability existed when all participating laboratories calibrated their sampling pumps with a single calibration system. The report indicates that the procedure was used to reduce the calibration variability apparent with each laboratory having calibrated its own pumps at its own facility before meeting at the site for the collaborative test. The variability was measured by sampling from a homogeneous atmosphere. No spatial or time variability was involved in sampling from the controlled concentration level test chamber. No real plant sampling situation can possibly approach the homogeneous conditions in a test chamber.

The appropriate frequency of calibration depends on the handling and use (abuse) the sampling pump has undergone. Specifically, pumps should be recalibrated after suspected abuse (such as dropping), when received from the manufacturer, and when repaired. Experience will determine an appropriate frequency of recalibration. A control chart approach can efficiently develop the information necessary for such decisions. At least until such experience is gained, pumps should be calibrated before being used in the field and at intervals during the field work if numerous samples are taken. The calibration should be checked upon return from the field.

The accuracy of the calibration depends on the calibration system itself. The choice of calibration system depends on the location at which the calibration is made and the facilities available to the industrial hygiene program (13). In the laboratory, a 1- or 2-liter burette or wet test meter is generally used. Other standard calibrating systems such as a spirometer, Marriott's bottle, or dry-gas meter could also be used.

The procedure for calibration with the soap bubble flowmeter follows (14). The calibration setup for personal sampling pumps with a cellulose membrane filter follows standard procedures. Since the flowrate indicated by the flowmeter of the pump is dependent on the pressure drop across the sampling device, the pump flowmeter must be calibrated while operating with a membrane filter and appropriate backup pad in the line.

1. While the pump is running, the voltage of the pump battery is measured with a voltmeter to assure that the battery is charged adequately for calibration.
2. The cellulose membrane filter with backup pad is placed in the filter cassette.
3. The calibration setup is assembled so that the air flows from room atmosphere through the soap bubble meter to the cassette, through the cassette to the sampling

pump, and to room atmosphere. A U-tube water manometer monitors the pressure drop between the cassette and the pump.

4. The pump is turned on, and the inside of the soap bubble meter is moistened by immersing the burette in the soap solution and drawing bubbles up the tube until they are able to travel the entire length of the burette without bursting.
5. The pump is adjusted to provide a flowrate of 2.0 liters/min.
6. The water manometer is checked to ensure that the pressure drop across the sampling train does not exceed 13 in. H_2O at 2 liters/min.
7. A soap bubble is started up the burette, and the time it takes the bubble to travel a minimum of 1.0 liter is measured with a stopwatch.
8. The procedure in step 7 is repeated at least 3 times, the results are averaged, and the flowrate is calculated by dividing the volume between the preselected marks by the time required for the soap bubble to travel the distance.
9. Data for the calibration should include the volume of air measured, elapsed time, pressure drop, air temperature, atmospheric pressure, serial number of the pump, date, and name of the person performing the calibration.

The specific requirements for the calibration procedure, the frequency of its use, and maintenance and operational notes must be permanently recorded since these records form an integral part of the quality control system and are invaluable in any court proceeding. Requirements for the calibration system itself are discussed later.

4.2 Direct Reading Instruments

The calibration of direct reading instruments involves not only flow but concentration level response calibration. For guidance on the general technical problems, consult Lippmann (13) Saltzman (15), and the air sampling instruments manual (16) of the American Conference of Governmental Industrial Hygienists (ACGIH). In addition, a number of evaluation reports have been developed; Johnson on NO_2 meters (17), McCammon on portable, direct reading combustible gas meters (18), and Parker and Strong on CO meters (19). These reports provide detailed performance evaluations for those classes of instrument. The calibration of direct reading instruments for physical agents is handled in a manner equivalent to that for chemical agents. Guidance for specific instruments should be available from the manufacturer or the literature. In some cases a calibration capability, such as for ultraviolet radiation, must be developed (20).

4.3 Analytical Instruments

The calibration system records and approach are equivalent for sampling equipment, direct reading instruments, and analytical instruments. The following discussion on the calibration system has been adapted from the NIOSH quality control manual TR-78 (3).

All equipment to be calibrated should have a permanently affixed record number (serial or property number). A calibration control card or sheet for each instrument should show identification number, description (including manufacturer, model, and serial number), location of use or storage, calibration procedure used, calibration interval, date of last calibration, signature of the person performing the calibration, due date for next calibration, and values obtained during the calibration. Calibration reports and compensation or correction figures should be filed with the calibration control card.

All equipment should be calibrated in a room in which the laboratory has provided controls for environmental conditions to the degree necessary to assure measurements of the specified and required accuracy. The calibration area should be reasonably free of dust, vibration, and radiofrequency interferences and should not be located near equipment that produces acoustical noise or vibration. Isolation of pressure, mass, and acceleration equipment from vibrations is particularly essential; isolation mounts, seismic masses, and other means of protection should be provided.

The laboratory calibration area should have adequate temperature and humidity controls. A temperature from 68 to 73°F and a relative humidity of 35 to 55 percent normally provide a suitable environment. A filtered air supply is a necessity in the calibration area. Dust particles are more than just a nuisance; they can be abrasive, conductive, and damaging to instruments. A measure of dust filtration can be provided in the air conditioning system by the washing action of sprays and atomizers, but this may need to be supplemented by electrostatic and/or mechanical filters of the activated charcoal, oil-coated or ribbon types.

Recommended requirements for electrical power within the laboratory should include voltage regulation of at least 10 percent (preferably 5 percent), low values of harmonic distortion, minimum line transients as caused by interaction of other users on the main line to the laboratory (separate input power if possible), and a suitable grounding system established to assure equal potentials to ground throughout the laboratory (or, isolation transformers may be used to operate individual pieces of equipment). Adequate lighting (suggested values, 80 to 100 foot candles) is necessary for work bench areas. The lighting may be provided by overhead incandescent or fluorescent lights. Fluorescent lights should be shielded properly to reduce electrical noise.

