

APPENDIX E

PROTOCOL FOR COMPRESSED AIR PROFICIENCY TESTING (CAPT) PROGRAM SAMPLE ANALYSIS

Purpose and Goal:

Firefighters using SCBA tanks, divers using SCUBA tanks, and workers using supplied breathing air apparatus are potentially exposed to unhealthy levels of oxygen, carbon monoxide, carbon dioxide, and total volatile hydrocarbons when equipment is not functioning properly. Individual laboratories have developed air sampling equipment and methods to collect representative samples from the breathing-air supply systems and the ambient environment. The laboratories have developed and use analytical procedures to quantify the collected samples. A proficiency testing program will significantly increase the level of confidence in those analytical procedures by demonstrating the ability of the laboratories to correctly quantify the concentration of the typical components of a gas mixture sample.

The Compressed Air Proficiency Testing Program (CAPT) is designed to share samples among participating laboratories. The laboratories analyze these samples to demonstrate that accurate analytical results can be generated by independent analysts following their own documented procedures. The CAPT group is open to participation by all analytical laboratories.

Background and Definitions:

The CAPT group is run by consensus of the participating laboratories. The CAPT group will meet routinely via email, teleconference, site visits, and at general industry events to discuss issues concerning test round performance, laboratory proficiencies, corrective actions, correspondence with accreditation groups, and other program issues. The group will designate a participating laboratory to document and share all decisions with members.

For the purposes of this protocol, the laboratory responsible for obtaining and distributing the gas mixture samples is referred to as the coordinating laboratory. The laboratories participating in the program are referred to as the participating laboratories. The coordinating laboratory is designated by the participating laboratories. However the coordinating laboratory must be an accredited laboratory through the AIHA or other accreditation program such as A2LA, using ISO 17025 or equivalent requirements. A laboratory must have a current rating of proficient in order to be a coordinating laboratory for the CAPT program. A coordinating laboratory can also act as a participating laboratory. The sample analysis results are reported to a designated statistical analyst for collating, statistical analysis, and reporting of acceptable/unacceptable results. The statistical analyst is also designated by consensus of the participating laboratories. The statistical analyst can be from a participating laboratory; however, the activities associated with supplying the results for the test rounds shall be kept separate from the activities associated with analyzing the gas mixtures.

The samples are ordered from an ISO 9000 registered gas supplier by the coordinating laboratory. The coordinating laboratory notifies the participating laboratories of the proper reference number sample for the proper round. The participating laboratories are responsible for setting up an account with the gas supplier and ordering the correct samples. The samples consist of oxygen, nitrogen, carbon dioxide, carbon monoxide, methane, ethane and total volatile hydrocarbons. The samples are appropriately identified by CAPT round number and

analyzed by the participating laboratories per each laboratory's standard analytical methods as if the samples were routine samples obtained from clients. The results obtained are reported as per this protocol. Normally a CAPT testing round will be performed four times per year. There is one cylinder for each round. Each cylinder will have seven reportable analytes. All valid rounds (for definition see statement 1b under heading During each CAPT round, the statistical analyst is responsible for:): will be used to determine acceptable/unacceptable results and reported. A flowchart illustrating the CAPT testing process is provided in Figure 1.

The coordinating laboratory will maintain and provide the AIHA and other accrediting organizations using the CAPT program copies of summary reports, corrective and preventive action reports, and the overall performance statistics per the coordinating laboratory's record retention guidelines. Information is typically, but not required to be, provided in an electronic format.

Responsibilities and Procedures:

During each CAPT testing round, the coordinating laboratory is responsible for:

1. Ordering gas samples from an ISO 9000 registered gas supplier of the following components and ranges.

Oxygen	Range 15 to 30%
Carbon dioxide	Range 300 to 1500 ppm
Carbon monoxide	Range 5 to 25 ppm
Methane	Range 5 to 15 ppm
Ethane	Range 4 to 20 ppm
Nitrogen	Balance of Mixture

(The gas supplier will make a master cylinder mixture and use it to fill cylinders that are sent to the participating laboratories. The gas supplier does not furnish or perform an analysis of the cylinder gas mixture.)

