# ENVIRONMENTAL TECHNOLOGY TESTING AND VERIFICATION PROTOCOL

FOR

## MERCURY AMALGAM REMOVAL TECHNOLOGIES

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## GLOSSARY

Accredited Laboratory: An analytical laboratory that has been assessed and approved by CAEAL, Canadian Association for Environmental Analytical Laboratories (Inc.).

Alarm Signal: An indicator manifesting an adverse condition affecting the efficiency of the mercury amalgam removal unit.

Alternative Hypothesis: The hypothesis that the technology proponent wishes to accept or verify. Also see null hypothesis.

Centrifugation: A process for separating solid particles from a suspension by using centrifugal forces to enhance particle settling.

Collecting Container: The part of the mercury amalgam removal unit intended for capturing and holding mercury amalgam waste.

Effluent: Treated water leaving a mercury amalgam removal unit.

Filtration: A process of removing suspended particles from a liquid by passage through a porous media.

Influent: Dental wastewater entering a mercury amalgam removal unit.

Maximum Filling Level: The level of the collecting container at which the efficiency of the mercury amalgam removal technology is not compromised.

Mean: A measure of the centre of a data set. It is estimated by the sum of the measurements divided by the total number of measurements constituting the sum. The mean of n observations from the random variable x is given by:

$$\text{Mean} = \sum_{i=1}^{n} x_i \Big/ n$$

Median: The median is that observation which divides the ranked observations in half. For an even number of observations the median is the average of the two middle observations. The median is equivalently known as the $50^{th}$ percentile.

Normal distribution: A specific probability distribution that is bell-shaped or symmetrical about a mean. The normal distribution has numerous attractive features that allow it to be widely used.

Null Hypothesis: The hypothesis that the technology proponent wishes to refute based upon the results of the technology testing. Also see alternative hypothesis.

Particulate Phase: A fraction of mercury particles with sizes equal to or larger than 1μm.

Performance Claim: A measurable, reproducible, verifiable and technology specific result that describes the performance of the environmental technology.

Population: A group or set of individuals, objects, or items whose properties are to be analysed, and inferences are to be made about.

Reference Laboratory: As part of the QA/QC Plan, split samples are sent to an accredited reference laboratory.

Removal Efficiency (%): Percentage of the total mercury retained by a mercury amalgam removal technology.

Sedimentation: A process whereby solid particles are allowed to separate from a suspension under natural gravitational forces.

Supernatant: Liquid above a sludge layer.

Type 1 Error: The probability of rejecting the null hypothesis when it should be accepted. This is set to 0.05 or 5% for the ETV Program. The type 1 error is conventionally designated as $\alpha$. In the context of the protocol, type 1 error would result in an incorrect technology endorsement.

Type 2 Error: The probability of accepting the null hypothesis when it should be rejected. The type 2 error is conventionally designated as $\beta$. In the context of the protocol, type 1 error would result in an incorrect technology dismissal.

Variance: A measure of the dispersion or spread of the data around the mean value. It is the sum of the squared deviations from the mean. The population variance may be estimated as:

$$\text{Variance} = \sum_{i=1}^{n} x_i^2 - \frac{\left(\sum_{i=1}^{n} x_i\right)^2}{n},$$

where n is the sample size and x is the variable for which the variance is being estimated.

The sample variance may be estimated as:

$$\text{Variance} = \frac{1}{n-1}\left[\sum_{i=1}^{n} x_i^2 - \frac{\left(\sum_{i=1}^{n} x_i\right)^2}{n}\right].$$

Verification: Verification is an independent third party evaluation of a performance claim for a product or process, when operated under specified conditions. A technology that has its performance claim confirmed by the evaluation is *verified.*

Warning Level: The level at which the collecting container should be cleaned or replaced. The warning level is always below the maximum filling level.

Warning Signal: An indicator manifesting an adverse condition likely to impair the efficiency of the mercury amalgam removal technology.

## ABBREVIATIONS

| | |
|---|---|
| CEPA | Canadian Environmental Protection Act |
| CWS | Canada-Wide Standard |
| DQOs | Data Quality Objectives |
| EC | Environment Canada |
| ETV | Environmental Technology Verification |
| ISO | International Organization for Standardization |
| MDL | Method Detection Limit |
| NSF | National Sanitation Foundation |
| O&M | Standard Operation Procedure |
| QA/QC | Quality Assurance and Quality Control |
| QAPP | Quality Assurance Project Plan |
| TCLP | Toxicity Characteristic Leaching Procedure |
| USEPA | United States Environmental Protection Agency |

# 1.0 INTRODUCTION

## 1.1 Background

Dental amalgam is a metal alloy commonly used in restorative dentistry. Mercury constitutes about 50% of the amalgam and is its most toxic component. During removal or replacement of tooth fillings, dental amalgam waste is discharged through vacuum suction systems into the wastewater stream. It was estimated that in Canada about 36 percent (800 kg/year) of amalgam waste ends up in the sewage system, accounting for more than a third of the total mercury loading into the sewage system. Another 36 percent goes to municipal garbage and landfills, where mercury has a potential to volatilize, and a smaller portion of the amalgam wastes are either recycled or stored as biochemical wastes.

The impact of the mercury emissions from dental amalgam is quite diverse. Soluble mercury can undergo bioaccumulation in the environment, posing developmental deficit risk to humans consuming contaminated fish and additional, and a mostly unquantified risk to fish-eating wildlife. Dental amalgam also contributes to airborne mercury deposition and soil contamination, in the case of the latter through application of sewage sludge for land farming.

In an effort to address the environmental hazard from dental amalgam mercury emissions, a Canada-Wide Standard on Mercury for Dental Amalgam Waste has been proposed. Based on the application of "best management practices", it has a target of a 95 percent national reduction in mercury releases from dental amalgam waste to the environment over a five-year period (by 2005). Within the Canada-Wide Standard, Best Management Practices are defined as requiring the installation of an ISO 11143 certified amalgam separator *or equivalent*[1], and appropriate management of dental amalgam waste, so as to prevent mercury from entering the environment. This standard requires the implementation of mercury amalgam removal technologies having high removal efficiencies.

This document is a general guidance document. It provides overall direction for the evaluation of dental amalgam removal technologies and details elements of the testing necessary so generated data is of sufficient quality and quantity for verification.

## 1.2 The Environment Technology Verification Program

The Environmental Technology Verification (ETV) Program was developed as a joint Environment Canada (EC) – Industry Canada initiative to support Canada's environmental industry by providing credible and independent verification of performance claims for environmental technologies. The objectives of the ETV Program are as follows:

[1] This protocol describes a test and verification methodology that is at least equivalent to ISO 11143.

- address Environment Canada priority issues by expanding its registry of verified technological options,
  - assist Canadian Environmental Protection Act (CEPA) delivery by validating pollution preventing solutions,
  - raise the "environmental bar" through recognition of innovative technologies, and
  - establish reciprocities with international ETV Programs.

Successful verification of an environmental technology performance claim(s) is accompanied by the award of a Verification Certificate to the technology proponent. This Certificate entitles the proponent to promote its technology in Canada and abroad using the ETV logo (subject to guidelines issued by ETV Canada). Completion of the program by the proponent also provides buyers of the technology with the assurance that the proponent's claim(s) regarding the technology is valid, credible and supported by quality test data and information.

The ETV Program is delivered and administered privately by ETV Canada Inc. on behalf of the Government of Canada. Environment Canada and Industry Canada are responsible for Program policy and general objectives through the license agreement. Under the provisions of this agreement, the private sector representatives provide input to Environment Canada on Program oversight and direction to ETV Canada Inc.

## 1.3 Purpose and scope of protocol

The purpose of this protocol is to facilitate the implementation of the CWS on Mercury for Dental Amalgam Waste in dental clinics across Canada by providing guidance in the assessment of mercury amalgam removal technologies. This Protocol may be utilized for amalgam removal technologies based on physical separation (ISO 11143 Types 1-4), and is also applicable to technologies that combine physical separation and adsorption of small particles and mercuric compounds. Performance is based on its ability to remove amalgam and the operation of a number design features which ensure its continued operation.

The ETV Protocol for Mercury Amalgam Removal Technologies is designed to be used by trained and qualified staff in testing agencies, and it requires the technology specific test plan, to account for specific testing requirements of a proponent's technology unit. It is not possible to foresee all possible scenarios; hence this document offers a test plan template, and also anticipates the use of best personal judgment.

**NOTE:** Some technology types combine both sedimentation and adsorption; and others utilize only sedimentation. This protocol is not designed or intended to determine lifespan of either the sedimentation or adsorption processes. It is designed to determine the ability of an amalgam removal unit to remove to >95% efficiency with 95 % confidence for the duration of the test specified, and on the standardized influent only.
A proponent has the choice (once preliminary data from verification testing is available to the test agent) as to whether to verify the technology as being able to meet the Canada -Wide Standard on Mercury for Dental Amalgam Waste only, or to also verify

technology based on the upper confidence interval around the mean of the Hg concentrations measured in the unit effluent.

## 1.4 Testing objectives

The following are the objectives of the mercury amalgam removal technology testing.

1. To test the technology, using a synthetic wastewater that is representative of wastewater from an ordinary dental facility, to establish the quantitative characteristics of that separator performance.
2. On the basis of tested performance, to determine whether the technology can achieve a mean removal efficiency of total mercury greater than 95%, expressed with 95% confidence.
3. To quantify the total mercury released into the environment.
4. As applicable, to examine the proper functioning of the following design features: warning system, alarm system for filling container, alarm system for malfunction, removal of filled collecting container, and maximum mass of filled collecting container.

It is not an objective to determine the lifespan of amalgam removal units.

### 1.4.1 Key Terms in Technology Verification

Information generated as part of the experimental program is used either to support performance claims, or to review and evaluate operating parameters with the purpose of making statements of performance evaluation.

A Performance Claim is a precise statement of performance supported by statistical analysis of the data. The Performance Claim for a mercury amalgam removal technology in the ETV program is required to be quantitative, reproducible, specific to operating conditions of the experimental program, and describes the total mercury removal performance of the technology. When these conditions are met, the Performance Claim will be eligible for examination leading to verification.

Verification is a third party examination of the performance claims, with supporting information and test data, for the purpose of validating the performance claim. The Performance Claim is verified when the verification confirms, through examination of objective evidence, that the specific performance is achieved.

Performance evaluation is supported by a systematic body of information and data on operating parameters that may impact technology's performance. Satisfying objective 3, above, provides the data for performance evaluation. Satisfying objectives 2 and 4 (and if the proponent so wishes, objective 3 also) provides the basis for the *Performance Claim* and its *verification*.

## 1.5 Overview of the Verification Process

The Environment Technology Verification of mercury amalgam removal technologies is comprised of three main stages, as follows.

### 1.5.1 Planning Stage

A proponent of a mercury amalgam removal technology initiates contact with ETV Canada and is provided with the following:

- this Protocol
- an example of a technology specific test plan
- contact information for pre-qualified test site(s)
- a copy of the verification protocol specific to mercury amalgam separators

a performance claim for amalgam removal technologies, in conformance with the CWS

The proponent selects a testing agency and provides detailed information to them and all other parties. This information is used in the development of the technology specific test plan (TSTP) which is a test plan with sufficient detail, so that someone unfamiliar with the specific technology could execute the testing. It contains but is not limited to the following: the overall management structure during testing, a description of the technology, conditions at the start of testing, frequency of sampling, analytical methods and data collection and management. An important element of the TSTP is a quality assurance plan.

### 1.5.2 Technology Testing and Reporting

At the completion of testing, a testing report is issued by the testing agency. The report notes and explains all deviations from protocol and the technology specific test plan. Source data should be included as well as summary data.

### 1.5.3 Performance Verification and Reporting

The last stage of the process is verification of the technology performance based on the results of testing and data analysis. This is done by the verification organization. At this stage, a verification report is generated.