All instruments should be calibrated and checked by qualified personnel. An outside calibration service group may schedule and perform these checks, but this does not relieve the laboratory of the responsibility for controlling, monitoring, and identifying calibration intervals and having the checks made on time.

All measurements or calibrations performed by or for the laboratory for the calibration program should be traced, directly or indirectly, through an unbroken chain of properly conducted calibrations (supported by reports or data sheets) to some ultimate or national reference standard maintained by a national organization such as National Bureau of Standards; an example of proper calibration procedure for standard quartz cuvettes appears in the literature (21). The ultimate reference standard can also be an independent, reproducible standard (i.e., a standard that depends on accepted values of

natural physical constants). A typical example is the cesium beam type of microwave frequency standard.

There should be an up-to-date report for each reference standard (except independent reproducible standards) used in the calibration system, and for any subordinate standards or measuring and test equipment if their accuracy requires supporting data. If calibration work is contracted out to a commercial laboratory or facility, copies of reports issued by the subcontractor should be kept available.

All reports should be kept in the calibration system file and should contain the following information: (1) identification or serial number of standard to which the report pertains, (2) conditions under which the calibration was performed (temperature, relative humidity, etc.), (3) accuracy of standard (expressed in percentage or other suitable terms), (4) deviation or corrections, (5) report number or designation; in addition (6) reports for the highest level standards of sources other than NBS or a government laboratory should bear a statement that comparison has been made with national standards at periodic intervals using proper procedures and qualified personnel, and (7) corrections that must be applied if standard conditions of temperature, gravity, air buoyancy, and so on, are not met, or if they differ from those at place of calibration, must be noted.

The description of the calibration program indicates that an extensive effort may be required. If the data to be generated by the industrial hygiene program are sufficiently important that related decisions may be challenged in court or elsewhere, the complete calibration program is cost effective. For other situations, the program manager must decide on an appropriate allocation of his resources among this and the other elements of the quality control system.

4.4 Preventive Maintenance

The preventive maintenance program complements the calibration program. An effective preventive maintenance program increases the reliability of measurement systems and decreases downtime. An inadequate preventive maintenance program will be responsible for increasing unscheduled downtime, a probable increase in total maintenance costs, and possibly a lack of trust in the validity of the data being generated.

A schedule of preventive maintenance should be keyed to the calibration program schedule. The frequency of the preventive maintenance program should be based on the equipment manufacturer's recommendations and cumulative experience. All records from the maintenance program should be kept as part of the records system and used to assure the validity of data generated by the industrial hygiene program.

4.5 Reagent and Reference Standards

A number of reagent standards suitable for laboratory programs are available from commercial sources. Standard reference materials (SRMs) are available from the National

Bureau of Standards. Out of approximately 900 SRMs available, about 40 have been prepared for environmental use. Another half-dozen have been specifically prepared for industrial hygiene use, and several more are to be released.

Calibration gases may be obtained from commercial suppliers. A cross-check program comparing the old and new tanks or tanks from several suppliers will serve to validate the calibration gases for the program. Such checking may be necessary because the responsibility for valid data lies with the industrial hygiene program itself.

The use of all available commercial analytical standards still leaves most of the industrial hygiene program's analytical needs without standards. The only recourse is the internal preparation of needed working standards for calibration and quality control purposes. The development of a diverse range of working standards for many elements in wide concentration ranges has been covered by Hill (22), who uses the working standards in a ratio of 1 : 10 where the unknowns cover a narrow concentration range and in even greater ratio for more diverse samples. Hill states: "Having calibrated our laboratory, the standards are still used daily on every set run as a datum and an early warning system to detect any problems that may develop. Any set exhibiting poor results on the included standards is immediately rerun, and the problem is identified and eliminated." Some literature (3) uses the term "control sample" in much the same sense as Hill used the term "working standard." As Hill concludes: "Millions of dollars may be spent upon the results of a large suite of chemical analyses. There is no mystery to obtaining the good analytical results needed to make the right decisions the first time; one must get or make the needed standards and use them continuously."

4.6 Control of Purchases

Common laboratory reagents and chemicals are generally bought to a specified grade or quality such as "ACS Reagent" grade or "Spectroquality." Experience will indicate differences between such materials from various suppliers. The main assurance of the quality of such materials is the routine use of reagent blanks in the analytical procedures. The shelf life should be determined and stocks rotated on a first in–first used basis.

The purchase of equipment may offer the program a greater opportunity to set performance requisites in the purchase specifications. Acceptance testing against the performance specifications protects the program.

In many cases the industrial hygiene program is obliged or desires to purchase analytical measurements from another laboratory. Since the data reported by the program are the program's responsibility regardless of where the analyses were made, the program must obtain valid data from outside sources. It must assure that such data are being generated by a laboratory whose quality control system is at least as effective as its own. A routine technique is to submit split samples, spiked samples, and blanks as blind samples.

4.7 Facilities

The role of facilities in assuring the quality of an industrial hygiene program's results is flexible. The best possible building and physical facility does not guarantee "good work"; on the other hand, "good work" may be produced under poor conditions. Good facilities certainly simplify and minimize an additional set of variables that the program does not want to have affecting the quality of the data produced. Downtime and time-consuming corrective action investigations should be minimized with adequate facilities. A number of books and manuals on the design of laboratory facilities can be consulted. It is important to minimize occupational safety and health problems in the design and/or development of laboratory space for the industrial hygiene program.

5 LABORATORY ANALYSIS CONTROL

The quality control system to provide for precise and accurate industrial hygiene measurements has been discussed in earlier sections for the program management and for its physical elements. Sections 5 and 6 cover the operational elements.

5.1 Sample Identification and Control

All samples taken or received for analysis must be logged in and identified with respect to type and source of the sample. The sample identity must be carefully and clearly maintained throughout the sampling and analysis–reporting cycle of events. The earlier discussions on chain-of-custody and record keeping (Sections 3.6 and 3.7) apply.