2. Ensuring that sample cylinders are available on and after the dates in the schedule below:

- 1) January 2 (for the first round of the year)
- 2) April 1 (for the second round of the year)
- 3) July 1 (for the third round of the year)
- 4) October 1 (for the fourth round of the year)

3. Ensuring that the gas vendor:

- a) Creates a master gas cylinder with concentrations of each analyte within the range called out above. The specific concentration is randomly selected by the gas vendor. The actual value is not known or reported to anyone by the gas vendor.
- b) Responds to timely to order requests.
- c) Maintains the master cylinder until the round is complete for the purpose of obtaining additional sample cylinders if there is a need for additional sample cylinders, such as cylinders arriving without adequate sample pressure due to leaks.

4. Handling all questions from participating laboratories with regard to the current round. A record of all issues and responses generated from the round will be documented and communicated to the CAPT participants for further review. No analytical data will be shared until after the round is closed.

5. Promptly notifying the participating laboratories in writing if the round must be repeated due to invalid sample items to be tested. An investigation will be made to determine the nature of the error, potential causes, and recommended corrective and preventive actions. This investigation will be documented and reviewed by the internal QA management of the coordinating laboratory. A summary of findings and corrective/preventive actions will be communicated to the CAPT participants and accrediting organizations using the CAPT program.
6. Maintaining a copy of the correspondence regarding technical assistance, corrective action/preventive action reports, individual laboratory result reports submitted, and summary reports for each round in accordance with internal record keeping policies of the coordinating laboratory. Documents must be retained for a minimum of three years from CAPT round date.

During each CAPT round, the participating laboratory is responsible for:

1. Setting up an account with the Gas Supplier.
2. Ordering the proper reference number round sample from the Gas Supplier.
3. Assigning personnel to analyze the samples who have been adequately trained by review of related documents (SOP's, protocols, methods) and shown to be proficient in the analytical technique used for the round. When the coordinating laboratory is also a participating laboratory or the participating laboratory also includes the statistical analyst, the personnel assigned to analyze the round shall not be involved with activities associated with preparing the round reports. Separate notebooks or other laboratory documentation methods consistent with the coordinating laboratory's quality procedures will be maintained for round participation, round coordination, and statistical analysis.
4. Analyzing the gas mixture samples for each round.
5. Reporting analyte test results for all rounds and reporting them by the established due date.

Typically there will be four rounds per year performed with the following data submittal deadlines for participating laboratories:

- 1) February 1 (for the first round of the year)
 - 2) May 1 (for the second round of the year)
 - 3) August 1 (for the third round of the year)
 - 4) November 1 (for the fourth round of the year)
6. Maintaining copies of test-round results reports in accordance with internal record keeping policies of the participating laboratory.

During each CAPT round, the statistical analyst is responsible for:

Collating the data for the round, determining each participating laboratory's proficiency rating and communicating the proficiency rating to each participating laboratory, and to any accreditation organizations as directed by individual participating laboratories.

The statistical analyst determines:

- 1) **Round Performance**
 - a) Removal of outliers.

The sample results for each analyte will be collated. The statistical control limits will be set by the following criteria. If there are more than five but fewer than 20 reported analytical results for any particular analyte, a calculation is made to determine the mean and the value of two standard deviations. Any results that fall outside the control limits of plus or minus two standard deviations from the mean are judged as outliers and removed from further statistical analysis. If there are more than 20 but fewer than 80 reported analytical results for any particular analyte, a calculation is made of three standard deviations. Any results that fall outside plus or minus three standard deviations from the mean are judged as outliers and removed from further statistical analysis. If there are fewer than five results or more than 80 results for any analyte, no outlier values are removed. In any case, the outliers will only be removed from the data set used for further statistical calculations of mean values and standard deviations to determine acceptable/unacceptable criteria.

