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# Quality Assurance in Breath-Alcohol Analysis*

Kurt M. Dubowski
*The University of Oklahoma Health Sciences Center, Department of Medicine and Forensic Science Laboratories, P. O. Box 26901, Oklahoma City, OK 73190 and Office of the State Director of Tests for Alcohol and Drug Influence, State of Oklahoma*

## Abstract

Evidential breath-alcohol testing requires an adequate quality assurance (QA) program to safeguard the testing process and validate its results. A comprehensive QA program covers (a) test subject preparation and participation; (b) the analysis process; (c) test result reporting and records; (d) proficiency testing, inspections, and evaluations; and (e) facilities and personnel aspects. Particularly important are the following necessary scientific safeguards as components of quality control: (a) a pretest deprivation–observation period of at least 15 minutes; (b) blank tests immediately preceding each breath-collection step; (c) analysis of at least duplicate breath specimens; and (d) a control test accompanying every subject test. These safeguards have withstood adversarial challenges in the judicial system for more than 30 years.

## Introduction

The concept of quality assurance (QA) is intuitively recognized and accepted by most persons engaged in providing products or services as necessary to assure that the latter meet defined standards. As applied to breath-alcohol† analysis, QA is a comprehensive ongoing program of activities designed and intended systematically to identify, control, and monitor all major factors that can affect the process and its outcome, namely the test result. The ultimate purpose of the QA program is to ensure to the maximum extent feasible that the entire testing process is valid and reliable and that the results obtained are true and correct. The QA concept as applied to measurements and other laboratory activities, of course, evolved and was adapted from its original application to quality control of manufactured products. As considered herein, quality control and quality assessment (1) are component elements of the overall QA program.

Some key QA elements and practices were proposed more than 30 years ago as "necessary scientific safeguards" for forensic breath-alcohol testing‡ (2) and have become widely recognized and practiced in such testing applied to traffic law enforcement. Since then, QA, and quality control in particular, have continuously evolved into an accepted body of knowledge, and the relevant practices have become standardized and refined. Two forces have been particularly involved in and responsible for these developments. The Committee on Alcohol and Other Drugs of the National Safety Council (NSC), established in 1936, has been concerned with many aspects and issues of the drinking–driving problem and has paid particular attention to the technology of breath-alcohol analysis; it has pioneered and implemented many standards for breath-alcohol testing (3). Under the impetus of vigorous legal challenges to forensic alcohol analysis and the testing of allegedly drinking drivers in particular (4–8), a massive body of appellate case law has arisen on both legal and technical issues of alcohol testing. This has also stimulated development and use of increasingly comprehensive and sophisticated QA practices in forensic alcohol testing. Still, a few now near-universal laboratory QA practices, such as use of control charts, have only rarely been used in connection with breath-alcohol testing (9). QA principles and practices as applied to chemical measurements have been much expanded and formalized in recent decades (10–13). An evolving body of appellate case law on QA issues has focused on certain judicial requirements for admissibility of alcohol test results as evidence. Lastly, the ongoing extension of Federally regulated breath-alcohol testing into the transportation workplace (14) will greatly expand the future scope of breath-alcohol testing and, undoubtedly, the extent of scrutiny it will undergo.

QA has become an indispensable accompaniment to forensic breath-alcohol analysis. Given the above background, this article is intended to serve as a ready reference on planning and implementation of such a QA program, especially for organizations and persons newly entering the breath-alcohol testing arena. However, most details of implementation are beyond the scope of this article. In governmentally regulated programs of breath-alcohol testing, the key QA components and elements

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† The unmodified term *alcohol* in this article refers to ethanol.

‡ The term *forensic breath-alcohol testing* in this article refers to such testing performed under mandate of law or under equivalent circumstances.

should be incorporated into the pertinent administrative rules, and operational minutiae should be omitted.

## Components and Elements of a QA Program for Breath-Alcohol Analysis

In designing an adequate QA program, it is useful to recognize the most common problems currently causing operational difficulties in forensic breath-alcohol testing programs and underlying successful legal challenges of breath-alcohol analysis results. These problems, shown in Table I, long ago superseded the technical limitations and inadequacies of early instrumentation used in breath-alcohol testing as sources of difficulty, especially since the advent, in 1973, of Federal standards, model specifications, and conforming products lists for such devices (15–17).