5.2 Intralaboratory Control

The principal operational element of the industrial hygiene program's quality control system is its intralaboratory control program.

5.2.1 Method Adaption and Validation

The adaption and validation of reference or other methods to the specific needs of the program comprise one of the most important elements. These specific needs may require validation because of matrix, interference, sensitivity, or other operational aspects unique to the sampling and analysis problems to be expected. Numerous texts (23–25), articles (26, 27), and other publications (12, 28–33) discuss the approaches and techniques of the collaborative test evaluation of sampling and/or analytical methods. The individual laboratory must assure itself that the methods it uses are "rugged" enough for the conditions of use entailed by its problems. Youden (23) extensively discusses "ruggedness testing" and its value to the analytical laboratory. Linch (34), Linning et al. (35), and Wilson (36–38) describe the types of error that may afflict a method, as

well as programs to detect, quantitate, and eliminate or correct for these determinate errors.

When the method is ready for intralaboratory validation, any number of protocols may be used. One such protocol (6) divides the overall program into two phases. The analytical variability and bias, if any, are evaluated by spiking samples for laboratory analyses. Six spiked samples at each of three levels (0.5, 1, and 2 times the permissible limit for routine sampling techniques) are analyzed by the laboratory. If the precision and bias are acceptable, the second phase is initiated. In the second phase, contaminant atmospheres are generated, sampled using the prescribed collecting techniques, and analyzed. Experimentally, it has been found desirable to determine sampling pump variability separately. Laboratory air-moving devices with low variability can then be used in the sampling of the contaminant. Independent verification of the contaminant concentration in the atmosphere being sampled provides a measure of the collection efficiency of the sampling device. To maintain symmetry, again six samples at each of the three levels specified previously are taken and analyzed by the analytical method.

By reasonably straightforward mathematical and statistical operations, the variability due to the individual components of analysis, of sample collection, and of pump error can be determined. These operations also can be combined to provide an overall determination of variability when a homogeneous atmosphere is being sampled. It is recognized that neither currently available statistical theory nor experience provides a validated quantitative estimate of the variability due to "representative" sampling. The bias of the sampling and analytical method can also be determined under the test conditions by comparing the values determined in the second phase with the concentrations of the contaminant "known" to be in the chamber at the time of sampling.

5.2.2 Instrumental Quality Control

The industrial hygiene laboratory many times finds itself using a basic analytical technique for a wide variety of materials. Atomic absorption spectrophotometry, X-ray analysis, and gas chromatography are common examples. In considering the quality control aspects of such procedures, emphasis should be directed to the common points, rather than the differences.

As an example, a common sampling and analytical technique for many organic materials involves charcoal tube adsorption, desorption with carbon disulfide (CS_2), and gas chromatography instrumental analysis (39). The sampling and analytical method has been validated by collaborative testing for seven solvents (12). The method has been evaluated for application to numerous materials. There are still materials that have not been checked out. Each new challenge is not unique, with the result that prior developmental and operational information does not apply. By checking the operation of the parts of the procedure and by using control samples of a similar "evaluated" material, the laboratory can with great confidence analyze for the new "unknown." The desorption efficiency must be specifically determined for the laboratory's operating condition for all materials. The gas chromatograph must be calibrated for the "unknown" for

quantitative analysis. However these operations can be done routinely rather than on a research project basis (40). The use of control charts for instrumental quality control is most appropriate. The monitoring of a critical performance indicator assures the analyst that the instrument is operating reliably. Control charts are developed in a later section.

5.2.3 Routine Samples

One of the most generally applicable and easily applied statistical quality control techniques is the Shewhart control chart. The Shewhart control chart technique can be applied to almost any area of somewhat repetitive measurements, including monitoring critical instrumental performance characteristics, analytical blanks, instrument calibration standards, and total analysis control samples, as well as monitoring the desorption efficiency determination for consistent technique, and ultimately, plant environmental control monitoring (41). For routine analytical procedures, control charts should be set up for the "control samples" or "working standards" discussed by Hill (22). The control chart for the "control sample" (3) will monitor the recovery of the procedure, thereby detecting errors that cause a shift in the process average (42). These sources of errors are due to calibration-type problems or changes in concentration of reagents (43).

A control chart for blank determinations will aid in detecting contamination-type problems. Reagent or sample contamination or certain instrumental operational problems will tend to cause a small constant absolute value shift in the determination. Such a shift would be difficult to detect at concentration levels up in the working range, but it is more easily found using blanks because the absolute value would be lost in the usual variability at higher concentrations. Excellent summaries of general precautions and techniques applicable to such problems are presented by the Intersociety Committee on Air Sampling and Analysis (44) and by Linch (45, 46).

If the "control sample" used in a determination is not a realistic simulation of regular environmental samples, it will be of value in determining the precision for recycled routine samples. The use of a "mercuric chloride in distilled water" (3) control sample because of instability problems associated with a "pooled mercury in urine" control sample is such a case. Such recycled samples should be more affected by interferences and matrix effects, therefore will yield a more realistic value, within laboratory precision or repeatability (47) on routine samples. Special considerations and techniques are applicable when automated procedures are used for high production routine work (48–50).

5.2.4 Single Samples or Infrequently Employed Procedures

The single-time or infrequently employed procedures present the greatest problems to the laboratory analyst. The analyst's unfamiliarity with the procedure to be used and probable unfamiliarity with the sample matrix and interferences presented to the procedure make him deservedly wary. Since almost certainly no SRMs or reasonable

substitutes will be readily available, the analyst must rely on his generally good technique (as validated with other procedures) and a limited assessment of recovery (51) and interferences on the subject sample. The basic recovery procedure (34) is summarized below.