References

Canada-Wide Standard on Mercury for Dental Amalgam Waste, Canadian Council of Ministers of the Environment, May 1, 2001.

Obenauf, P., and Skavroneck, S., Mercury Source Sector Assessment for the Greater Milwaukee Area, the Pollution Prevention Partnership and the Milwaukee Metropolitan Sewerage District, September 1997.

Ross & Associates Environmental Consulting Ltd., Draft Report for Mercury Reduction Options, Great Lakes Binational Toxic Strategy, September 1, 2000.

# 2.0 Development of the approach

The Canada-Wide Standard on Mercury for Dental Amalgam Waste requires the use of ISO 11143 certified dental amalgam separators *or equivalent* in all dental facilities. In this Chapter, a brief overview of the methodology employed in the ISO standard is presented. An alternative protocol for the verification of mercury amalgam removal technologies, developed by National Sanitation Foundation (NSF) under the United States Environmental Protection Agency (USEPA) ETV program, is considered as well.

The key concepts in developing the methodology for the Canadian ETV Protocol for Mercury Amalgam Removal Technologies are discussed, and formulation of the approach is given. This protocol requires a performance that is *at least equivalent* to ISO 11143.

## 2.1 ISO 11143 Standard

### 2.1.1 Overview

ISO 11143 Standard for Testing Efficiency of Separators is a certification standard for amalgam separators that remove mercury amalgam from a dental wastewater stream (1).

This standard considers amalgam separators based only on physical separation (i.e. centrifugation, filtration, sedimentation, or combination of these methods). Separator performance is tested using synthetic water with a prescribed amalgam particle distribution. The particle size distribution has been derived from data generated by a number of actual dental treatment centres. The synthetic water has particles in the following three size distributions: 500-3150 μm (population one), 100-500 μm (population two) and 1-100 μm (population three). Sieve analysis is used to identify particles belonging to populations one and two, while population three is quantified by X-ray absorption with sedimentation.

The ability of amalgam separators to remove amalgam is assessed for two conditions of the collecting container – empty and nearly full. Three tests are completed at each condition and an average mass removal is calculated. If the lower of the two average values is at least 95%, and a number of non-performance criteria are met, then the technology is certified. The separator efficiency is evaluated based on removal of total mercury of particle size > 1 μm.

### 2.1.2 Implementation Challenges

At the date of issue of this document, X-ray absorption with sedimentation, an analytical technique used to characterize amalgam particle size distribution for the smallest population, is not available in Canada. Without ready access to this method, the ISO 11143 standard would be difficult to execute.

ISO certification of the separators is based on a decision rule. The success or failure of a separator is decided using a numeric criterion. Since a decision is made based on two averages obtained from a small data set (i.e. three values), there is a probability that the sample size is insufficient, and a different result would be obtained should a larger data set be used. Typically, the ISO11143 data set would not suffice for a statistical verification of performance.
The literature suggests that soluble material, material smaller than 0.45 μm, may be a major contributor to the overall mass loading to the environment (2-4). During ISO testing, only the removal of particles larger than 1 μm is evaluated, and hence the ability of dental amalgam separators to capture mercuric compounds smaller than 1 μm is not considered. As a result, on one hand, some ISO 11143 certified amalgam separators may not be efficient enough to bring the mercury level of the treated dental wastewater in compliance with municipal regulations, such as Toronto Sewer Use By-law (5). In summary, the removal efficiency of separators capable of removing material smaller than 1 μm is not addressed by the ISO standard.

The amalgam particles used in ISO 11143 synthetic water range between 1 and 3150 μm in size. Dental facilities have chairside traps, installed at each dental chair, with openings of approximately 70 μm. Therefore, under typical operation conditions, amalgam separators would only have to remove particles less than 70 μm in size. The efficiency of removal of particles of the size that actually enter the typical technology unit is not measured by ISO 11143. Since average mass removal is calculated, and total mass of the larger particles would predominate, the actual removal efficiency of the separator under true operating conditions would be biased toward a higher-than-actual removal efficiency.

## 2.2 NSF Verification Protocol

### 2.2.1 Overview

NSF protocol for the verification of mercury amalgam removal technologies was developed for the purpose of verification testing of the technologies under the US ETV Program (6).

Under the guidelines of the NSF protocol, dental amalgam removal technologies are tested in operating dental facilities using a portion of the wastewater generated daily. Prior to the installation of a dental amalgam removal technology, the wastewater is characterized for a period of 5 weeks (25 working days). Dental wastewater characterization is carried out by collecting 24-hour composite samples and analyzing them for both total and soluble mercury. The NSF protocol implies that, after influent characterization, a decision on the acceptability of the dental facility as a test site is made, depending on the variability in the influent mercury concentration. However, the acceptable level of the variability is not specified.

The dental amalgam removal technology is installed after the completion of the influent wastewater characterization and acceptance of the test site. Samples of wastewater treated by the technology are collected and analyzed in a manner similar to the influent characterization. The minimum number of sampling events recommended in the NSF protocol is twenty five. In addition, residuals retained within the technology are sampled and analyzed for soluble and total mercury once a week. Based on the total mercury content in effluent and residuals, the removal efficiency of the dental amalgam removal technology is calculated weekly. The efficiency is expressed on a mass basis. The prescribed testing program yields five values for removal efficiency.

### 2.2.2 Advantages

Following are the advantages of the NSF testing protocol:

- Results obtained from the technology testing under this protocol are indicative of its performance in a real operating dental facility, reflecting transient conditions in mercury concentration, fluctuations in the operating level of the technology and changes in wastewater flow due to conditions such as start-up and shutdown times.
- Testing guidelines outlined in the NSF protocol generate a test program that can be carried out by most consulting engineers and testing agencies. Mercury analysis is available at a number of accredited laboratories across the country.
- The testing program produces five values of removal efficiency, drawn from 25 sampling events. These can be expressed as an average, obtained under known operating conditions, and a 95% confidence level.
- Both total and soluble mercury can be quantified.

The disadvantages of the NSF testing protocol:

- The test is costly in both personnel time, sample analysis processes and elapsed time (at least 10 weeks) for collection of the full set of samples.
- Since the sample stream is an actual dental wastewater, extensive precautions must be instituted to avoid bacterial contamination of the site, and health hazard to the personnel
- Cooperation of a working dental office is required to provide the test site, as well as some training of the staff in the office. Availability of a test facility cannot be guaranteed.

## 2.3 Formulation of the Approach for the Canadian ETV Protocol for Mercury Amalgam Removal Technologies

Some major considerations in developing the methodology are:

- The mercury content of dental wastewater is highly variable. Factors affecting this variability include the number of amalgam fillings removed and replaced each day, hydraulic disturbances that re-suspend mercury amalgam particles settled in

pipe lines, and the use of line cleaners which can solubilize mercury accumulated on the interior of the pipes.

- Dental wastewater is a heterogeneous stream with a broad range of amalgam particle sizes (from less than 1 to over 3100 μm). The amalgam particles settle out of the solution at various velocities depending on their size, with the larger particles settling in the first few minutes to an hour (2). For mercury analysis, only small quantities of water are required. Due to high heterogeneity of the stream, it is difficult to obtain a *representative* grab sample. Therefore a composite sample is obtained. This will need to be collected in a suitable sized vacuum (also known as suction) canisters (such as manufactured by Bemis, or Cardinal)

- Each mercury amalgam removal technology is designed to target a set of operating conditions (i.e. number of operatories, installing location, type of vacuum pump system, maximum water flow, etc.). Some technologies can be used for a wider set of operating conditions, while others have more limited application. As it is important that technology testing is conducted under operating conditions anticipated in its design, this introduces the need for a Technology Specific Test Plan to outline specific conditions for each technology testing and to note any exceptions to the standardized experimental approach for each technology.

The plan and approach for the Canadian ETV Testing and Verification Protocol for Mercury Amalgam Removal Technologies is summarized below:

- Taking into consideration the characteristics of the NSF and the ISO testing programs, elements of both are included in the experimental design of the Canadian Protocol. This includes technology testing using a synthetic wastewater having the key attributes of wastewater generated by a dental office.

- Verification of reproducible unit-to-unit performance requires data drawn from testing of replicate units. Consequently, three copies of a mercury amalgam removal technology are tested.

Wastewater used in testing is generated by amalgam removal from synthetic teeth.

This wastewater differs from wastewater generated by a dentist's office in a several respects:
Absence of Biological Material.

- Dental wastewater may contain pathogens and thus its handling requires special procedures.

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- A dentist's office routinely cleans the operatory with line cleaners. Research studies (Pederson et al 2001) have shown that many cleaners solubilize particulate mercury settled out in lines between equipment and within the storage reservoir of the separator. Disinfection is unnecessary in the absence of biological material and patients. Soluble mercury results reported by this study will underestimate the effluent soluble mercury concentrations expected during periods during or just after the addition of a biocide.
- The presence of biological material will promote the growth of biofilms on surfaces that comes into contact with it. If the removal technology is filtration based then the absence of biological material and hence significant biofilm growth could either increase or decrease amalgam capture as realized at a dental office.

Absence of both Biological Matter and Dentin

- The material generated will be plastic and amalgam. Due to the absence of both biological matter and dentin, solids collected in the chair side trap, the separator, and the vacuum/water container will have a higher mercury concentration than an operating dentist's office.

Consistency

When wastewater is generated by an operating dentist's office, wastewater composition is influenced by the number of patients seen and the treatments received. Use of a synthetic wastewater allows the class of restoration, the bur design, the amalgam type and the number of amalgams removed to be controlled. A more consistent wastewater stream should result in higher reproducibility in the results when multiple units of the same technology are tested. It also allows the performance of different technologies to be directly compared when testing is done at the same facility. From previous findings, the variability of the influent is taken as small in comparison to the effluent, and it is upon variability of the effluent that statistical analysis is focused.

**Calculation Methods**

The Canadian ETV Program verifies performance claims, supported by statistical analysis. It acknowledges that no statement can be made with 100% certainty, and thus performance claims have an associated confidence level, as defined in statistical terminology; the Program standard is 95% confidence.

The statistical analyses for technology testing presented in this chapter are presented as the Primary claim and the Optional claim

The Primary claim utilizes values for the mean or median removal efficiency, and tests hypotheses on the basis of these calculations. It is used to verify conformance to the Canada-Wide Standard for mercury (%) removal from dental wastewater
The Optional claim is the testing used to estimate at a level of 95% confidence that the true mean (or median) value of mercury concentration in the effluent is less than a specified upper limit of concentration. **The proponent is responsible for deciding whether to verify the technology based on the Primary claim only or both the Primary claim and Optional claim. If verification to meet the Optional claim is required, then the proponent's TSTP specifies an upper limit for the test.**

A decision as to whether the technology satisfies the CWS requirement for minimum total mercury removal efficiency of 95% is to be made upon completion of the program. The Canadian ETV Program verifies performance claims, statements of performance supported by statistics. It acknowledges that no statement can be made with 100% certainty, and thus performance claims have an associated degree of confidence; the Program standard is 95% confidence.

Based on the data generated during testing the first copy of the technology, the number of additional samples required should be determined. If the hypothesis (95% removal of the mercury with 95% confidence) is not statistically accepted, then the statistical power of the test is calculated. That is, if five sampling events do not generate enough statistical power, then testing of the same copy of technology is continued until adequate number of samples is obtained. This step in the testing and evaluation assures that a technology is not dismissed as non-performing, at the 95% confidence level.

ISO 11143 standard examines a number of non-performance requirements associated with the design of the amalgam separator. To ensure that the technologies tested using this Protocol are equivalent to ISO certified equipment, examination of these design functions is included in the testing program.

## References

International Organization for Standardization, International Standard for Testing Efficiency of Separators, ISO 11143:1999(E), 1999.