**Table I. The Most Common Problems and Lapses in Forensic Breath-Alcohol Analysis**

- inadequate rules and regulations
- lack of a comprehensive quality assurance program
- lack of control test(s) accompanying every subject test
- failure to observe and adequately document a proper pretest deprivation–observation period
- failure to test replicate breath specimens
- lack of periodic personnel retraining

A comprehensive QA program must address all relevant preanalytical, analytical, and postanalytical factors. It should thus cover (a) test subject preparation and other preparations; (b) the analysis process; (c) test result reporting and records; (d) performance and proficiency testing, inspections, and evaluations; and (e) facilities and personnel aspects. The elements of a comprehensive QA program are enumerated in Table II.

**Table II. Elements of a Quality Assurance Program for Forensic Breath-Alcohol Testing**

- comprehensive Federal- or state-level regulation of the system
- facilities, apparatus, and equipment
- personnel aspects
- the testing process
- performance and proficiency testing
- records and reports
- inspections, reviews, and evaluations

The components of the several QA program elements are set forth in Tables III through IX. Many of those components are encompassed within Good Laboratory Practice standards for laboratories. Many of them also appear, in one form or another, in current regulations or guidelines for forensic urine drug testing (FUDT) or for human performance forensic toxicology. The former are exemplified by the Department of Health and Human Services' guidelines for Federal workplace drug-testing programs (18) and by standards for accreditation of FUDT laboratories adopted by the College of American Pathologists (19); the latter are exemplified by the SOFT/AAFS forensic toxicology laboratory guidelines (20).

**Table III. Quality Assurance in Forensic Breath-Alcohol Analysis: Subject Matter of Administrative Rules Regulating the System**

- statutory, regulatory, or other authority for the system
- organization, operations, procedures, and policies of the regulatory agency or entity; rule making
- powers, authority, and duties of the rule-making agency or entity
- conferral and delegation of authority and responsibility for system elements (central control, local operations, testing protocols, training, inspections, etc.)
- personnel aspects (including training and supervision)
- sites, facilities, and laboratories
- licenses, permits, and fees
- specimens
- apparatus, devices, equipment, and materials
- analysis of alcohol in breath (and other specimens), operating procedures, and protocols
- records, reports, and information
- evaluation of the system, inspections, etc.
- administrative law: orders, challenges, petitions, hearings, individual proceedings, disciplinary actions, appeals

**Table IV. Quality Assurance in Forensic Breath-Alcohol Analysis: Facilities, Apparatus, Equipment, and Materials**

*Centralized functions*

- specifications of site and facilities requirements
- specifications of equipment, apparatus, and materials
- type approval of devices and modifications; amendments and deletions
- type approval of materials; amendments and deletions
- review and evaluation of local records and reports concerning equipment and devices

*Local functions*

- routine inspection and maintenance of sites, facilities, and equipment
- repair and servicing of equipment
- performance and device-parameter testing (operating temperatures, blanks, control tests, etc.)
- recording and reporting of incidents, problems, and actions taken concerning equipment and devices

**Table V. Quality Assurance in Forensic Breath-Alcohol Analysis: Personnel Aspects**

- classification and nomenclature of personnel
- qualifications of testing program director(s), instructors, supervisors, and analysts
- initial training and certification of instructors, supervisors, and analysts
- periodic retraining and recertification of instructors, supervisors, and analysts
- personnel performance reviews
- remedial actions

**Table VI. Quality Assurance in Forensic Breath-Alcohol Analysis: The Testing Process**

- detailed analysis protocol(s); operating procedures
- subject preparation
  - deprivation–observation period
  - elimination of foreign objects or substances from mouth
  - exclusion of emesis, eructation, regurgitation
- operational safeguards
  - purging of analyzers
  - blank analysis before and after each breath specimen
  - analysis of duplicate breath specimens
  - retention of breath or breath-alcohol specimens
  - use of procedural checklists
  - printout of test results
  - control tests
- records and reports
- performance and proficiency testing
- inspections, reviews, and evaluations

**Table VII. Quality Assurance in Forensic Breath-Alcohol Analysis: Performance and Proficiency Testing**

- purpose, intent, and effect of performance and proficiency testing (P/T)
- internal and external P/T schemes
- establishment and validation of target values of P/T specimens
- combined system P/T testing: analyst, analyzers, testing protocol, reports, and records
- frequency, scheduling, and logistics of P/T activities
- remedial actions

**Table VIII. Quality Assurance in Forensic Breath-Alcohol Analysis: Records and Reports**

- enumeration of records, reports, and forms authorized and required; purpose and contents
- preparation of records and reports
- distribution of reports and forms; disclosure of information
- retention and destruction of records
- confidentiality, security of, and access to records, reports, and information