The recovery procedure applies the analytical method to (1) a reagent blank, (2) a series of standards (covering the expected range of concentration of the sample), (3) the sample itself (at least in duplicate), and (4) the recovery samples. The recovery samples are prepared by adding known quantities of the substance sought to separate portions of the sample itself. Each portion of the sample should be equal to the size of sample taken for the run. The substance sought should be added in sufficient quantity to overcome the limits of error of the analytical method, but without causing the total in the sample to exceed the range of the standards used.

The results are corrected by subtracting the reagent blank from each of the other determined values. The resulting standards are then graphed by plotting readout (y-axis) versus concentration (x-axis). From this graph the amount of contaminant (or substance) in the sample alone is determined. This determined value is then subtracted from each of the recovery samples consisting of sample plus known added substance. The resulting amount of substance divided by the known amount originally added, and multiplied by 100, gives the percentage recovery.

The basic recovery procedure may be applied to a colorimetric, flame photometric, fluorimetric, titrimetric, gravimetric, and other analytical techniques.

An example of the recovery procedure as applied to a lead in blood analysis appears in Table 24.1.

In other methods, the internal standard procedure may be effectively used (34, 52). The internal standard technique serves primarily for emission spectograph and polarographic procedures. This procedure enables the analyst to compensate for electronic and mechanical fluctuations within the instrument.

The internal standard method involves the addition to the sample of known amounts of a substance that will respond to the instrument in a similar manner to the contaminant being analyzed. The ratio of the measurement of the internal standard to the measurement of the contaminant is the value used to determine concentration of contaminant present in the sample. Changes in instrumental conditions during analyses should affect the internal standard and the contaminant in the same manner and degree, and the determination will compensate for such changes. The internal standard should be of similar chemical reactivity to the contaminant and approximately the same concentration anticipated for the contaminant. It should be a substance as pure as possible. Other constraints may be more critical for specific analytical techniques.

Since the occasional sample presents the greatest uncertainty and potential problems to the industrial hygiene analytical laboratory, major efforts of senior staff are required to ensure the quality of such work. The difficulties, the time involved, and the infrequency of such samples also present a special challenge to the person responsible for the reporting of such efforts. Elwell and Lawton (53) have reported on a "relative value structure" to aid in such reporting.

Table 24.1 Lead in Blood Analysis (34)

Basis. A 10.0-gram sample of blood from the blood bank pool, ashed and lead determined by double extraction, mixed color, dithizone procedure.

Lead Added (pg)	Optical Density	Lead Found (pg)		Recovery (%)
		Total	Recovered	
None—blank	0.0969	—	—	—
5: Calibration point	0.2596	—	—	—
None	0.1427	1.6	—	—
None	0.1337	1.3	—	—
None	0.1397	1.4	—	—
None	0.1397	1.4	—	—
Average	0.1389	1.4	—	—
2.0	0.1805	2.9	1.5	75
4.0	0.2636	5.4	4.0	100
6.0	0.3372	7.8	6.4	107
8.0	0.3925	9.4	8.0	100
10.0	0.4437	11.4	10.0	100
30.0 total	—	36.9	29.9	96

Mean error = $36.9 - (30.0 + 5 \times 1.4) = 0.1$ μg for entire set
$= 2.9 - (2.0 + 1.4) = 0.5$ μg for 2 μg spike
Relative error = $(0.1 \times 100)/37.0 = 0.27\%$ for entire set
$= (0.5 \times 100)/3.4 = 14.7\%$ for 2 μg spike

5.3 Interlaboratory Testing

It has been recognized that external proficiency analytical testing on a continuing basis is essential to assure quality (54). The American Industrial Hygiene Association (AIHA) laboratory accreditation program (55) includes satisfactory continued performance in a proficiency analytical testing program as an integral requirement for accreditation. Such a program offers the laboratory director confirmation of the effectiveness of the internal quality control program. Ratliff (56) has reported the development of the National Institute for Occupational Safety and Health Proficiency Analytical Testing (PAT) program used by NIOSH and OSHA, and subsequently AIHA.

The industrial hygiene program will need to supplement such a program by splitting or exchanging samples with one or several other laboratories interested in the same

problem. These informal programs should be documented and appropriate credit taken for the value of the data so generated.

6 SAMPLE HANDLING, STORAGE, AND DELIVERY

The logistical aspects of sample handling, storage, and delivery impose a significant constraint on some industrial hygiene programs. When the industrial hygienist must rely on common transportation systems, whether plane, truck, mail, or parcel delivery, his options are limited. The use of bubblers and absorbing solutions become a "method of last resort." The risk of loss of samples, or of instability of the collected samples over a several-day transport time, and the attendant cost of doing a resurvey, make other alternatives attractive despite any inherent limitations or difficulties. The industrial hygienist who can personally, or by courier, transport his samples (collected in bubblers) back to the laboratory in a few hours may be able to choose more specific, more accurate, or more economical sampling and analytical methods.

The industrial hygiene program manager should ensure that operating procedures, chain-of-custody procedures, and records are adequate for the specific needs of the program. Sampling and shipping procedures are available for many industrial hygiene samples (4). Perishable samples, even milk (57), can also be safely and routinely shipped. The shipping procedures must consider Interstate Commerce Commission rules and other applicable shipping regulations.

7 STATISTICAL QUALITY CONTROL

Statistical quality control involves the application of statistical techniques to the appropriate areas of the industrial hygiene quality control program. For routine samples or for instrumental quality control programs, the Shewhart control chart is the simplest and most appropriate technique (42, 58, 59).

7.1 Control Charts

The industrial hygiene program should institute a control chart for an instrument or a procedure (control sample, or blank or recycled samples) when it is more efficient to consider the procedure to be semiroutine than to use the single or occasional sample procedures outlined earlier and advocated by Linch (34, 45, 46).