- b) Determination of round validity.
Since there are typically seven possible reportable analytes, the validity of each analyte will be determined separately. If more than two analytes are not valid in a round, the entire round is determined to be invalid. The following criterion must be met to determine whether the analyte is valid: overall relative standard deviation (RSD) is less than 20% with outliers removed.
- c) Actions required by an invalid round.
If the RSD criterion is not met, the analyte will be considered invalid. If more than two analytes are invalid, this will create an invalid round. If this happens, the coordinating laboratory will work together with its internal QA management and the CAPT group to immediately investigate the cause(s) of the invalid round and determine appropriate corrective action and preventive action. The coordinating laboratory will notify all participating laboratories of the invalid round, and the round will be repeated or dropped if there are at least two valid rounds that will be completed during the calendar year that contain a total of at least 10 valid analytes. A makeup round shall be performed if necessary to ensure that there are at least 10 valid analytes provided to the CAPT participating laboratories each calendar year.
- d) Acceptable/unacceptable scores from the statistical analysis of the round analytes.
There are two methods used to determine acceptability. One is the Z score limiting values; the other is Absolute Difference. An acceptable score for a round analyte is determined by using the Z score limiting value unless the STDV divided by the numerical value of the Absolute Difference is less than 0.34. Then the Absolute Difference value is used to determine an acceptable score for an individual round analyte.
- e) Determining Z Score values.
 - i) The mean is calculated for each analyte with outliers removed.
 - ii) The standard deviation is calculated for each analyte with the outliers removed.
 - iii) A Z score is calculated by subtracting the analyte mean value from each laboratory reported analyte value and dividing this by the standard deviation.
 - iv) Any Z score between -3 and $+3$ (inclusive) is acceptable. Any score less than -3 or greater than $+3$ is unacceptable.
- f) Determining Absolute Difference values.
Absolute Difference is used because it is possible that some analytes will approach the detection limits on the low end of the analytical ranges or the data set for an analyte is

very tightly grouped, thus making the Z values using standard deviations inappropriately small.

The Absolute Difference is determined by adding the below respective analyte ranges to the mean value calculated without outliers. An acceptable Absolute Difference score is given to the reported analyte value if it is within the calculated Absolute Difference.

- Oxygen $\pm 1 \%$
- Nitrogen $\pm 2 \%$
- Carbon dioxide ± 30 ppm
- Carbon monoxide ± 2 ppm
- Methane ± 2 ppm
- Total Volatile Hydrocarbons ± 3 ppm
- Ethane ± 3 ppm

2) Lab Performance

- a) A laboratory must participate in all rounds to be assessed for proficiency (initial or continuing).
- b) Laboratories are required to report at least five analyte values per round to be assessed for proficiency (initial or continuing). If less than five analyte values are reported by a participating lab on one round the lab will not be rated for proficiency on that round.
- c) A laboratory's proficiency rating will be based on accumulated results for the last two consecutive rounds. A laboratory will be rated proficient if 90% or more of the accumulated results over the last two consecutive rounds are acceptable. The statistical analyst will determine acceptability of each result submitted using the Z-Score or Absolute Difference methods, as applicable, and will calculate the ratio of the number of acceptable results to the total number of sample results reported and determine the percentage of acceptable results. This percentage will then be compared to the 90% standard stated above to determine the proficiency for each participating laboratory.
- d) Laboratories using CAPT for accreditation purposes must notify the statistical analyst of non-participation with appropriate excuse information for non- participation consistent with the accreditation organization's policies. The excuse documentation must be submitted to the appropriate accrediting organization along with the CAPT round results.
- e) The confidentiality of the participating laboratories will be maintained.
- f) Any issues or concerns that a participating laboratory may have regarding its proficiency rating will be handled by the CAPT group.
- g) Decisions on all questions before CAPT will be based on sound scientific judgment and without bias and pressures from employer or other outside influences.