Cailas, M.D., et al., Physico-chemical Properties of Dental Wastewater, Water Environment Federation, 67th Annual Conference and Exposition, Chicago, Illinois, October 15-19, 1994.

EIP Associates, Mercury Amalgam Treatment Technologies for Dental Offices, Technical Memorandum, Prepared for Palo Regional Water Quality Control Plant, July 10, 2000.

Hosmer, D.W. and Lemshow, S., Logistic Regression J. Wiley and Sons, 2000

Stone, M.E., et al., Mercury Levels and Particle Size Distribution in the Dental Unit Wastewater Stream at Naval Dental Centre, Norfolk, Virginia; Presented at the International Symposium on Separation Technologies for Dental and Other Health Care Facilities, Chicago, Illinois, August 22-25, 1995.

City of Toronto, Draft Sewer Use By-law, Draft No. 6, April 2000.

NSF International, Protocol for the Verification of Mercury Amalgam Removal Technologies, April 2001.

# 3 Program Organization Structure

This chapter describes the organizational structure of the program for mercury amalgam removal technologies testing and subsequent verification. The participating bodies and their respective functions are discussed. The communication structure diagram is presented in Figure 3.1.

## 3.1 Technology Proponent

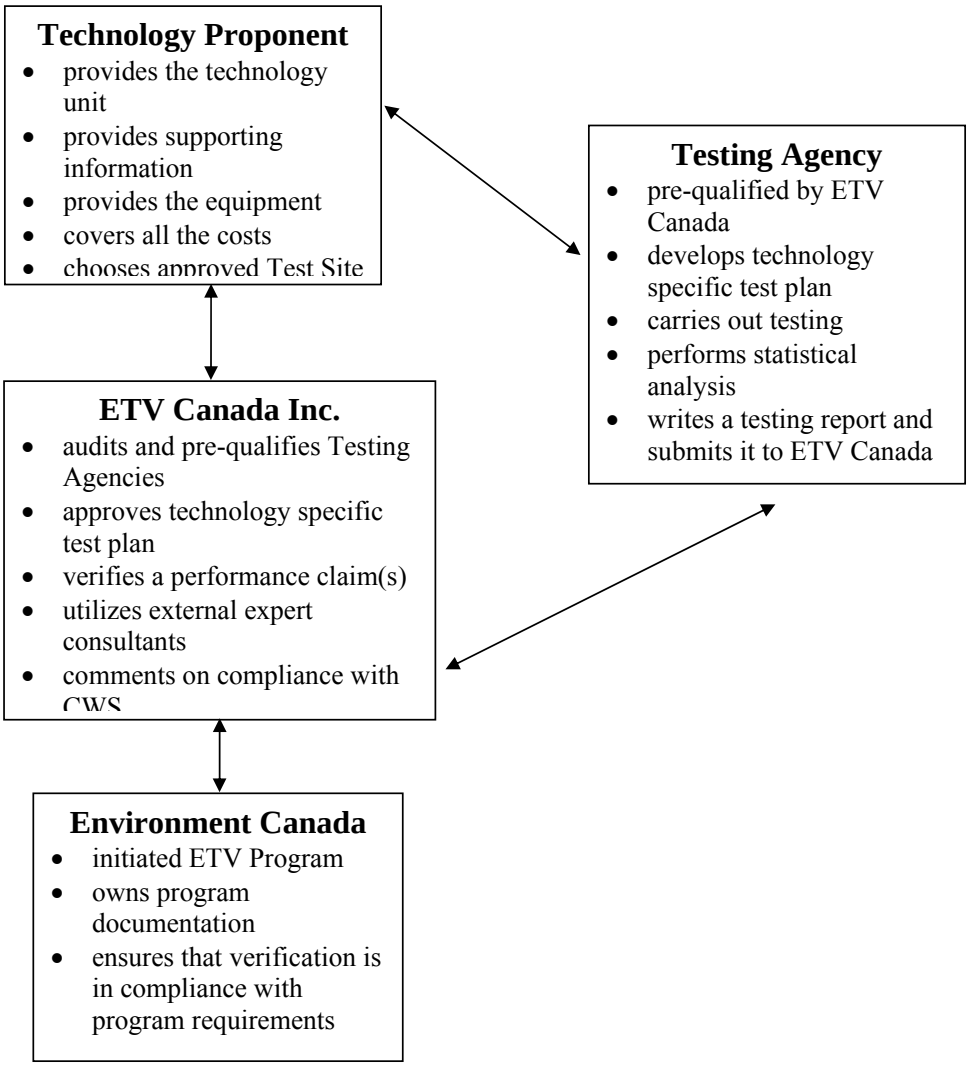
The Technology Proponent is an organization that designs and/or manufactures and sells a mercury amalgam removal technology and is seeking verification. The Technology Proponent initiates the process by contacting ETV Canada Inc.

The proponent chooses a testing agency from a list of pre-qualified candidates and enters into a contract with them. The testing agency is provided with detailed information about the technology, including supporting references and literature sources and any existing relevant data on technology performance. It also provides field-ready equipment to be tested accompanied by the complete operations and maintenance manuals, as well as personnel training documentation.

## 3.2 Testing Agency

The Testing Agency, pre-qualified by ETV Canada Inc., develops a technology specific test plan and executes it. Activities undertaken during testing include: sending samples to an accredited laboratory, receiving laboratory results and ensuring the quality assurance / quality control plan is being properly executed. At the conclusion of testing, the testing agency is responsible for preparing and sending the final report to ETV Canada Inc.

**Figure 3.1 Program Communication Structure**




## 3.3 Verification Organization

Environmental Technology Verification (ETV) Canada Inc. is a Verification Organization for the assessment of mercury amalgam removal technologies. ETV Canada periodically audits and pre-qualifies Testing Agencies. It co-ordinates a review of the TSTP prior to testing. The test report should be forwarded to ETV Canada who co-ordinates and oversees the verification process. ETV Canada Inc. in turn forwards it to a verification entity, a consultant who has been identified as having expertise in this area. The verification entity sees that the testing and the generated data meet the program

standards in terms of scientific soundness, completeness and quality. The verification entity makes a recommendation to ETV Canada.

## 3.4 Environment Canada

The ETV Program is an Environment Canada program delivered by ETV Canada Inc. under a license agreement. Environment Canada owns all program documentation, including the current ETV Protocol for Assessment of Mercury Amalgam Removal Technologies. Environment Canada is responsible for ensuring that verification work is done in compliance with program requirements.

# 4. Technologies for Verification

Dental amalgam removal technologies are devices installed downstream from the cuspidor and the chairside trap, that have the explicit purpose of removing amalgam. The mercury concentration in the treated wastewater leaving the unit should comply with appropriate federal, provincial and municipal regulations.

## 4.1 Technology Performance Objectives

The performance objectives of the mercury amalgam removal technology shall be explicitly formulated by the proponent in the statement of the technology performance claim. This statement shall include, but is not limited to, the following information:

- the trade name of the technology,
- the date of testing,
- reference to the technology specific test plan and operation and maintenance procedures,
- operating conditions under which the water quality objectives are achieved.

To conform to the Canada-Wide Standard (CWS) on Mercury for Dental Amalgam Waste, the mercury amalgam removal technology shall satisfy the following requirements:

- The removal efficiency of mercury amalgam removal technology shall be at least 95 percent of total mercury.
- The technology shall incorporate a number of features in its design that ensure safe and efficient functioning of the unit. The detailed discussion of these design functions is presented in Section 4.3.
- When applicable, the technology shall meet general requirements of the Canadian Electrical Code for medical and electrical equipment. (It is the responsibility of the verification organization to check the compliance of the technology with applicable Canadian electrical standards through review of the appropriate documentation provided by the proponent).

The experimental plan for evaluation of technology's removal efficiency and design functions is given in Chapter 6.0.

## 4.2 Classification of Mercury Amalgam Removal Technologies

For the purpose of this Protocol, the classification of mercury amalgam removal technologies is based on the type of separation process employed in the design. It should be noted that only technologies based on physical or physico-chemical separation are covered by the Protocol. The technology classification is consistent with the one used in ISO11143 and includes the following four types, plus one type not listed with ISO.

Type 1 – Centrifugal

Centrifugation is a process for separating solid particles from a suspension by using centrifugal forces to enhance particle settling. In a conventional tank or tube solid particles will settle in a liquid medium as a result of natural gravity. Centrifugal forces created during the spinning cycle of the centrifuge's rotor increase this settling rate. Therefore, centrifugation is sometimes called enhanced sedimentation. The settling rate of the solid particles is also affected by their size, shape, density, viscosity of the liquid medium and the rotor speed. In amalgam removal systems, centrifuges spin water out to the sides of the unit forcing the particulate phase to sediment on the outer surface. They are most effective for removing larger particles, typically greater than 3 μm. Strong suction of the dental unit and heat produced by the fast water movement can interfere with the performance of the amalgam removal technology based on centrifugation.

Type 2 – Sedimentation

Sedimentation is a process whereby solid particles are allowed to separate from a suspension under natural gravitational forces. This is probably the most common separation method used in mercury amalgam removal technologies. Similarly to centrifugation, the settling rate of the particles is dependent on their size, density, shape and viscosity of the liquid. Settling of the amalgam particles is favoured by slow flow rate and longer distance for the particles to travel. Logically, sedimentation units are designed to reduce the speed of the wastewater downflow with baffles or tanks. At the end of the working day, the wastewater is usually allowed to remain undisturbed in the tank for a period of time to facilitate settling. Then, the "clear" water from the top portion of the tank is passed into the sewage system, while amalgam particulate phase is trapped inside the tank. Sedimentation is also most effective for the removal of larger particles.

Type 3 – Filtration

Filtration is a process of removing suspended particles from a liquid by passage through a porous media. The filter media is the barrier that lets the liquid pass, while retaining a certain portion of the solid phase. The proportion of solid particles separated during the filtration depends on the type of the filter media used and, ultimately, on the maximum pore size of that media. The flow of the treated liquid can be driven by gravity, pressure applied upstream of the filter medium, vacuum created downstream, or centrifugal force applied across the medium. In mercury amalgam removal systems, there could be either a graded series of filters installed to raise the efficiency of the filtering process, or just a single filter (or membrane) with very small pore sizes. Separation of smaller amalgam particles, in the order of a few microns, can be achieved by means of filtration.

Type 4 – Combination of Methods 1 to 3

Amalgam removal technologies falling under Type 4 of the classification system can employ any combination of separation methods outlined above (Types 1, 2 and 3).

Type 5 - Adsorptive Media [Type 5 is not an ISO classification]

Adsorption is a physical process that relies on attraction of the mercuric compounds and very small dental amalgam particles to the adsorbent, or media, surface. The attractive force is proportional to the pore size, the pH, the particle and ion size and the concentration of the mercury and mercuric compounds. Some dental amalgam removal technologies follow a separation process, e.g. sedimentation, with an adsorption process. Typically, such technologies have a higher removal efficiency than those that utilize physical particle separation alone (Types 1 to 4)

For proponents who have technologies of types not covered by this Protocol, ETV Canada Inc. will provide an adaptation of the test and verification protocol suited to the requirements of the technology.

## 4.3 Design Functions

The CWS on Mercury for Dental Amalgam Waste requires amalgam separators that are ISO 11143 certified amalgam separators *or equivalent*. The criteria include a number of design functions that ensure safe performance of the amalgam separator, and they are mandatory for mercury amalgam removal systems. Testing of these design features shall be carried out as a part of the technology assessment process.

### 4.3.1 Warning System

A warning system shall be incorporated in the design of the mercury amalgam removal technology to indicate the degree of filling that requires cleaning or replacement of the collecting container. The described system shall include a warning signal activated at the warning level of the container filling capacity and prior to reaching its maximum level. In case that the warning system is not part of a Type 2 amalgam removal technology design, the requirement can still be met provided the manufacturer clearly states controllable maintenance and disposal procedures for proper functioning of the unit.