7.1.1 Purposes

The control chart is both a diagnostic and a reliability tool. Since the control chart differentiates between the usual pattern of random variation (from indeterminate errors) and mistakes or biases (due to determinate errors), it can be used to trouble-shoot a

procedure or to make it more rugged. In the process, the weak points of the procedure, whether due to interferences, instability of sample, reagents or equipment, or required operator judgments, are identified (or determined) and eliminated. The resulting procedure has become "ruggedized" by this use of the control chart. The second use of the control chart is to establish the normal operational precision and stability of the sampling and/or analytical method or measurement system. As experience is gained, a reliable, valid value of routine precision will be developed. This value has built into it the "real world" sources of variability that the industrial hygiene program routinely faces. The evaluation of the measuring process stability (accuracy or bias) permits the program to make validated decisions with respect to whether plant processes have actually changed environmental or biological concentration levels or whether an apparent change is due to the inability of the industrial hygiene program to make reliable measurements. Such knowledge may obviously affect management decisions on hazard control equipment investments. The third use of control charts is as a monitoring instrument on the procedure or measurement system itself. The control chart provides immediate objective evidence of reliable operation or detects impending (trends) or actual problems (out-of-control points) with the procedure or measurement system. Corrective action can then be initiated by the industrial hygiene program, making the corrective action costs (Section 3.10) internal and not external (including loss of credibility).

7.1.2 Parameters to be Controlled

The calibration of a direct reading instrument such as a combustible gas meter can be checked by the use of commercial calibration kits. A calibration check on each day of use, before and after the day's survey, guarantees valid data throughout the day and backup if the measurements are challenged. A number of radiation survey instruments have "check sources" on the instrument. The surveyor performs the check and can even plot the result directly on a small control chart taped to the side of the instrument. These calibration checks are not a substitute for full individual contaminant response calibrations, but they do provide an objective means of determining their appropriate frequency and offer assurance of reliable measurements between such calibrations.

Laboratory instruments, whether used to calibrate sampling equipment or to measure analytical response, such as spectrophotometers, gas chromatographs, atomic absorption instruments, or radiation spectrometers, can be monitored for continued calibration and reliable performance. If an instrument's response can be completely calibrated for a given procedure in a few minutes, it may be more efficient to recalibrate each time a procedure is run. If, however, the instrument can be calibrated only infrequently by some reference or transfer standard, if calibration is quite expensive, involving weeks of effort, such as for a gamma radiation spectrometer, if economies can be achieved by checking a couple of points on a calibration curve, or if a critical response parameter can be monitored, a control chart is appropriate. Not only may economies in operational costs be realized, but greater reliability and comparability of data over longer periods of time will be achieved.

Total analysis quality control uses the control chart for routine analytical procedures to monitor the procedure's performance on "control samples," blanks, and "recycle samples" where used.

7.1.3 Type of Control Chart

The Shewhart control chart measures both measurement process variability and calibration stability. The Shewhart or $\bar{X}$ and R chart uses the range R to estimate process variability. The average of these individual measurements provides the $\bar{X}$ for monitoring the stability of the procedure or indicating how well it is maintaining its calibration. There are other types of charts that use the standard deviation to measure variability or a moving average, or individual values, to measure process stability (60). These are special application tools that may be more appropriate after the procedure or instrument is known to be in a "state of control" through use of the $\bar{X}$ and R chart. The cumulative sum or cu-sum chart is more complex to institute and is not as rugged for situations not already in a "state of control." In most cases the basic Shewhart or $\bar{X}$ and R chart can be easily and effectively used.

7.1.4 Trial Control Charts

The industrial hygiene program often has some historical data on which to develop "trial control limits." These data are invaluable in getting a start on an individual problem. As experience is gained, the control limits are recalculated, and decisions based on these control limits are better. The advantage of initially using historical data is the gain of several weeks to several or many months in developing effective control limits.

7.1.5 Calculation of Control Limits

The calculation of control limits is a straightforward exercise. Grant (42), Linch (34), and others (3, 58, 60–62) have shown the mechanics of such calculations. Another presentation (8) develops the following format:

1. Calculate R for each set of measurements.
2. Calculate $\bar{R}$ from the sum of R divided by the number of sets (or subgroups) k.
3. Calculate the upper control limit (approximately $3s$) on the range by $UCL_R = D_4\bar{R}$. There will be no lower control limit where there are six or fewer values in each set (subgroup) k. The value of D_4 for duplicate analyses from Table 24.2 is $D_4 = 3.27$.
4. Calculate the upper warning limit (approximately $2s$) on the range by $UWL_R = D_5\bar{R}$. The value of D_5 for duplicate analyses from Table 24.2 is 2.51.
5. Construct the control lines and plot the consecutive analyses on graph paper. Circle or highlight any values outside the control limits. Corrective action to investigate and eliminate the causes will be taken after each out-of-control point as it happens. Less

Table 24.2 Control Chart Lines Factors (58)

Factor	Two Measurements per Set	Three Measurements per Set
D_4	3.27	2.57
D_5	2.51	2.05
A_2	1.88	1.02

vigorous follow-up should happen for each value outside the warning limit but within the control limit.

6. Calculate $\bar{X}$ for each set of measurements.
7. Calculate $\bar{\bar{X}}$ or the mean of the $\bar{X}$'s for the set of measurements.
8. Calculate the upper and lower control limits by $UCL_{\bar{X}} = \bar{\bar{X}} + A_2\bar{R}$ and $LCL_{\bar{X}} = \bar{\bar{X}} - A_2\bar{R}$. The value of A_2 for duplicate analyses from Table 24.2 is 1.88.
9. Calculate the upper and lower warning limits by $UWL_{\bar{X}} = \bar{\bar{X}} + (\frac{2}{3})\, A_2\bar{R}$ and $LWL_{\bar{X}} = \bar{\bar{X}} - (\frac{2}{3})\, A_2\bar{R}$.
10. Construct control lines and plot the consecutive analyses on graph paper. See step 5.

The development of trial control limits from the laboratory's own experience is most appropriate and realistic. However other sources of information can be used. Collaborative test data can be used for developing these trial limits until the laboratory's own experience is developed. The data of Table 24.3 is taken from a NIOSH report.