**Table IX. Quality Assurance in Forensic Breath-Alcohol Analysis: Inspections, Reviews, and Evaluations**

- purpose and objectives of inspections, reviews, and evaluations; fact-finding
- authority and responsibility for inspections, reviews, and evaluations
- subject matter and extent of inspections: sites, facilities, apparatus and equipment, operations, and records
- conduct of inspections and reviews
- frequency, scheduling, and logistics
- reports and records of inspections and reviews; feedback and other uses of the information developed

## Quality Control: Necessary Scientific Safeguards

Quality control constitutes a system of activities, techniques, and procedures to promote, protect, and assure the validity and reliability, to a stated level of confidence, of the measurement process and its output (i.e., breath-alcohol analysis results). Probably the longest standing and most recognized components of quality control in this context are the necessary scientific safeguards. They have undergone little change since I addressed them in 1960 (2) and have successfully withstood adversarial challenges in the judiciary system. Those safeguards that I consider to be indispensable in forensic breath-alcohol measurement appear in Table X, and their integration into the breath-alcohol analysis is shown in Figure 1. Each of the safeguards appearing in Table X has been endorsed and recommended by the NSC Committee on Alcohol and Other Drugs (21,22) and incorporated into many state-level regulations, for example, those of Oklahoma (23).

**Table X. Necessary Scientific Safeguards in Forensic Breath-Alcohol Measurement**

- a pretest deprivation–observation period of at least 15 minutes
- blank tests immediately preceding each breath specimen collection step
- analysis of at least two separate consecutive breath specimens
- an appropriate control test accompanying every subject test

Two other highly desirable safeguards are a result printout produced by a printer integral to or externally linked to the analyzer and contemporaneous use and marking of a step-by-step checklist when nonautomated, manual analyzers are employed. Several other, related safeguards have been recommended by

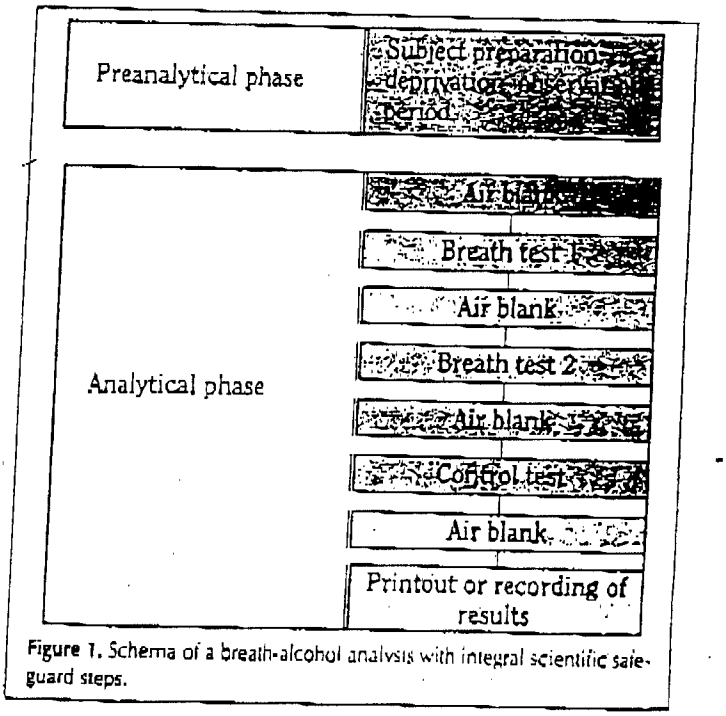


**Figure 1.** Schema of a breath-alcohol analysis with integral scientific safeguard steps.

the NSC Committee on Alcohol and Other Drugs. The committee has stated that "Suitable breath specimens are those in which the ethyl alcohol was substantially in equilibrium with the alcohol of the pulmonary arterial blood plasma. 'Deep lung air' (alveolar air) is such a specimen" (21). It has also recommended that "The quantity of breath analyzed for its alcohol content shall be established only by direct volumetric measurement, or by collection and analysis of a fixed breath volume" (21). The predominant breath-sampling features of current generation breath-alcohol analyzers are in accord with these precepts (24).

Control tests in breath-alcohol analysis are performed chiefly with breath-alcohol simulators, which are devices for the preparation and delivery of vapor specimens of known alcohol concentration, prepared by equilibrating a flowing gas such as air with an aqueous alcohol solution of known concentration, at fixed temperature (24–27). The resultant vapor effluent has a predictable and controllable alcohol concentration and appropriately simulates alcohol-containing breath for use in calibrating analyzers, control tests, and analyst training. Simulators are critically dependent upon properly prepared and validated alcohol reference solutions for producing vapor-alcohol effluents of specified, known alcohol concentration. The NSC Committee on Alcohol and Other Drugs has issued recommendations for preparation and validation of alcohol reference solutions for this application (28). Alcohol mixtures in inert gases, such as argon or nitrogen, stored under high pressure in cylinders or at lower pressure in disposable cans, are another form of alcohol standard for calibrating and control test purposes (24).