### 4.3.2 Alarm System for Collecting Container

An alarm system shall be incorporated in the design of the amalgam removal technology to indicate when the maximum filling level of the collecting container has been reached. The manufacturer shall specify the maximum filling level, the level at which the claimed efficiency of the equipment is not compromised. The alarm system for the collecting container shall include an alarm signal activated at the maximum filling level and disabled upon cleaning or replacement of the collecting container. In case that the alarm

system for the collecting container is not part of a Type 2 amalgam removal technology design, the requirement can still be met provided the manufacturer clearly states controllable maintenance and disposal procedures for proper functioning of the unit.

### 4.3.3 Alarm System for Malfunction

For amalgam removal technologies employing centrifugal separation (Types 1-3, if applicable), any malfunction should be accompanied by activation of an alarm system which is disabled only upon successful correction of the malfunction.

### 4.3.4 Removal of Filled Collecting Container or Filter

The design of the mercury amalgam recovery technology shall permit an easy and safe removal of the collecting container and (or) filter. There shall be no release of the contents of the container or filter into the sewage system during the removal. It shall also be possible to securely seal the collecting container, filters or unit itself so that further handling and transportation will not result in leakage.

### 4.3.5 Maximum Mass of Filled Collecting Container

The mass of the fully loaded collecting container or filters shall not exceed 15 kg to facilitate their handling.

## 4.4. Acceptability into the Program

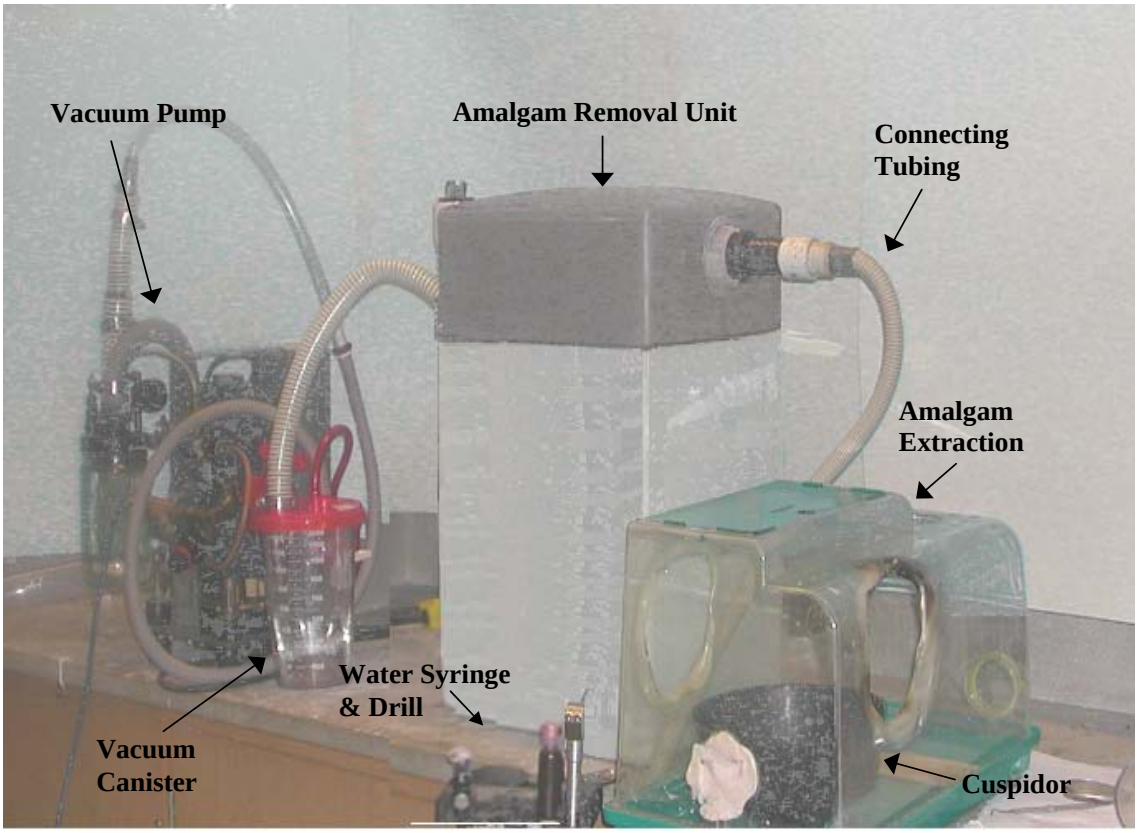
In order to be accepted into ETV Program, a mercury amalgam removal technology shall satisfy the criteria outlined in Section 4.1. There are some additional program requirements.

- The technology conforms with existing standards for health and safety of workers and public, as well as to other federal, provincial, and/or municipal regulations that may apply to a mercury amalgam removal technology. It is beyond the scope of the Program to conduct a critical validation of the technology's compliance with applicable regulations. It is the responsibility of the technology proponent to ensure that such regulations and guidelines are satisfied.
- The technology, including all components, is a full-scale commercial unit currently in production. The technology prototype or a pilot scale unit is not acceptable for verification under this protocol.
- Standard operation and maintenance procedures accompany the application of for verification.
    - QA/QC plan for the technology manufacturing shall be submitted with the TSTP, as three different units of the technology are tested for the verification of the performance claim(s).

# 5. Test Site Requirements

The proponent of the technology shall approve a testing site from one or more pre-qualified test sites. The pre-qualified test site(s) have the capacity to generate the required synthetic wastewater. It is the proponent's responsibility to ensure the testing conditions presented by the test site are compatible with the physical requirements of the technology. Figure 5.1 details the basic set up of a test site.

**Figure 5.1 Basic set up of the test site**




## 5.1 Requirements for the Test Site

The following physical conditions shall be assessed before making a selection of the test site:

- accessibility to installation of technology and sampling equipment;

- sufficient space for easy operation and maintenance of the unit, and for conducting the sampling of the dental wastewater in accordance with the test plan;
- minimal distances between the sampling point and the influent point

The compatibility of a specific technology with a test site is of major importance for overall success of the technology testing. Parameters to be considered are: room for installing the technology, the existence of the recommended type of vacuum pump system, and short lengths of pipe accessible for visual inspection.

Since testing is done with synthetic water, a test run is completed by treating the wastewater generated during the removal of 10 amalgams per day (producing one effluent sample), for a minimum of 5 days (for the first unit installed) representing roughly one week's effluent from a typical 3 chair dental operatory. Other important factors necessary are standardization of the testing process. The following topics are not intended to be all inclusive.

**The restored teeth:**

- The plastic teeth used for amalgam removal must be prepared as restorations under standard dental conditions – namely using standard dental mercury amalgam material (type recorded) and standard dental filling procedures.
- The restored teeth are weighed in batches of 10 for the influent, the amalgam is removed under standard amalgam extraction conditions, and the empty teeth weighed again.
- The teeth must be from the same batch – as 10 % of all influent samples (5 teeth out of 50 etc) are required for quality control. This group of teeth is to be composited and sent to the analytical laboratory for mercury solid analysis. Assuming an influent loading of 50 teeth for unit 1, this means 55 restored teeth are collected from the same batch, and 5 samples of removed amalgams (removed in the same drilling way as all the samples) sent composited together for mercury analysis.
- The teeth type (premolar, lower molar and upper molar) must also be recorded and consistent for all units
- The batch of plastic teeth from which amalgam is removed is to be weighed before and after amalgam extraction.
- The plastic teeth from which amalgam needs to be removed need to be weighed before amalgam extraction.

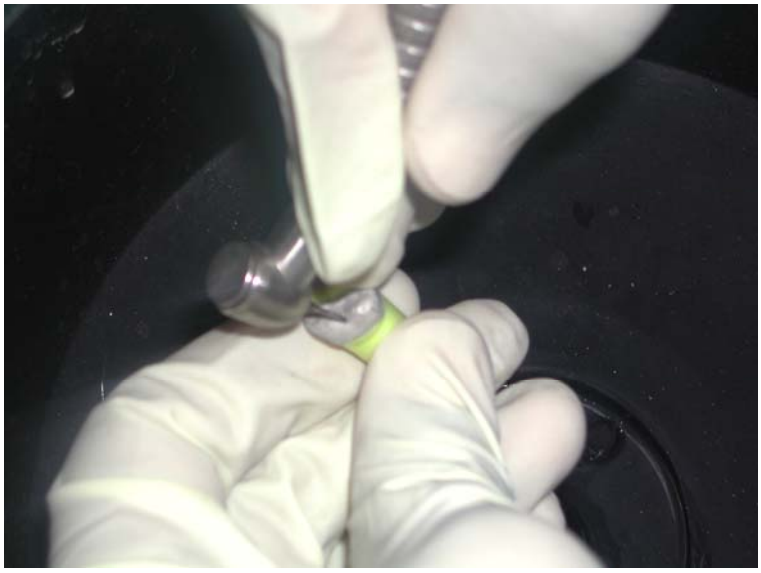
**Hand piece / Drilling equipment/air – water syringe:**

- Air turbine high speed drill (e.g. 300,000 rpm)
- New water cooled fluted carbide burs
- Water Syringe must be flushed and rinsed before use
- This equipment must be used in a way that simulates standard dental amalgam removal

- A constant amount of rinsing using the syringe should be used to help standardize influent test run loadings

Figure 5.2 highlights an extraction method involved in amalgam removal from teeth

**Figure 5.2 Extraction of amalgams from teeth**



**Tap water used in air/water syringes (used during extraction of amalgam):**

- Concentration of mercury must be measured by approved CAEAL accredited laboratory for mercury testing
- Proponent must supply information before testing begins to name other parameters in syringe water to be laboratory tested. These parameters may influence the ability of vendors technology to remove mercury as required
- Must be used in the dental water syringe in quantities and flow rate suitable for the amalgam removal technology
- Flow rate must be measured based on normal dental operating procedures
- At the end of the test run for each unit, some additional line flushing (of a measured amount of tap water – equivalent to the amount normally used in line sanitation) should be used to ensure as much of the influent reaches the unit and vacuum canister as possible.

### The amalgam restoration extraction enclosure:

- A specially designed enclosure in which amalgam removal occurs must be made, or be available from previous testing runs. This is to ensure that during the drilling process, **ALL** amalgam removed from the restoration is passed into the opening (cuspidor) of the vacuum tubing to enter the chairside trap and is not lost as spatter etc.

Figure 5.3 details an enclosure in which amalgams are removed into a cuspidor

**Figure 5.3 Example of enclosure in which extractions occur**

**The chairside trap:**

- Chairside trap must be new and clean and the mesh should be 0.7 mm
- Weighed before use
- New trap used for each new technology unit installed and at least once every 5 effluent samples taken

**Vacuum piping (connections to the amalgam removal unit)**

- Must be clean/new (to prevent mercury contamination)
- Transparent
- Must be flushed with lots of clean water before installing 2nd and 3rd amalgam removal units

**The vacuum pump:**

- Conventional high airflow volume suction (wet or dry acceptable) (Type must be recorded)

**The amalgam removal unit and connecting equipment (pipes etc):**

- Equipment to be tap water flushed before use to remove mercury
- LEAK CHECK (run tap water through the whole system)
- Amalgam removal unit set up needs to be installed and inspected by the vendor.
- A signed/dated letter from the vendor confirming the set up is ready for testing must be submitted to ETV Canada before testing commences.
- IF the unit if based on:

(1) sedimentation principles to remove amalgam, and
(2) it contains a large (litres) sedimentation tank
(3) the sedimentation tank is based on full tank lip spillover of wastewater to exit the unit sedimentation tank must be first filled with tap water (of known mercury concentration). If this is not done, for the amount of influent added in the testing period, little or no effluent will be available for collection in the vacuum canister.