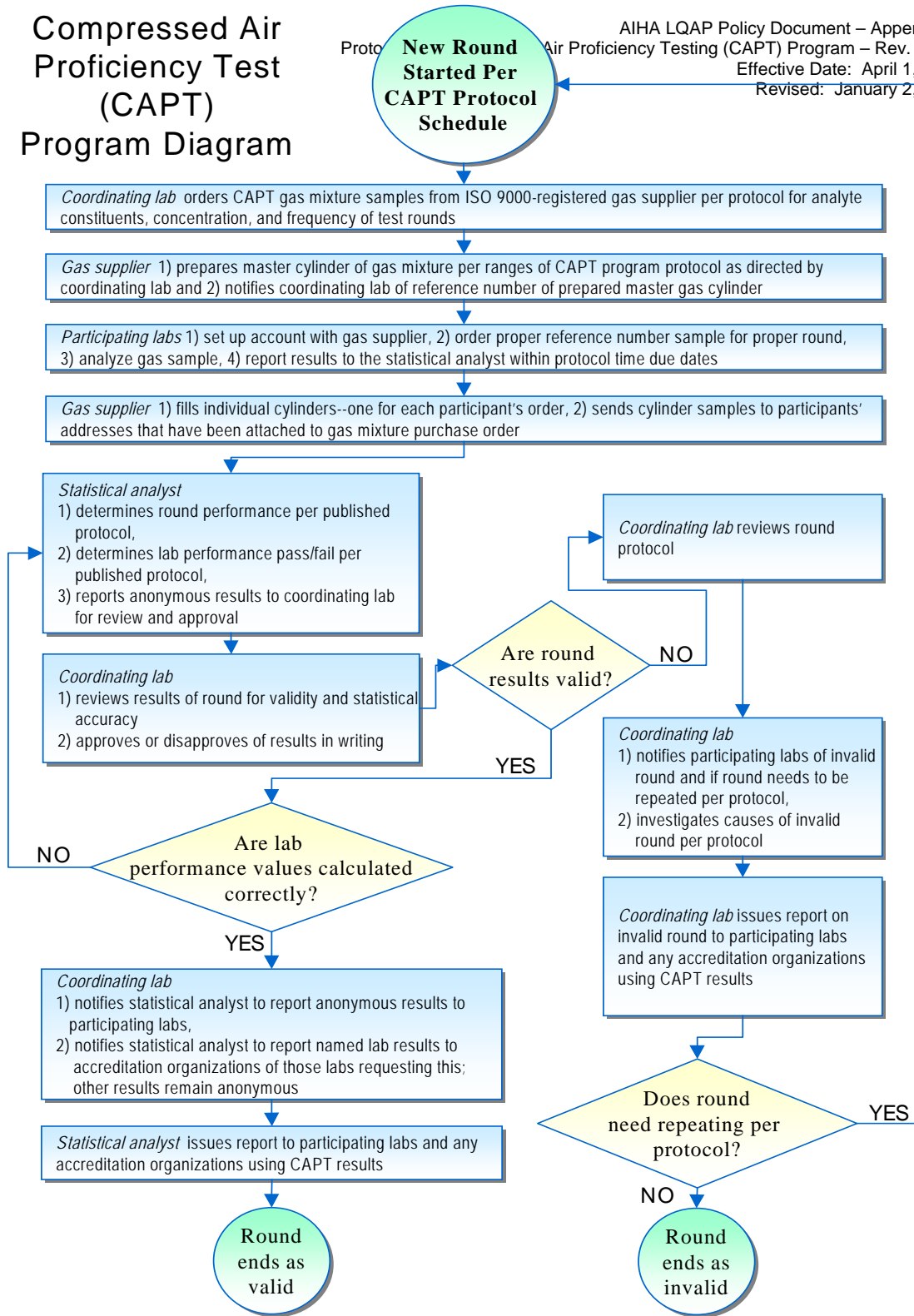
3) Round Results Reporting

Results are sent to all participating laboratories and accrediting organizations directed by participating laboratories and include the following information:

- a) Name and address of the coordinating laboratory
- b) Date of report issue
- c) Descriptive title
- d) Laboratories identified by an ID (not by name except versions sent to accrediting organizations with respective laboratories named seeking accreditation)
- e) Results of the gas sample to be tested (reported in units of ppm by volume and percent as appropriate per analyte) per Lab Performance section above
- f) Results from all participating parties (reported in units of ppm by volume and percent as appropriate per analyte) and calculated averages and standard deviation per Lab Performance section above

Compressed Air Proficiency Test (CAPT) Program Diagram

AIHA LQAP Policy Document – Appendix E
 Air Proficiency Testing (CAPT) Program – Rev. 5(AE)
 Effective Date: April 1, 2007
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Attachment 1: Compressed Air Proficiency Test (CAPT) Program Diagram