The nomenclature and units employed in reporting the results of analyses for alcohol in human biological specimens have tended to be somewhat esoteric and, at times, confusing. There are also distinctive international differences. Fortunately, a universal convention on the units to be used for reporting breath-alcohol concentrations has arisen in North America, and the matter is now settled. Based on a proposal by Mason and Dubowski (29) and the subsequent 1975 recommendation of the NSC Committee on Alcohol and Other Drugs (30), the Uniform Vehicle Code and Model Traffic Ordinance in 1979 adopted the following definition of alcohol concentration: "Alcohol concentration shall mean either grams of alcohol per 100 milliliters of blood or grams of alcohol per 210 liters of breath" (31). The latter units for stating breath-alcohol concentration have been widely adopted and employed in the scientific literature and incorporated into state traffic laws, state regulations on alcohol testing, and relevant Federal regulations (32,33). For law enforcement applications, the convention is to report alcohol concentrations (in g/210 L for breath-alcohol or g/dL for blood-alcohol) to two decimal places and to truncate (i.e., drop entirely) the third decimal place.

## Discussion and Recommendations

A comprehensive and up-to-date set of regulations governing all important aspects of a given program of forensic breath-alcohol testing is fundamental and indispensable. It needs to be a living document and thus should be revised as often as necessary to reflect ongoing statutory changes, case law, and other controlling events. Equally important is a comprehensive written quality assurance plan. It should be reviewed frequently and referred to constantly; therefore, it should also be succinct and organized in such a way that its key elements are easy to locate.

It is understandable that the most attention in a QA program and in quality control measures for breath-alcohol analysis tends to be fixed on the testing aspects. Though not as prominent, the preanalytical and postanalytical aspects of forensic breath-alcohol testing enumerated in Table III are as important as the analytical aspect for maintaining the desired quality and standards. Of particular significance are the facilities and personnel aspects of both overall regulations and the QA plan because they are often slighted inappropriately. For both fixed facilities and equipment and for personnel, the tendency is to attend to these matters only at the onset of a program. Further changes or modifications in sites, equipment, and other facilities should be held to the same standards as the original factors and proper documentation used. The same policy pertains to personnel replacements (e.g., breath-alcohol analysts). Especially to be avoided with respect to the latter is on-the-job "echelon training", that is, the unofficial and informal inheriting of information about the task from a departing incumbent. As in the children's game of "telephone," the end product of such hand-me-down instruction often bears little or no resemblance to the original.

Although all aspects of the actual testing process are important in a QA sense, the scientific safeguards are the most critical. A pretest deprivation–observation period of at least 15 minutes should precede the subject test. During that time period, the test subject must refrain from intake of food or drink, smoking, or presence of foreign objects or substances in the mouth (especially use of breath-fresheners and mouthwash), and there must also be assured absence of regurgitation of gastric content or emesis. In any of the latter events, the mouth is rinsed thoroughly with water at body temperature, and the 15-minute deprivation–observation period is repeated. The 15-minute pretest period is amply sufficient to assure that prior intentional ingestion of alcoholic beverages or inadvertent intake of other alcohol-containing substances will not affect the accuracy of the breath-alcohol analysis through contamination by "mouth alcohol" (34,35). Purging of the analyzer with ambient air free of volatile substances prior to collection and analysis of breath or alcohol-vapor specimens is a fundamental requirement for accuracy of the analysis. With automated devices, the microprocessor-controlled operation can be, and usually is, factory-programmed so as to perform an ambient air purge cycle and initial blank test automatically whenever the test sequence is initiated. A blank test result within acceptable preestablished limits is a prerequisite to the next step, as illustrated in Figure 1. With most manual devices, a purge step is not automatically performed but is equally indispensable, as is the subsequent manual rezeroing of the result scale for analyzers so equipped. Use of an appropriate checklist, which can be incorporated into the report form, and marking of each step as it is performed are recommended safeguards with manual analyzers.