**Cleaning agents/ bleach**

- Not to be used

## 5.2 Quality control blind standards

- Must be prepared at concentrations of mercury similar to those expected from the undiluted (by additional water added by wet vacuum pump) unit effluent
- Ideally should contain all the additional elements present at their respective concentrations in the solid amalgam used in the restorations (e.g. silver, copper etc)

- Must be preserved at pH 2 before shipping to amalgam removal unit test site.
- Should be stored at 4°C in clean container.

## 5.3 Requirements for Sample Acquisition and Handling

**Baseline mercury measurements**:

Of the whole set up of cuspidor, chairside trap, vacuum tubing, amalgam removal unit, to the sample canister (**before any restoration amalgams are extracted**)

**Sample collection canister:**

- Must be able to operate under dental system vacuum (e.g. vacuum/suction canisters).
- Canister may need modification of its lid to ensure vacuum is unhindered (e.g. by removal of devices/floats in a canister lid exit port designed to prevent fluids escaping into vacuum pump)
- Suitable for vacuum tubing pipe size used in apparatus test set up
- Pre cleaned and proofed for mercury by CAEAL accredited mercury testing laboratories
- Non mercury adsorbing/absorbing and non releasing of mercury (e.g. Teflon/Polypropylene) – inner polypropylene liners of vacuum canister may be satisfactory.
- Suitable sized vacuum canister volume (e.g. 3 litres) to ensure that sample is not lost into the vacuum effluent

**Figure 5.4 An example of a vacuum canister with inner "liner" used to collect effluent**


**Labelling**

- Must be suitable coding to prevent analytical laboratory knowing the concentration of mercury in the containers

**Preservative acid (to preserve effluent sample and standards to pH2):**

- Trace metals grade nitric acid

**pH meter:**

- To be calibrated with new pH 4 and pH 7 buffers

- Electrode to be cleaned (rinsed) with low mercury water after each insertion into sample containers to prevent sample to sample mercury contamination

**Water for cleaning pH meter electrode etc:**

- Must be deionized reverse osmosis grade water (i.e. very low mercury)

**Sample shipping:**

- Samples sent in the (sealed) vacuum canister
- Must be in lockable cooler containing blue ice to maintain 4°C for shipping
- As soon as possible and within maximum sample storage holding times as determined by Standard Methods etc

**Volume of water collected in each effluent sample container**

- Must be recorded by mercury analysis laboratory (as well as rinsate volume)

### 5.4 Requirements for analytical laboratory measuring mercury in samples

- CAEAL accredited for mercury analysis in solids and liquids
- Pretested by sending known blind solid amalgam samples to confirm accuracy and precision
- Pretested by sending blind mercury/silver standard solutions (prepared using NIST traceable standards and with mercury silver concentration the same as used in the restored amalgams) to confirm accuracy and precision
- Must digest the complete sample in the effluent sampling container and measure the volume of acid/deionised water rinsate and its Hg concentration
- The laboratory must show consistent and satisfactory recovery /accuracy/precision on the solid/aqueous mercury samples for it to be designated as the approved analytical laboratory

## 6. Experimental plan

### 6.1 Introduction

Chapter 6 describes the experimental plan for testing the performance of mercury amalgam removal technologies, using synthetic wastewater generated during the removal of amalgam fillings. The experimental plan standardizes, to the extent possible, testing conditions (e.g. sampling location and frequency, analysis requirements) under which mercury amalgam removal technologies are to be assessed. Differences from the standardized procedures must be noted in the TSTP.

Some additional key concepts for the experimental program are:

- The quality of the effluent water is evaluated in terms of total mercury.

Performance claims are expressed in terms of : Compliance with the Canada-Wide Standard and Total mercury removal.

- Performance is evaluated for three replicates of the technology.
- It is assumed that the technology is designed to be installed upstream of the dental facility's vacuum pump system, in a central location.

The manufacturer's operations manual should be the guideline for operations, preventative maintenance and safety. As a matter of practice, the residuals retained within the technology should be treated as a hazardous waste, since they are expected to have high concentrations of mercury.

## 6.2 Methodology Overview

Figure 6.1 provides an overview of the experimental plan for testing mercury amalgam removal technologies. Successful treatment is indicated by an average removal efficiency of total mercury greater than 95% expressed at a 95% confidence level. Testing is conducted for three replicate units of the technology using the same wastewater (the same test site). A single test consists of treating the water generated by the removal of ten restorations. With the first copy of the technology, five tests are carried out.

An installation of a new chairside trap is required prior to commencement of each test. This is done to ensure that the quality of the dental wastewater used for testing is not affected by the performance cycle of the chairside trap. Upon acceptance of the test site, the testing of the first copy of the technology begins. A letter from the proponent accepting suitability of the test and unit set up should be obtained prior to starting the testing.

**Figure 6.1 Methodology Overview**

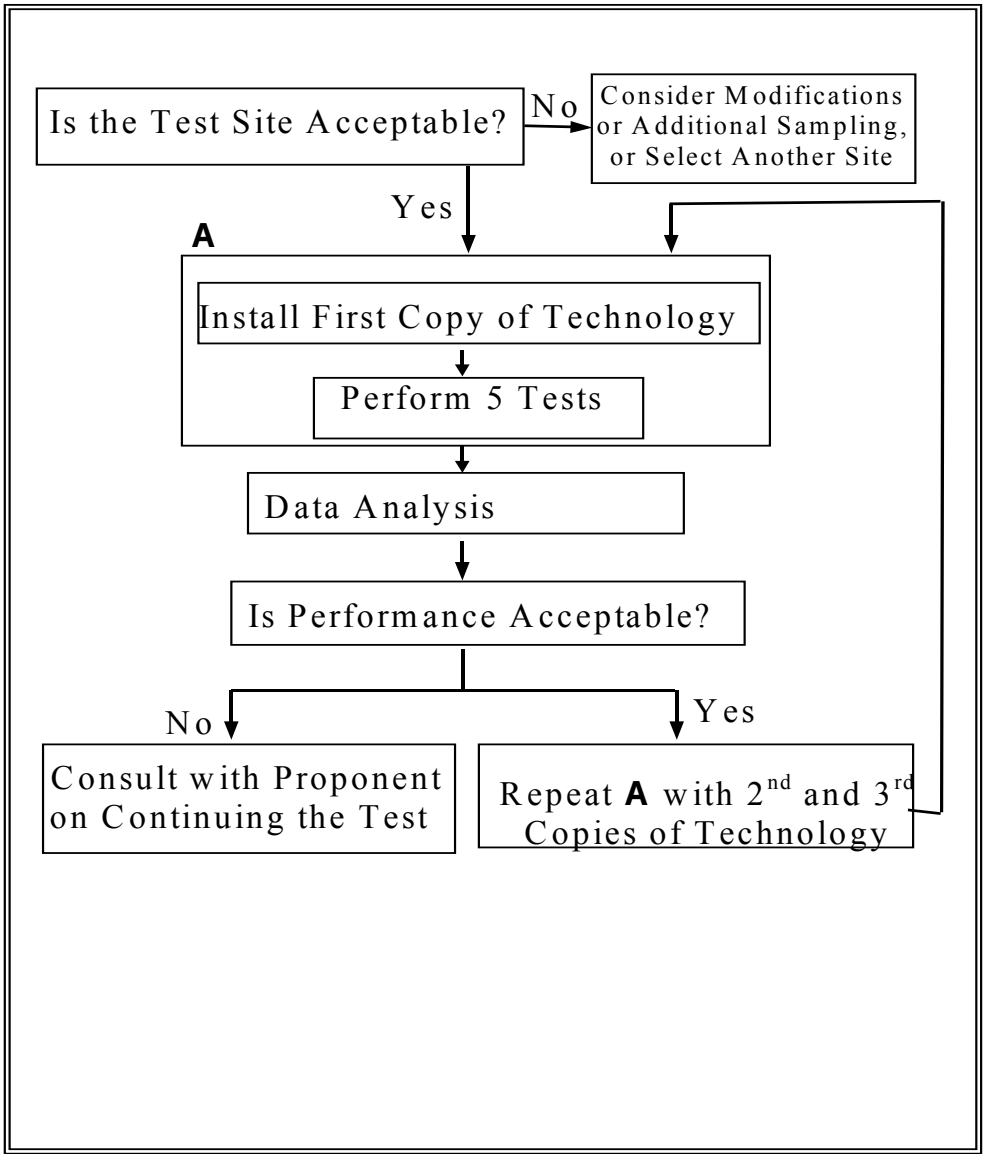
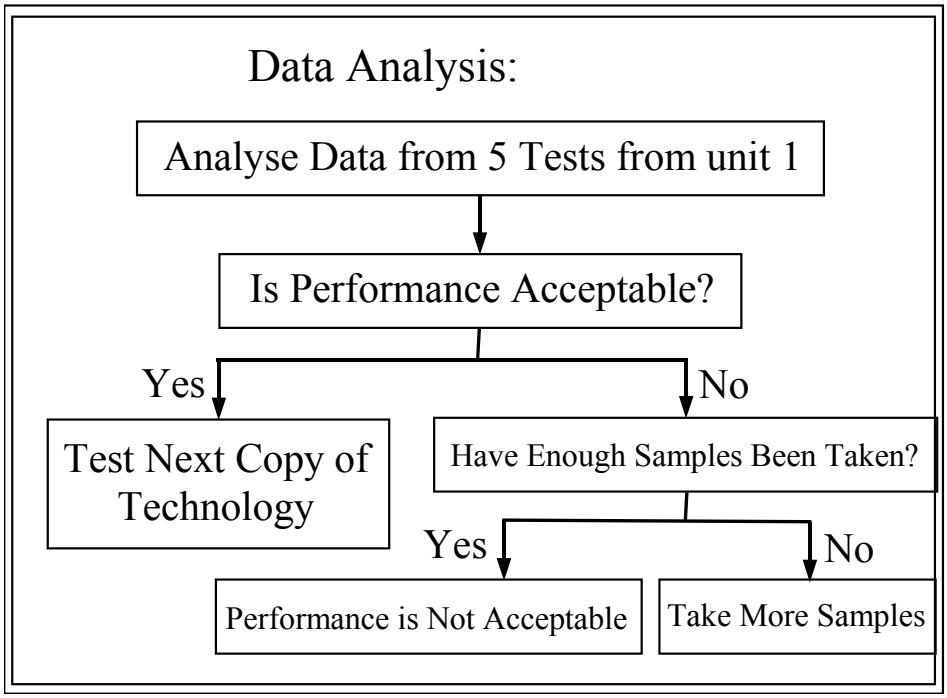


**Figure 6.2 Two Step Data Analysis**




The data generated during the five tests using the first copy undergoes a two step analysis (Figure 6.2). The number of sampling events shall be assessed. It is important to assess the number of sampling events in terms of statistical power, since the consequence of having too few samples would be poor precision for estimating the mean removal efficiency of the technology unit. This could result in a determination, incorrectly, of the unit's non-performance, simply due to insufficient statistical power. Another result could be a determination, incorrectly, that the unit is performing well.

There are two options for statistical analysis of the data, once statistical analysis confirms that sufficient data has been collected. The Primary claim verification utilizes values for the mean or median removal efficiency, and tests hypotheses on the basis of these calculations. It is used to verify conformance to the Canada-Wide Standard for mercury (%) removal from dental wastewater
The Optional claim verification is the testing used to estimate at a level of 95% confidence that the true mean (or median) value of mercury concentration in the effluent is less than a specified upper limit of concentration.

Both options apply to Figure 6.2

Therefore, before concluding testing the first copy of the technology, it is essential to make a calculation to check that an adequate number of samples have been taken. Whether or not there is an adequate number of sampling events can be determined using sample size calculations analysis described in Chapter 8. If a sufficient statistical power of the test is achieved based on five sampling events, then the testing of this unit is declared to be completed. Otherwise, the testing of the same copy of the technology continues. If there is a high probability that the first copy of technology is not performing, the feasibility of continuing the testing program with other copies shall be evaluated. If performance of the first copy is acceptable, then testing is repeated with the second and third copies of technology.