The calculation of trial control limit values from the data of Table 24.3 is set up in Table 24.4.

The calculation of control chart lines using the information from Table 24.4 and factor values from Table 24.2 are given in Table 24.5.

7.1.6 Interpretation of Control Limits

Standardized control chart calculation and graphing formats are available from many sources (3, 8, 42). The trial control limits were calculated for one concentration range. Other parts of the working range may require different control limits. The NIOSH collaborative test data (12) indicate that at least for all levels except the level near the detection limit of the method, a single percentage value could be used to express the variability. In such a case it would be easy to convert all ranges into a percentage value and calculate for all values a "%R." The accuracy or bias plot then becomes useful over the working range by plotting the percentage deviation of the average of each set of control tubes from its known or nominal value. The control tubes would ideally be generated using known concentrations of airborne contaminant but could also be made

Table 24.3 Benzene Found in Duplicate Analyses (12)

Laboratory	Benzene (mg/tube)
1.	1.50, 1.70
2.	1.53, 1.73
3.	1.56, 1.57
4.	1.67, 1.88
5.	1.40, 1.98
6.	1.33, 1.42
7.	1.45, 1.62
8.	1.49, 1.69
9.	1.42, 1.61
10.	1.12, 1.27
11.	1.36, 1.53
12.	1.43, 1.57
13.	1.59, 1.59
14.	1.38, 1.55
15.	1.17, 1.44

Table 24.4 Data for Calculation of Control Chart Lines

	Measurements			
Laboratory	1st	2nd	Average, $\bar{X}$	Range, R
1	1.50	1.70	1.60	0.20
2	1.53	1.73	1.63	0.20
3	1.56	1.57	1.57	0.01
4	1.67	1.88	1.78	0.21
5	1.40	1.98	1.69	0.58
6	1.33	1.42	1.38	0.09
7	1.45	1.62	1.54	0.17
8	1.49	1.69	1.59	0.20
9	1.42	1.61	1.52	0.19
10	1.12	1.27	1.20	0.15
11	1.36	1.53	1.45	0.17
12	1.43	1.57	1.50	0.14
13	1.59	1.59	1.59	0.00
14	1.38	1.55	1.47	0.17
15	1.17	1.44	1.31	0.27
Σ			22.82	2.75
$\bar{\bar{X}}$			1.52	
$\bar{R}$				0.18

Table 24.5 Calculation of Control Chart Lines

Formula	Example
1. $\bar{R} = \Sigma R \div k$	1. $\bar{R} = 2.75 \div 15 = 0.18$
2. $UCL_R = D_4\bar{R}$	2. $UCL_R = 3.27 \times 0.18 = 0.59$
3. $UWL_R = D_5\bar{R}$	3. $UWL_R = 2.51 \times 0.18 = 0.45$
4. $\bar{\bar{X}} = \Sigma\bar{X} \div k$	4. $\bar{\bar{X}} = 22.82 \div 15 = 1.52$
5. $UCL_{\bar{X}} = \bar{\bar{X}} + A_2\bar{R}$	5. $UCL_{\bar{X}} = 1.52 + 1.88 \times 0.18 = 1.86$
6. $LCL_{\bar{X}} = \bar{\bar{X}} - A_2\bar{R}$	6. $LCL_{\bar{X}} = 1.52 - 1.88 \times 0.18 = 1.18$
7. $UWL_{\bar{X}} = \bar{\bar{X}} + \frac{2}{3}A_2\bar{R}$	7. $UWL_{\bar{X}}1.52 + \frac{2}{3} \times 0.34 = 1.75$
8. $LWL_{\bar{X}} = \bar{\bar{X}} - \frac{2}{3}A_2\bar{R}$	8. $LWL_{\bar{X}} = 1.52 - \frac{2}{3} \times 0.34 = 1.29$

by spiking a known quantity of the liquid contaminant onto the charcoal in the sampling tube. The latter technique is essentially that used for the determination of desorption efficiency. Analogous techniques for producing control samples can be developed for other measurement systems.

As the industrial hygiene program gains experience with a measurement system, the current data are used to calculate new control limits to replace the trial control limits. Periodically, the validity of the control limits should be checked and recalculated if appropriate.

7.2 Data Analysis Techniques

Numerous data analysis techniques are useful in the industrial hygiene program. Standard textbooks and handbooks such as the NBS handbook by Natrella (63) and quality control manuals (3) should be consulted for approaches and example problems. Consultation with a statistician can be of great help in selecting and applying the most appropriate approach to a specific data analysis problem.

7.3 Data Validation

Data validation is accomplished by a critical review of a set of data based on previously determined criteria. For large amounts of data from automatic measurement systems, a computer program may be used (8). For more usual industrial hygiene program sets of data, the analyst or surveyor and supervisor should determine whether the set of data conforms to the program's requirements for precision and accuracy. At least a spot check to assure the accuracy of calculations and conversions should be made. The measurement or analytical report (may be a report form) should be checked for transcription errors, omissions, and mistakes. Any outlier values or values widely different from the expected, based on a history of measurements from the area of the

survey, should be specifically checked out to assure the industrial hygiene program that a real change in plant operations rather than a measurement error has taken place. This determination of consistency with past (expected) values may not be possible. An efficient way of automatically alerting the industrial hygiene program to such a situation is to develop a control chart based on operational experience. Trends and changes in plant operations may be more readily detected and interpreted using such an approach. Linch (34) discusses such a case, a lead in urine analysis program.

7.4 Sampling Plans

Sampling plans for acceptance sampling of such items as detector tubes can be an efficient tool for the industrial hygiene program. Their use in developing a sampling program for environmental or biological monitoring is discussed elsewhere in this book.

8 QUALITY CONTROL PROGRAM AUDIT

8.1 Internal Evaluation

The industrial hygiene program should periodically seek assurance that the elements of the quality control system are living up to the program's expectations for the "return on invested resources." Other program elements not directly related to quality control, such as compliance with statutory rules and regulations, and other controlling programmatic standards such as company or agency policies, should also be audited.