Repeating an analysis is a widely employed QA practice in chemical analysis. Collection and sequential analysis of at least two separate breath specimens has become accepted practice, as recommended by the NSC Committee on Alcohol and Other Drugs. The Committee recommended that "The breath samples should be collected at intervals of not less than 2 nor more than 10 minutes, after an initial deprivation period of at least 15 minutes" (22). Any difference between the duplicate results greater than a predefined maximum should be regarded as an indication of a potential problem. Conversely, acceptable agreement of the duplicate results eliminates the unrecognized presence of such actual or supposed irregularities as the effects of mouth alcohol, alleged radio frequency interference with the instrumental analysis, and other confounding factors (36). The sequence of a positive initial, or screening, test followed by another breath-alcohol test after a specified waiting period does not constitute duplicate breath testing nor is such a second test correctly designated as a confirmatory analysis unless it utilizes a different chemical principle (37). Although it is useful in reducing the possibility of random error, repeating an initial or screening test by the same method or equipment does not truly constitute confirmation of the result (38). It is, however, designated as such in the U.S. Department of Transportation (DOT) workplace alcohol testing rule if an evidential breath-testing device approved by the National Highway Traffic Safety Administration is employed (39); the difference in philosophy is there termed merely "semantic".

Control tests accompanying every human subject test are an essential form of scientific safeguard. In essence, a control test constitutes a total system check because it tests the contribution of the alcohol analyzer, its calibration, the analysis process, the analyst's function, the environment, and the reporting process. Virtually all automated breath-alcohol analyzers and certain manual analyzers are factory-calibrated rather than calibrated at or near the time of a subject test by means of verified standard reference materials. Given these circumstances, a control test result within acceptable preestablished limits of its independently established target value, combined with a negative blank result, provides adequate assurance of proper calibration. That combination also eliminates any potential for unacceptable effects due to the testing environment, such as contamination of the analyzer by chemical interferents in the ambient air. The generally accepted course of action in the event that a control test result (termed by DOT to be an "external calibration check") is unacceptable is to take the involved analyzer out of service and to sequester and invalidate all subject test results obtained with it since the most recent satisfactory control test prior to the occurrence. The frequency and regularity of control tests are, therefore, of practical concern for the system. The optimal arrangement is at least one control test accompanying every subject test, as proposed in Table X. Validation and verification of the control test target value is a critical step in this quality control activity. When simulators are used for control tests, as required under the DOT workplace alcohol testing rule (40), at least two variables controlling the control target value need to be checked and properly validated: the ethanol concentration of the aqueous simulator solution and the simulator temperature at which the alcohol equilibration occurs. The former is a laboratory task in which the ethanol standards used should be traceable to National Institute of Standards and Technology (NIST) SRM 1828. The latter must necessarily be performed at the test site, at the time of the control test; it should be done by thermometry using a device with calibration traceable to a NIST-certified thermometer, such as NIST SRM 934. Lastly, performance of control tests does not constitute calibration and should not be termed as such.

As previously mentioned, QA principles and practices applied to breath-alcohol testing have become highly refined in most respects. One missing component is external performance or proficiency testing, which is often termed P/T. In contrast with the situation in blood-alcohol analysis for forensic and other purposes, there is no nationwide program of external P/T activities or surveys for breath-alcohol analysis. Simulator solutions of known alcohol concentration could be so used, but the local results obtained are critically dependent upon the characteristics and functioning of the simulator used, especially the accuracy and stability of the intended equilibration temperature, which is usually 34°C. Preparation and distribution of small disposable containers with pressurized gas or vapor samples of known, validated ethanol concentration are feasible but not currently practiced for P/T purposes. Ultimately, demand for recognized external P/T programs will undoubtedly arise, probably as the result of adversarial proceedings, for example, litigation challenging breath-alcohol results and personnel actions based on them. There is a school of thought on decentralized testing that holds that the more limited and rudimentary the training and supervision of the analysts, the greater the need for an effective external P/T program.

In concluding this consideration of QA and related topics, the following recommendations are offered to persons responsible for establishing and conducting breath-alcohol testing programs: (a) Periodically review the entire program and the QA scheme for problems, omissions, and needed changes; (b) conduct mandatory control tests accompanying all subject tests; (c) conduct analysis of at least duplicate breath specimens; and (d) monitor the pertinent appellate court case law, and be guided by it. Also suggested is the following strategy for identifying inadequacies in the QA program: Engage in reversal-of-roles. If you were a qualified expert consultant for a party challenging your testing program or an outcome, were fully informed about your breath-alcohol analysis system, and had access to all records, what would you criticize or challenge?

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**Dubowski KM.**

University of Oklahoma Health Sciences Center, Department of Medicine, Oklahoma City.

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