Evaluation of the performance of each replicate unit is followed by the comparison of the performances among the three units. If there is no significant variation in performance of replicate units, the technology performance is assessed and reported by pooling data from testing the replicate units. If the variability in the performance of replicate units does not allow pooling the data, then results of the testing program are reported for each replicate unit.

## 6.3 Development of the Technology Specific Test Plan

The technology specific test plan shall be developed by the testing agency with comments from the technology proponent, and approved by the verification entity. The technology specific test plan should be prepared following the general guidelines outlined in this protocol. A thorough study of the particular technology should precede the plan development, to ensure that all conditions specific to this technology are reflected in the plan.

The technology specific test plan should address the specific objectives of the testing program, detailed experimental design, including sampling and analytical procedures, as well as data analysis and presentation. In preparing the TSTP, the test agency is encouraged to reference this document in all respects, and to use the TSTP to (a) outline differences from the standard procedures, (a) explain special requirements of the proponent's technology and (c) provide detail, to accommodate any additional aspects unique to the particular technology.
.

## 6.4 Influent Characterization

Use of a synthetic wastewater reduces the requirements for influent characterization.

As the mercury content of the purchased amalgam is expected to be between 43-50%. *The mercury content of material removed from a number of synthetic teeth will be determined. The restorations will be at least nine months old and hence the curing process is essentially complete. It is expected that very little plastic will be removed during the removal of the restorations since removal is occurring under optimal conditions. At least 10% of the number of amalgams used per unit need to be removed from and be in addition to the same batch of teeth used as influent for each unit. These samples of amalgam will be sent for analysis. The laboratory results will provide a weight percentage of mercury. Note: For all amalgams sent to a laboratory for analysis*

- *A reference standard (of known mixed metal content) must be submitted too.*
- *For the amalgam samples collected, it must be ensure no teeth material is present in the sample sent. Any tooth material other than amalgam would reduce the amount of mercury measured.*
- *Amalgams chosen must come from the same batch as used for unit influent so as to be representative of the teeth processed through the amalgam removal unit*
- *The amalgams used in the testing must be of named, consistent mercury amalgam type, so as to ensure that the concentration ratio of all amalgam metals in the influent is consistent. Also as the range of mercury concentrations recommended by different manufacturers for use in amalgam preparations is variable around 50% Hg, amalgams with the highest (most challenging) mercury concentrations should be used.*
- *The amalgam samples are collected from the 'stockpile' of teeth used in testing. However all samples are removed from the teeth and composited together before analysis – then sent to the laboratory as one sample for analysis. The reason for this is that previous tests show consistency between individual amalgams mercury content.*
- *A minimum of 5 amalgams need to be removed and composited for submission to the analytical laboratory to represent (but are prepared in addition to) the 50 (minimum) amalgams used as influent for unit 1 (10%). Also for unit 2 and 3, an (additional) 10% of the number of amalgams samples used as influent for unit 2 and 3 need to be removed from the teeth and composited to form one sample for each unit.*

*During the placement of the amalgam a mercury rich layer is on the surface of the restoration. This mercury rich layer is removed during the final shaping of the amalgam. The expected mercury concentration in the amalgam will be less than the mercury concentration of the purchased amalgam due to the losses during placement. The material generated during the amalgam removal will be both amalgam and plastic material. The analysis of 10% of amalgams used per unit (prepared in addition to the number of amalgams used per unit) will provide a rough number for the amount of mercury in the amalgam after the condensed mercury layer is removed.*

The synthetic teeth can be weighed before and after restoration removal. The mass difference can be expressed as mass of mercury using the results of the analysis described above. Also, the influent tap water at the test site must be characterized for parameters

(e.g. pH or hardness) as recommended by the proponent that may affect the technology operation.

### 6.4.1 Sampling Location

The synthetic dental wastewater flows through a chairside trap before it enters the separator. Larger particulate material (i.e. material larger than the filter openings in the trap) is removed by the chairside trap. The presence of a chairside trap as part of the experimental set up mimics the equipment layout at an operating dental office. The separator will be placed at the same elevation as the operatory. The distance between the operatory and the separator should be minimized since the possibility of settling of amalgam particles in lines is a loss that is not measured or calculated.

It is assumed that the separator is installed before the vacuum pump. Proponents of the technologies, that require installation at other locations in the dental facility, shall contact the verification organisation to discuss possible alternative testing and verification procedures.

There are two types of vacuum pump systems commonly used in dental facilities. These are dry and wet vacuum pump systems shown in Figures 6.3 and 6.4 respectively. As a general guideline, the influent sampling shall take place upstream of the air-water separator in the case of the dry vacuum pump, and upstream of the vacuum filter in the case of wet vacuum pump system. In most dental offices, wet vacuum pumps are used.

**Figure 6.3 Dry Vacuum Pump System**

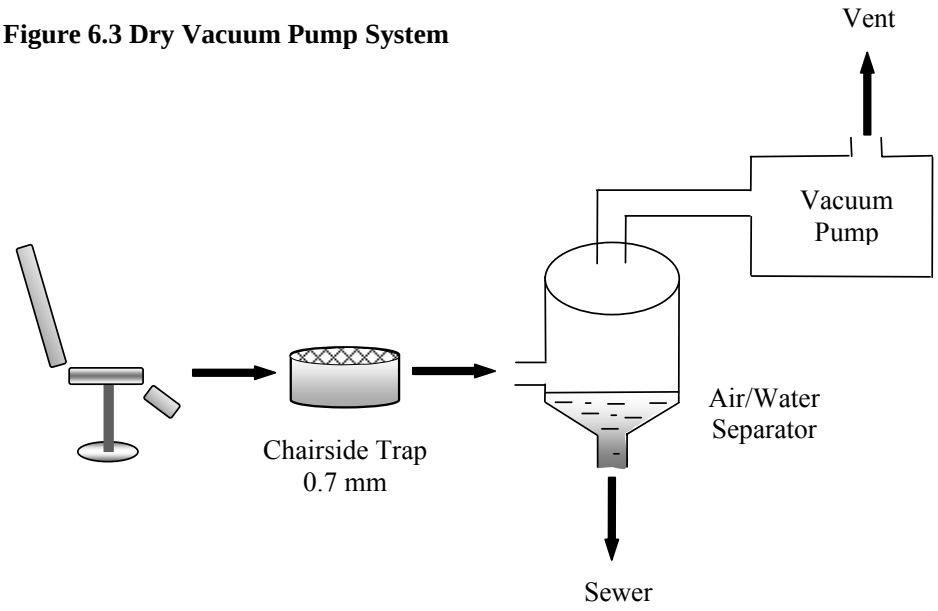
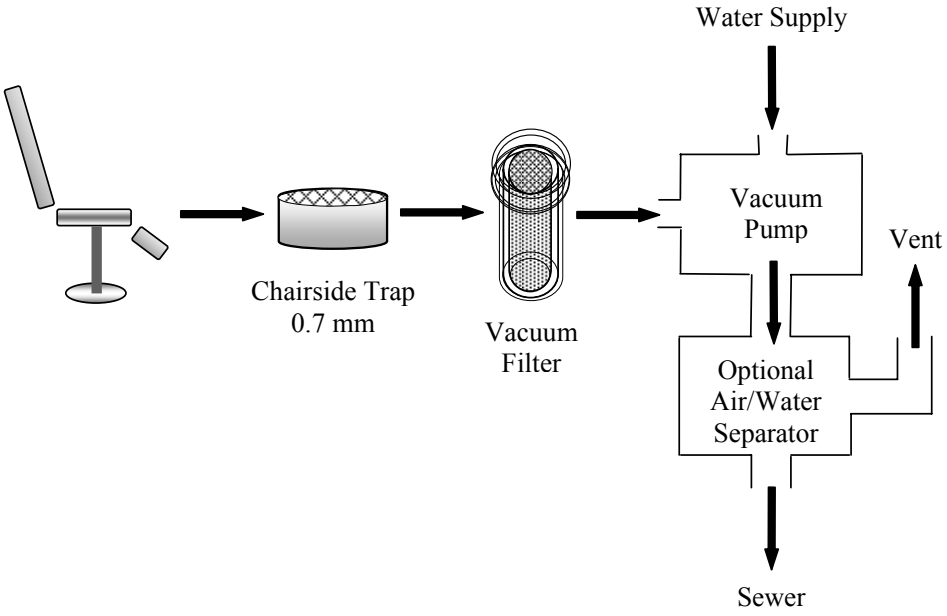


**Figure 6.4 Wet Vacuum Pump System**



The sampling container shall be capable of collecting the wastewater under vacuum. The choice of the container volume shall be made based on the expected sample volumes, allowing for some additional volume of water to be used to rinse the piping after amalgam removal – this will also be collected in the container. Details on the sampling equipment shall be presented in the technology specific test plan.

## 6.5 Commissioning

The mercury amalgam removal technology unit shall be commissioned following the work plan developed by the testing agency based on the O&M manual(s) provided by the proponent. The work plan for commissioning shall be incorporated into the technology specific test plan. The commissioning conditions, necessary modifications and observations on the technology operation shall be described in the testing report presented to the verification organization. Prior to its installation, the technology unit shall be free of any mercury compounds.

## 6.6 Technology Testing

The testing of the technology shall be conducted according to the technology specific testing plan. The main purpose of the technology testing is to generate data for it's performance evaluation and to examine proper functioning of its non-performance features. A new chairside trap should be installed before testing each replicate unit of the technology. The statistical analysis of the results starts immediately after completion of the first 5 sampling events in the testing of the first replicate copy of the technology. From this point on, the statistical analysis and technology testing become interrelated – statistical analysis becomes a guiding tool throughout the remainder of the testing program. Data obtained from each copy of the technology is used to evaluate this unit's performance. The performance of technology is evaluated by comparing and pooling (if appropriate, depending on statistical analysis of data) the results from all replicate units. Statistical analysis associated with technology testing and performance evaluation is given in Section 8.

### 6.6.1 Objectives

The following are the technology testing objectives:

- To quantify the concentrations and mass loading of total mercury in the effluent water treated by the technology
- To evaluate performance of each copy of the technology.
- To determine whether the technology achieves its performance claim under operating conditions specified by the proponent.
- To examine the proper functioning of the design features described in Section 4.3

### 6.6.2 Effluent Sampling Location

The effluent water shall be sampled as close as possible and at the same elevation as the outlet of the technology unit. The precise location of the effluent sampling shall be indicated in the technology specific test plan.

**Effluent and Residuals Sampling Method and Analysis**

Sampling equipment for effluent characterization includes sampling containers, and any additional piping for redirection of the water flow.
Sampling equipment used to collect the wastewater residuals from the collecting container of the technology shall be non-metallic or constructed in a way that prevents the residuals from being in any contact with metals. The containers also must be cleaned and proofed.

Effluent characterization involves collecting the entire wastestream from the amalgam separator. It starts with at least 5 sampling events. Depending on the statistical power additional test runs could be required. In the case of the collecting container overflowing with the effluent water, the sample shall be discarded, as it would not be suitable for the analytical testing. Note: At the end of the testing runs (but under the same influent loading experiments), at least 2 additional samples collected in the vacuum container need to be collected. These samples will not be digested nor preserved, but the volume of the liquid measured, and the whole sample filtered through a suitable filter (under 0.1 microns) to determine the solid and soluble mercury content of the effluent. This information will be useful for the proponent to determine whether the amalgam removal unit is more efficient at removing soluble mercury or particulate mercury amalgam.