Auditing of operating procedures can be accomplished having a supervisor or an operator/analyst other than the person conducting the routine measurements or analyses perform the procedures. A second set of calibration equipment and reference standards can be acquired for checking sampling equipment calibration procedures and operational equipment. A "transfer standard" such as NBS uses for some basic measurements could be employed by several programs in a cooperative program.

8.2 Self-Appraisal Quality Control Check List

Ratliff (56) has adapted standard manufacturing quality program audits and vendor qualification procedures to the needs of the analytical laboratory. The following checklist has been modified to more broadly cover the needs of the overall industrial hygiene program laboratory functions. Ratliff used a standard of 3.8 average score as acceptable. An average score of 2.5 to 3.7 indicated a need for improvement. It was felt that an average score of less than 2.5 indicated a risky situation, requiring immediate correction.

INDUSTRIAL HYGIENE PROGRAM SELF-APPRAISAL QUALITY CONTROL CHECKLIST

		Score
1. The acceptance criteria for the level of quality of the industrial hygiene laboratory's routine performance are:		
a. Clearly defined in writing for all key or critical characteristics.	5	
b. Defined in writing for some characteristics, and some are dependent on experience, memory, and/or verbal communication.	3	
c. Only defined by experience and verbal communication.	1	_____
2. Acceptance criteria for the level of quality of the industrial hygiene program's routine performance are determined by:		
a. Monitoring program performance in a structured program of inter- and intralaboratory evaluations.	5	
b. Program determination of what is technically feasible.	3	
c. Program determination of what can be done using currently available equipment, techniques, and manpower.	1	_____
3. The quality control coordinator has the authority to:		
a. Affect the quality of measurements by inserting controls to assure that the methods meet the user's needs for precision, accuracy, sensitivity, and specificity.	5	
b. Reject suspected results and stop any method that produces high levels of discrepancies.	3	
c. Submit suspected results to laboratory management for a decision on disposition.	1	_____
4. Accountability for quality is:		
a. Clearly defined for all program elements and their chiefs where their actions have an impact on quality.	5	
b. Vested with the quality control coordinator, who must use whatever means possible to achieve quality goals.	3	
c. Not defined.	1	

5. "Quality" in the industrial hygiene program long-range planning:

   a. Is considered an important factor with regard to changing user demands, new applications, legal considerations, and technical advances in control and methods. 5
   b. Is considered part of the technology or service. 3
   c. Is not considered a factor for planning purposes. 1 _____

6. Calibration, measuring, gauging, and analytical instruments are:

   a. Maintained operative, accurate, and precise by regular checks and calibrations against stable standards which are traceable to the National Bureau of Standards. 5
   b. Periodically checked against a zero point or other reference and examined for evidence of physical damage, wear, or inadequate maintenance. 3
   c. Checked only when they stop working or when excessive defects are experienced that can be traced to inadequate instrumentation. 1 _____

7. Reagents and chemicals (critical items) and sampling system components such as detector tubes are:

   a. Procured from suppliers who must submit samples for test and approval before initial shipment. 5
   b. Procured from suppliers who certify that they can meet all applicable specifications. 3
   c. Procured from suppliers on the basis of price and delivery only. 1 _____

8. Reagents, chemicals, and sampling systems (or components) are:

   a. Checked 100 percent against specification and quantity, and for certification where required, and accepted only if they conform to all specifications. 5
   b. Spot-checked for proper quantity and for shipping damage. 3
   c. Released to program personnel by the receiving clerk without being checked as described in a or b. 1 _____

9. Discrepant purchased systems and materials are:

   a. Submitted to a review by quality control and chief chemist for disposition. 5

b. Submitted to the operational program elements for determination on acceptability. 3
c. Used because of scheduling requirements. 1 _____

10. Inventories are maintained on:

a. First-in, first-out basis. 5
b. Random selection in stock room. 3
c. Last-in, first-out basis. 1 _____

11. Inventories are:

a. Identified with respect to type, age, and acceptance status. 5
b. Identified with respect to material only. 3
c. Not identified in writing. 1 _____

12. Reagents and chemicals and sampling system components (e.g., detector tubes) that have limited shelf life are:

a. Identified with respect to shelf life expiration date and systematically issued from stock only if they are still within that date. 5
b. Issued on a first-in, first-out basis, expecting that there is enough safety factor that the expiration date is rarely exceeded. 3
c. Issued at random from stock. 1 _____

13. The operating conditions of the methods are:

a. Clearly defined in writing in the method for each significant variable. 5
b. Controlled by supervision based on general guidelines. 3
c. Left up to the field personnel or bench chemist/analyst. 1 _____

14. Operational procedures are checked:

a. During the measurements for conformity to operating conditions and to specifications. 5
b. After the measurements or analyses to determine acceptability of the results. 3
c. Not at all. 1 _____

15. Revisions to technical operational procedures and sampling/analytical methods are:

a. Clearly spelled out in written form and distributed to all parties affected on a controlled basis, which assures that the change will be implemented and permanent. 5
b. Communicated through memoranda to key people who are responsible for effecting the change through whatever method they choose. 3
c. Communicated verbally to operating personnel, who depend on experience to maintain continuity of the change. 1 _____

16. Changes to methods and other operational procedures are:

a. Analyzed to make sure that any harmful side effects are known and controlled before revision implementation. 5
b. Installed on a trial or gradual basis, monitoring the product to see whether the revision has a net beneficial effect. 3
c. Installed immediately with action for correcting side effects taken if they are evident in the final results. 1 _____

17. Revisions to operational procedures and sampling/analytical methods are:

a. Recorded with respect to date, serial number, and so on, when the revision becomes effective. 5
b. Recorded with respect to the date the revision was made on written specifications. 3
c. Not recorded with any degree of precision. 1 _____

