

QUALITY ASSURANCE AND QUALITY CONTROL IN  
BREATH ALCOHOL MEASUREMENT PROGRAMS USING  
INTOXILYZERS SUCH AS THE INTOXILYZER 8000C.

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- INTOXILYZERS 5000 & 8000 ARE USED IN THE USA
- INTOXILYZERS 5000C & 8000C ARE USED IN CANADA
  
- THE DIFFERENCE IS ONLY IN THE SEQUENCE OF AIRBLANKS, CALCHECKC, DIAGNOSTICS AND SUBJECT TESTS. OTHERWISE THE INSTRUMENTS ARE IDENTICAL.

# RECENT CHANGES IN LEGISLATION

- IN CANADA DUI OFFENSES ARE CRIMINAL CODE OFFENSES.
- EQUIVALENT TO FELONIES IN THE USA.
  
- RECENT LAW IN CANADA (C2) CONSIDERS INTOXILYZER MEASURED BAC AS CONCLUSIVE EVIDENCE. THIS HAS CONSIDERABLY CHANGED THE DEFENSE OF THESE CASES IN COURTS COMPARED TO THE CARTER DEFENSE.
- CAN MAINLY BE REBUTTED BY SHOWING THAT THE INSTRUMENT MALFUNCTIONED OR WAS OPERATED IMPROPERLY.
- THIS CAN ONLY BE DONE BY OBTAINING PROPER DOCUMENTATION FROM THE PROSECUTION SOURCES.

- What are the documents needed for this purpose?
- Crown/Prosecutor's toxicologists: Just the Intoxilyzer printout is sufficient. If the cal-check is OK and no error messages are present, then the instrument and procedures are OK.
- Defense Toxicologists: Need all the maintenance and downloaded data since cal-check deals only with aqueous standards and does not deal with interferences. Also needs to make sure that maintenance was done properly to ensure that all components worked properly. These include diagnostics, interference detectors, RF detectors, slope detectors and others.

# QUALITY ASSURANCE AND QUALITY CONTROL

- QA: Comprehensive on-going program in which systematic procedures are put in place for the entire testing process.
  - Requirements of air blanks, duplicate tests, 15 minutes deprivation, maintenance of instruments and accessories, training of operators, overall management of the program.
- QC: Set of procedures and tests to assure that the measurement output i.e. subject BAC is reliable and accurate.
  - Blank tests, diagnostics, calibration checks and duplicate subject tests

GOOD QC PROCEDURES ARE NOW NEEDED UNDER THE PRESENT LEGISLATION.

- LESSONS CAN BE LEARNED FROM OTHER LABORATORIES AT HOSPITALS, GOVERNMENT LABS AND INDUSTRY AND ADOPT THE WELL DEVELOPED PROCEDURES FOR INSTRUMENTAL MICRO ANALYSIS. THE FOLLOWING DEVELOPMENTS CAN BE CONSIDERED AND INCORPORATED IN BREATH ALCOHOL ANALYSIS IN THE FIELD AS SOON AS POSSIBLE.

# DEVELOPMENT OF PROPER COMPOSITE AND MATRIX MATCHED CONTROL SAMPLES AND PROTOCOLS.

- SIMPLE AQUEOUS ALCOHOL STANDARD AS THE PRIMARY AND ONLY MEANS OF ENSURING PROPER FUNCTIONING OF THE INTOXILYZERS AND ALL ITS COMPONENTS IS INSUFFICIENT.
- AQUEOUS MIXED VOLATILES IN-HOUSE SECONDARY CONTROLS CONTAINING, ETHANOL, ACETONE, ISOPROPYL ALCOHOL AND RELEVANT OTHER CHEMICALS.
- BLOOD STANDARDS CONTAINING MIXED VOLATILES WHICH ARE CERTIFIED REFERENCE MATERIAL (CRM) SHOULD BE DEVELOPED.
- STANDARDS SHOULD BE RUN BEFORE AND AFTER EACH SUBJECT TEST.

# PROFICIENCY TESTING OF EACH UNIT.

- A CENTRAL ADMINISTRATIVE UNIT HAS TO BE ESTABLISHED FOR THIS PURPOSE.
- PERIODIC DOUBLE BLIND SAMPLES SHOULD BE SENT AND THE RESULTS ANALYSED TO DETERMINE ACCURACY OF EACH UNIT.
- THE NOT-SO-WELL PERFORMING UNITS NEEDS TO FURTHER STUDIED AND THE PROBLEMS RECTIFIED.
- THE RESULTS OF THE PROFICIENCY TESTING SHOULD BE AVAILABLE ON A CENTRAL WEBSITE.



# CENTRAL UNIT TO COLLECT ALL MAINTENANCE AND QA DATA

- A CENTRAL UNIT TO COLLECT ALL THE MAINTENANCE AND QA DATA OF INTOXILYZERS, SIMULATORS AND OTHER RELEVANT INFORMATION WOULD BE HELPFUL IN ACCESSING SUCH DATA. A WEBSITE WOULD BE HELPFUL.
- DIRECT ACCESS TO THIS WOULD HELP REDUCE UNECESSARY LITIGATION AND COURT TIME IN DISCLOSURE AND RELATED ISSUES.

# RESEARCH

- IMPROVEMENTS IN CHEMICAL ANALYTICAL INSTRUMENTS HAVE BEEN MAINLY MADE BY UNIVERSITIES, ACAMEDICIANS AND RESEARCH WORKERS IN THIS FIELD.
- KNOWLEDGE AND IMPROVED PROTOCOLS CAN ONLY BE DEVELOPED BY SUCH EXTERNAL STUDIES BUT NOT WITH MANUFACTURERS INFORMATION ONLY.
- THE INTOXILYZERS USED IN THE FIELD SHOULD BE EASILY AVAILABLE TO SUCH RESERCHERS. THE GOVERNMENT SHOULD ENSURE THAT APPROVED INSTRUMENTS ARE OPENLY AVAILABLE TO SCIENTISTS.