From each test, after the amalgam removal unit effluent has been measured (volume and total mercury concentration), the inside of the collecting container shall be rinsed using distilled or deionized mercury free water, scraped for any adhering solid particles and rinsed again. The volume of water used during the entire rinsing shall be measured. The dilution of the sample with the rinse water shall be accounted for during the analysis. The empty sampling container shall be further rinsed with a 1% solution of nitric acid and, then, with the distilled or deionized mercury free water before being used for the next sampling event. The rinsing solution volumes **must** be recorded. The rinsates should be collected in one container to minimize dilution errors.

Table 6.1 details all the main samples to be taken during the testing process.

**Table 6.1 Sample analysis required for testing**

| | **ANALYSIS** | | | | |
|---|---|---|---|---|---|
| | **Test site analysis** pH: confirm to <pH2 after preservation | **Approved CAEAL accredited (Hg) laboratory analysis** | | | |
| | | **Mercury concentration of solid amalgams (Mercury Amalgam used in influent)** | **Proofing (mercury content after cleaning) (ppb)** | **Total Mercury concentration (ppb)** | **Other measurements** |
| **SAMPLE COMES FROM:** | | | | | |
| **PRETEST ANALYSIS:** | | | | | |
| **All new vacuum canisters (liners) to be used in the testing** | | | **After (acid/deionized water) cleaning at approved CAEAL accredited laboratory** | | |
| **Baseline mercury loading** | All samples (i.e. syringe water, and effluent | | | (a) Flushed (syringe) water | |

| | | | | | |
|---|---|---|---|---|---|
| | collected in vacuum container BEFORE ANY AMALGAM REMOVALS)<br><br>and<br><br>Measure syringe flow rate | | | and<br><br>(b) Effluent from running of whole system without amalgam removal (collected in vacuum canister) and after flushing lines with tap water | |
| **DURING TEST ANALYSIS:** | | | | | |
| **UNIT 1**<br><br>**Effluent collection vacuum canisters after sample collection (1 canister per 10 amalgams collected)** | All samples | 10 % of the number of mercury amalgam removals samples<br><br>(e.g. if 50 amalgam removals per unit– five additional solid amalgams (no tooth) need to be composited and sent to laboratory)<br><br>. | | Every effluent sample collected in vacuum canister | VOLUME (ml) COLLECTED in Every effluent sample in vacuum canister |
| **QC Samples for Unit 1 tests** | All samples | An additional mercury amalgam reference standard needs to be submitted to analytical laboratory | | 10% of all samples sent (blind standard and blank) | |
| **UNIT 2**<br><br>**Effluent collection vacuum canisters after sample collection (1** | All samples | 10 % of the number of mercury amalgam removals samples<br><br>(e.g. if 50 amalgam removal per unit– five additional | | Every effluent sample collected in vacuum canister | VOLUME (ml) COLLECTED in Every effluent sample in vacuum canister |

| | | | | | |
|---|---|---|---|---|---|
| **canister per 10 amalgams collected)** | | solid amalgams (no tooth) need to be composited and sent to analytical laboratory) | | | |
| **QC Samples for Unit 2 tests** | All samples | An additional mercury amalgam reference standard needs to be submitted to analytical laboratory | | 10% of all samples sent (blind standard and blank) | |
| **UNIT 3**<br><br>**Effluent collection vacuum canisters after sample collection (1 canister per 10 amalgams collected)** | All samples | 10 % of the number of mercury amalgam removals samples<br><br>(e.g. if 50 amalgam removal per unit– five additional solid amalgams (no tooth) need to be composited and sent to analytical laboratory) | | Every effluent sample collected in vacuum canister | VOLUME (ml) COLLECTED in Every effluent sample in vacuum canister |
| **QC Samples for Unit 3 tests** | All samples | An additional mercury amalgam reference standard needs to be submitted to analytical laboratory | | 10% of all samples sent (blind standard and blank) | |

NOTE: ALL SAMPLES SENT TO APPROVED CAEAL ACCREDITED ANALYTICAL LABORATORY MUST BE SENT UNDER **CHAIN OF CUSTODY**

The methods used for sample collection, preservation, storage, as well as analytical procedures and procedures for field and laboratory QA/QC shall be USEPA Methods (1), Standard Methods (2), or methods previously specified by ETV Canada. These methods and procedures shall also be indicated in the technology specific test plan.

Operations and Maintenance Performance

During technology testing, operations and maintenance performance of each unit shall be monitored and observations shall be presented in the testing report. This involves monitoring various qualitative and quantitative O&M performance indicators. Examples of quantitative O&M performance indicators are given in the outline on the technology specific test plan example (Appendix A). Qualitative O&M performance indicators may include parameters such as ease of operation and effect of the technology on the operation of the vacuum system. The O&M performance indicators to be monitored shall be identified by the testing agency with the input from the proponent.

### 6.6.3 Testing of Technology Design Functions

The proper functioning of design features mandatory for mercury amalgam removal technologies considered under this Protocol shall be examined during the technology testing.

#### 6.6.3.1 Test of Warning System

*When applicable*, the testing of the warning system shall be carried out on each mercury amalgam removal unit that was tested for efficiency. For the test of the warning system, an amalgam removal unit should be filled to 70% of the maximum filling volume with glass beads of 1 mm diameter, and then just slightly below the warning level with glass beads having a maximum diameter of 0.3 mm. The filling of the unit is continued until an alarm signal is activated.

*6.6.3.2 Test of Alarm System for Collecting Container*

*When applicable*, the testing of the alarm system for the filling container shall be carried out following the testing of the warning system on the same mercury amalgam removal unit. The amalgam removal unit should be filled to 70% of the maximum filling volume with glass beads of 1 mm diameter, and then filling should be continued over the warning level and just below the maximum filling level, with glass beads having a maximum diameter of 0.3 mm. The filling of the unit is continued until an alarm signal is activated. At this point, the collecting container and (or) filter is to be removed according to the manufacturer's instructions, and the timely deactivation of the signal is checked.

*6.6.3.3 Test of Alarm System for Malfunction for Type 1 technology*

For amalgam removal technologies of Types 1 and 4 (if Type 4 includes centrifugal separation), the following tests of the alarm system for malfunction shall be conducted:
Stop or hinder the centrifuge rotation by blocking the centrifugal drive. Note whether an alarm signal is activated.

Upon turning the drive supply off, note whether an alarm signal is activated.

*6.6.3.4 Removal of Filled Collecting Container*

Following the manufacturer's instructions, remove the full collecting container and check for any noticeable spills of either liquid or collected material in the areas adjacent to the collecting container and amalgam removal unit.

*6.6.3.5 Maximum Mass of Filled Collecting Container*

Weigh the full collecting container or filters to an accuracy of ± 2%.

## References

EF Pederson, ME Stone, JC Ragain, RA Auxer, RS Karaway and SL Davis (2001) Mercury solubilization by dental line cleaners. J Dent Res. 80

United States Environmental Protection Agency, Methods and Guidance for Analysis of Water, EPA 821-C-99-008, Office of Water, Washington, DC, 1999.

American Public Health Association, Standard Methods for the Examination of Water and Wastewater, 20th Edition, 1015 Fifteenth Street, NW Washington, DC 20005-2605, 1998.

## 7.0 Quality control

The Quality Control (QC) program is implemented wherever samples are taken for analysis. QC is a set of activities designed to ascertain data quality and specific samples such as blanks and standards used to monitor quality and uncertainty in the data. QC is an activity carried out through specific instructions to the test agency. This is in addition to and a separate activity from any calibration or QC samples carried out by the analytical laboratories.

A total of 10% of the analytical stream is used for various QC samples. For every 10 analytical samples of any type (treated effluents), an average of one appropriate QC sample is scheduled. Measurement uncertainty is the dispersion of values that could be reasonably attributed to the analyte and can be calculated from the QC samples.

### 7.1 Precision

Precision is the degree of mutual agreement among individual measurements. Split, duplicate and replicate testing demonstrates precision of sampling, analysis and technology deployment. Precision can include different levels of uncertainty sources arising from:

- analysis in the lab
- differences between replicate technologies

Replicate technologies consist of two or more "identical" technologies deployed on the same type of influent stream of amalgam.

### 7.2 Accuracy

Accuracy is the difference between a sample result and a true or reference value. Control standards, blanks and reference materials demonstrate accuracy of results. Accuracy or recovery can be affected by many things including:

- Blank contamination from sampling or lab activities
- Differences in calibration standards
- Method or matrix recovery issues

Field blanks are reagent pure water known to contain no analyte. Field blanks are run as 10% of the sample queue.

Field Control Standards are analytical standards prepared independently of the calibration standard and run as unknowns. Field Control Standards are run as 10% of the sample queue.

A summary of QC samples is shown in Table 7.1. Spiked samples will generally not be done as the sample handling required may cause problems.

**Table 7.1 Summary of QC samples used**

| QC sample type | Frequency |
|---|---|
| Field Blank | 10% |
| Field Control standard | 10% |
| Replicated technology | As specified in TSTP |

The choice of the analytical procedures shall permit quantification of the most measurements above the method detection limit (MDL). The other data quality objectives shall ensure that data variability or bias due to sampling and analysis error is small in relation to the amalgam removal effect(s) that is of interest.

## 7.3 Sampling and Sample Tracking Procedures

The sampling method shall be explicitly described within the context of the experimental design, including sampling equipment, location and frequency, holding and settling times, storage/transport conditions, etc. Reference may be made to Standard Operating Procedures (SOPs) or sampling manuals where sampling methods are described.

Sample tracking procedures, which consist of labeling samples, recording them clearly in log books, filling out sample submission or chain-of-custody forms and maintaining computerized sample tracking systems, shall also be outlined in the QAPP. Log books must be supplied to ETV Canada.

## 7.4 Analytical Procedures and QA/QC

The analytical methods to be used for mercury analysis (or any other analyses required) shall be identified by reference to appropriate methods manuals and SOPs. Laboratories shall have internal SOPs that are available for inspection.

Laboratories shall also have an internal QA/QC system documented in SOPs. It shall include, for example, analyst training and qualification systems, sample tracking and data management systems, internal performance audits, control charts for analytical precision and spike recovery, frequent instrument calibration checks, and reagent blank checks concurrent with each batch of samples analyzed.

Standard Method 1020 (American Public Health Association) outlines appropriate QA/QC activities for laboratories. Standard Method 1030 describes specific QC checks that shall be performed.

Laboratories shall also be able to demonstrate successful participation in external interlaboratory studies for the analytes of interest to the project and shall be accredited by CAEAL (Canadian Association for Environmental Analytical Laboratories (Inc.)) for these analytes.

In the context of the technology testing program, some checks on technology operation can be appropriate, besides checks on the analytical system. Appropriate daily and weekly QA/QC checks on technology operation shall be determined by the testing agency in conjunction with the technology proponent.

### 7.5 Data Validation, Reporting and Management

The data from chemical analyses shall be reviewed as it is generated; by comparison of concurrent QC sample results to Laboratory control limits. If any technology testing results are associated with QC samples that do not meet Laboratory control limits, the analyses shall be repeated, if possible, or the test results shall be assigned an appropriate data quality "flag", i.e. a remark code in the data record indicating the nature of the data quality issue. These quality remarks shall appear with the test data on all laboratory data files and reports.

The QC data reported by the laboratory shall also be reviewed against the DQOs that have been defined for the project. Senior key staff responsible for the project quality assurance shall flag any test data associated with QC data that do not meet these DQOs. These remark codes, as well as laboratory remark codes, shall appear with the data in all project data files and reports.