18. The capability of the measurement or sampling/analytical method to produce within specification limit is:

a. Known through method capability analysis ($\overline{X}$–R charts) to be able to produce consistently acceptable results. 5
b. Assumed to be able to produce a reasonably acceptable result 3
c. Unknown. 1 _____

19. Measurement or sampling/analytical method determination discrepancies are:

a. Analyzed immediately to seek out the causes and apply corrective action. 5

b. Checked out when time permits. 3
c. Not detectable with present controls and procedures. 1 _____

20. Decisions on acceptability of questionable results are made by:

a. A review group consisting of the chief chemist, the chief field industrial hygienist, quality control personnel, and others who can render expert judgment. 5
b. An informal assessment by quality control. 3
c. The bench chemist/analyst or field personnel. 1 _____

21. Final acceptance of the results is made:

a. By replicating statistically adequate samples. 5
b. By routine acceptance because of lack of complaints. 3
c. On faith. 1 _____

22. Follow-up action is:

a. Taken to identify assignable causes for "suspect" determinations. 5
b. Taken to make sure that method errors have been corrected. 3
c. Not considered necessary. 1 _____

23. Data reports on quality are distributed to:

a. All levels of management. 5
b. One level of management only. 3
c. Quality control only. 1 _____

24. Quality reports contain:

a. Information on trends, required action, and danger spots. 5
b. Information on suspected analyses and their causes. 3
c. Number of analyses per month. 1 _____

25. Quality control analysis is performed to:

a. Seek out the optimum levels of operation. 5
b. Provide for highlighting trouble spots. 3
c. Fix the blame for substandard results. 1 _____

26. When key personnel changes occur:

a. Specialized knowledge and skills are retained in the form of documented methods and descriptions. 5
b. Replacement people can acquire the knowledge of their predecessors from co-workers, supervisors, and detailed study of specifications and memoranda. 3
c. Knowledge is lost and must be regained through long experience or trial and error. 1 _____

27. The people who have an impact on quality, bench chemists, industrial hygiene field personnel, supervisors, and so on, are:

a. Trained in the reasons for and the benefits of standards of quality and the methods by which high quality can be achieved. 5
b. Told about quality only when their work falls below acceptable levels. 3
c. Reprimanded when quality deficiencies are directly traceable to an individual's work. 1 _____

28. Training of new employees is accomplished by:

a. A programmed system of training where elements of training, including quality standards, are incorporated in a training checklist; the employee's work is immediately rechecked by supervisors for errors or defects, and the information is fed back instantaneously for corrective action. 5
b. On-the-job training by the supervisor, who gives an overview of quality standards; details of quality standards are learned as normal results are fed back to the employee. 3
c. On-the-job learning, with training on the rudiments of the job by senior co-workers. 1 _____

29. Auditing of the quality control program is:

a. Performed on a random but regular basis, to verify that all quality procedures are being implemented and are effective. 5
b. Performed whenever a suspicion arises that there are areas of ineffective performance. 3
c. Never performed. 1 _____

30. If the costs of quality are known, the major portion of the expenditure is in:

a. Prevention. 5
b. Appraisal. 3
c. External or internal failure (duplicate determinations to correct errors; reruns). 1 _____

31. Corrective action to reduce failure costs is:

a. An ongoing program with specific objectives, measurements, and target dates. 5
b. Taken when deficient results threaten schedules. 3
c. Taken after considerable losses have occurred in the laboratory or in the field. 1 _____

32. The management, through the NIOSH Proficiency Analytical Testing program or other external evaluation mechanisms, regards the laboratory's performance quality as:

a. Significantly better than peer laboratories. 5
b. About the same as peer laboratories. 3
c. Significantly worse than peer laboratories. 1 _____

33. Support for laboratory quality goals and results is indicated by:

a. A clear statement of quality objectives by the top executive, with continuing visible evidence of sincerity to all levels of the organization. 5
b. Periodic meetings among the section heads of service, field operations, research and development, and quality assurance on quality objectives and progress toward their achievement. 3
c. A "one-shot" statement of the desire for product quality by the top executive, after which the quality control staff is on its own. 1 _____

34. The quality control system is:

a. Formalized and documented by a set of procedures clearly describing the activities necessary and sufficient to achieve desired quality objectives from initial design through to final delivery to the user. 5

b. Contained in operational methods and procedures or is implicit in those procedures; experience with the materials, product, and equipment is needed for continuity of control. 3
c. Undefined in any procedures and left to the current managers or supervisors to determine as the situation dictates. 1 _____

Summary

Strong points:

Weak points:

Improvement goals:

8.3 External Evaluations

External evaluations of environmental programs such as that for water laboratories (64) have been in existence for many years. Clinical laboratories have been involved in such programs at least since the passage of the Clinical Laboratories Improvement Act of 1967. The American Industrial Hygiene Association program has initiated (55) and validated (65) an accreditation program for industrial hygiene analytical laboratories. The Occupational Health and Safety Program Accreditation Commission (66) (administrative aspects are being handled by the AIHA) was set up by sponsoring occupational health and safety professional societies and has developed and validated (67) program standards and audit criteria for evaluating the overall quality of the occupational health and safety function of an employer (whether a private company, a nonprofit institution, or a governmental agency). Such external evaluation programs will assure industrial hygiene program management and facility management that the safety and health function compares favorably with peer groups, or will objectively identify areas of needed improvement to achieve that status. These programs are continuing, thus ensuring that operational capabilities are maintained over a long period of time.

9 SUMMARY

This chapter has covered the philosophy and scope of quality control in the industrial hygiene program. The elements of such a program have been grouped and developed for the areas of program management; equipment, standards, and facilities; laboratory

analysis control; sample handling, storage, and delivery; statistical quality control techniques; and program audits. A high score on the Industrial Hygiene Program Self-Appraisal Quality Control Checklist indicates that an industrial hygiene quality control program is effective. External evaluation, however, provides corroborative evidence that may carry more weight with the users of the industrial hygiene program's efforts.

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