Data management systems shall have a standardized tabular format with fields for all pertinent information, e.g. sample name and number, collection date, laboratory number, analysis date(s), analysis results, data quality codes, etc. All QC sample results shall be readily identifiable as distinct from other sample results. Restricted access and backup procedures shall ensure the integrity of all data files. Table 7.2 is an example of the format of data spreadsheets

**Table 7.2 Example of spreadsheet for data**

| | **Data required from testing laboratory** | | | | | | **Data from approved CAEAL accredited mercury analytical laboratory** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Sample source** | Weight of restored teeth | Weight of teeth (after amalgam removal) | Weight of amalgam | Weight of chairside trap empty | Weight of chairside trap after amalgam removals | Weight of amalgams retained by chairside trap | % mercury in solid amalgam samples sent to lab<br><br>Percent amalgam in solid amalgam blind standard | Concentration of amalgam Hg (mg/L) in vacuum canister (MUST INCLUDE ACID /DEIONIZED WATER RINSATE CONC'N DATA) | Volume of effluent in vacuum canister | Concentration of blanks (Hg) | Concentration of blind standards (Hg) |
| **Unit 1** | | | | | | | | | | | |
| Test 1 (10 amalgams) | | | | | | | | | | | |
| Test 2 (10 amalgams) | | | | | | | | | | | |
| Test 3 (10 amalgams) | | | | | | | | | | | |
| Test 4 (10 amalgams) | | | | | | | | | | | |
| Test 5 (10 | | | | | | | | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| amalgams) | | | | | | | | | | | |
| **Unit 2** | | | | | | | | | | | |
| Test 1 (10 amalgams) | | | | | | | | | | | |
| Test 2 (10 amalgams) | | | | | | | | | | | |
| Test 3 (10 amalgams) | | | | | | | | | | | |
| Test 4 (10 amalgams) | | | | | | | | | | | |
| Test 5 (10 amalgams) | | | | | | | | | | | |
| **Unit 3** | | | | | | | | | | | |
| Test 1 (10 amalgams) | | | | | | | | | | | |
| Test 2 (10 amalgams) | | | | | | | | | | | |
| Test 3 (10 amalgams) | | | | | | | | | | | |
| Test 4 (10 amalgams) | | | | | | | | | | | |
| Test 5 (10 | | | | | | | | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| amalgams) | | | | | | | | | | | |
| **Testing Agent: Print name with signature and date on completed form** | | | | | | | | **Chain of custody forms must be completed for all shipping to laboratory** | | | |

Note: This is an example spreadsheet: The amount of tests per unit will depend on the performance of the unit

| **Additional required data** | **Value** |
|---|---|
| Flow rate from water syringe | |
| Baseline mercury concentration | |
| Analysis of influent water for other parameters requested to be tested by the proponent *(specify parameters)* | |
| Other *(describe)* | |

### 7.6 Data Quality Assessment and Corrective Actions

Senior key staff responsible for the project quality assurance shall review the project database after completion of the test of Unit 1, to assess the degree to which DQOs are being achieved. This can be expressed as a percent of samples meeting DQOs. In case any trends toward non-compliance with DQOs emerge, corrective actions shall be taken in accordance with the Corrective Action Plan.

Corrective action planning is the responsibility of the Project Manager from the testing agency, assisted by Quality Assurance staff. The Corrective Action Plan shall outline options for problem investigation and correction. Investigation is a necessary first step to identify the probable cause of a quality problem. A probable cause must be identified before specific actions can be taken to solve the problem. Options for investigative and corrective action are provided in Table 7.3.

**Table 7.3: Options for Investigative and Corrective Actions**

| Problem Nature | Investigative and Corrective Actions |
|---|---|
| Blank Too High | Investigate sources of contamination.<br>Replace contaminated lots of bottles or reagents. |
| Poor Analytical Precision | Investigate analyst technique.<br>Correct analyst technique if appropriate. |
| Poor Total Precision | Investigate sampler and analyst technique.<br>Correct sampler or analyst technique if appropriate. |
| Recovery Low or High | Verify continuing calibration.<br>Analyze for possible interfering substances.<br>Investigate analyst technique.<br>Correct analyst technique if appropriate. |
| Calibration Check Fails | Repeat check with new check standard.<br>If failure confirmed, recalibrate instrument.<br>If not, switch to new check standard. |

### 7.7 Quality Assurance Reporting

The Data Quality Assessments and any Corrective Actions taken shall be summarized in Quality Assurance Reports. This information needs to be in the laboratory notebook supplied to ETV Canada at the end of testing. These reports are usually prepared by the project QA Officer and

submitted to the Project Manager. They serve as a record of any data quality issues and corrective actions taken, which may be useful in later data interpretation. They also demonstrate the degree of data quality associated with the project.

All data and other raw material shall be provided in the appendix.

## 8.0 Data Analysis, Verification and Reporting

In review, a basic reminder of the data analysis is that it is composed of 2 sections, one for the Primary Claim and the other for the Optional claim:

**Primary Claim:**

- For one unit estimate the mass of Hg entering unit.
- For the same unit estimate the mass of Hg lost.
- Calculate whether the technology can remove more than 95% Hg. If yes, what sample sizes are needed? Is the requisite sample size prohibitively expensive? If yes, stop, if no continue
- For each of the remaining two units estimate mass of Hg entering unit.
- For each of the remaining two units estimate mass of Hg lost.
- Generate 95% CL for mean or median mass of Hg lost (might be three of these or one depending on whether data can be combined.)
- Multiply mass of Hg entering unit by 0.05. Is the UCL mean or median mass of Hg lost less than this value. If yes, technology can with 95% confidence meet the Canada-Wide Standard on mercury from dental amalgam wastes.

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**Optional Claim:**

- Measure concentration of effluent Hg for three units.
- Combine data if possible.
- Generate 95% CL for mean or median effluent Hg concentration (might be three of these or one depending on whether data can be combined.)
- Is the UCL mean or median effluent Hg concentration less than the desired (e.g. regulatory) value. If yes, the technology can with 95% confidence meet the desired value.

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The data analysis is linked to the methodology of the experimental design outlined in Section 6.2. It is important to reread Section 6.2 and 6.4 to become familiarised with how the data points are obtained. In this chapter the description of statistical methods and guidance on their use for data analysis are presented. The chapter provides the rationale, supplementary equations and tables for use of the statistical methods. The reporting requirements are discussed at the end of the chapter:

1. for the testing report to be prepared by the testing agency
2. for the verification report to be prepared by the Verification Entity

The technology proponent who enters the technology test and verification program could be primarily interested in showing compliance with the Canada-Wide Standard (CWS), but also may have interest in showing compliance with a pre-determined value of total mercury in the discharge from the technology unit. Upon completion of the technology test, the data exists for

both purposes. Two different streams of data analysis are required, both of which are described here. The two potential options for performance verification are:

- PRIMARY CLAIM - The technology meets the Canada-Wide Standard, re percentage mercury removal
- OPTIONAL CLAIM - The technology discharges a total mercury concentration that is less than a pre-determined value.

The test data must be reviewed and analyzed for the PRIMARY CLAIM. If the proponent chooses to add the OPTIONAL CLAIM, then the proponent is requested to supply a pre-determined mercury concentration as the initial test-goal for the data review and analysis

**The proponent is responsible for deciding whether to verify the technology based on the Primary Claim only or both Primary and Optional Claims.**

## 8.1 Statistical Data Analysis – Hypothesis Testing

The Canadian ETV program employs statistical analysis for verification of performance claims by technology proponents. Performance evaluation of technologies is largely based on the verification of technology testing results with the use of hypothesis testing of proponent claims. Hypothesis testing is a statistical technique used to objectively select one conclusion from two possible choices – null hypothesis and alternative hypothesis at a prespecified level of confidence.

When sampling from a population, it is not possible to prove that a performance claim or hypothesis is true. It is possible to disprove (null) hypotheses and then accept an alternative hypothesis. The alternate hypothesis is the central statement of the performance claim. Therefore, a performance claim must be posed in such a way that the process of disproving it verifies the claim. The Null Hypothesis ($H_o$) is the hypothesis being disproved, and Alternative Hypothesis ($H_a$) is the hypothesis being accepted, if sufficient evidence exists to reject the null hypothesis.

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The underlying assumption for the hypothesis relating to the mean value is that the distribution of data is normal. Prior to testing the hypotheses, it is therefore required to establish the normality of the observations. Depending on the normality of the data, or not, either the mean or the median removal efficiency shall be used to test the hypotheses on the technology performance. Similarly for the Optional Perfomance claim, the mean or median concentration of effluent mercury shall be used to test the two hypotheses.

Note:
(1) Where possible for all the tests, it is important to ensure that all the observations are independent of another. However, creating such testing conditions may be prohibitively expensive.
(2) For some larger (multi litre volume) sedimentation based technologies, unit effluent is only emitted once the sedimentation chamber is full. For testing with such systems, to produce effluent, the large sedimentation chamber in the unit needs to be filled with tap water before testing to allow effluent to be collected from the first influent addition. As a result of the initial

water volume of the sedimentation tank, the technology effluent concentration due to dilution will be lower than under normal operating conditions (i.e. without the added water).
(3) This Testing and Verification protocol design means that the initial technology effluent mercury concentration will not be affected by potential occlusion of the unit by biofilms etc. that may occur in a normal (amalgam in biological matrix) dental office amalgam removal unit. The effluent mercury concentration and percent mercury removal therefore needs to be seen in this context.

## 8.2 Data Analysis for the Technology Test

**PRIMARY CLAIM – Canada-Wide Standard**

The CWS requires compliance with a removal efficiency of 95% or better. The following calculation yields a value for removal efficiency.

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Efficiency Calculation

The removal efficiency (E, %) of mercury amalgam removal technology can be calculated using the following equation:

$$E = \left(1 - \frac{Hg_{eff}}{Hg}\right) * 100\%,$$

Where:

$Hg_{eff}$ = mass of total mercury in the effluent sample, Units = mg;

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$Hg$ = mass of total mercury in the influent (downstream of the chairside trap), per sample,

Deleted: m

There are five samples, and from this data the mean or median value, and its confidence interval, is calculated. Because the CWS target is 95% removal, the value of total mercury entering the amalgam removal unit is required. For comparison to the mean value, and calculation of the percentage removal, the value of total mercury mass (from the residual mercury in the effluent) $Hg_T$ as a mean of 5 effluent samples is calculated as follows:

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$Hg_T = \sum_{(I = 1 \text{ to } 5)} \{m_{t(i)}\} / 5$ where $m_{t(i)}$ is the value of the weight of effluent total residual (aqueous and solid) mercury from each of the 5 sample collection runs

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The weight of total mercury going into each sampling sequence is known, and therefore 5 values of the weight of effluent residual total mercury can be averaged. This number is calculated, and not subjected to a statistical test for confidence interval, because the variation[2] in this value will not cause a significant difference to the end calculation of percentage removal. Following standard statistical analysis procedures, the data is analysed by means of hypothesis testing to verify the claim made regarding performance of the technology.

In the case of performance claim for mercury amalgam removal technologies to meet the Canada-Wide Standard on Mercury for Dental Amalgam Waste, the null and alternative hypotheses can be formulated as follows:

*Ho: The mean or median value of total mercury is greater than $Hg_T$ X 0.05 with 95% confidence.*

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[2] In the rare situation where the removal efficiency calculated is very close to 95%, further statistical tests will be applied. – see footnote 12 too

*Ha: The mean or median value of total mercury is less than or equal to $Hg_T$ X 0.05 with 95% confidence.*

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When the null hypothesis is disproved, the alternative hypothesis can be accepted, and the performance claim is verified.

**OPTIONAL CLAIM**

In the case of performance claim for total mercury removal to meet a pre-determined concentration standard, (DV), the null and alternative hypotheses can be formulated as follows:

*Ho: The mean or median value of total mercury is greater than DV with 95% confidence.*

*Ha: The mean or median value of total mercury is less than or equal to DV with 95% confidence.*

When the null hypothesis is disproved, the alternative hypothesis can be accepted, and the performance claim is verified.

## 8.3 Statistical Analysis Worksheets (SAWs)

8.3.1 Flowcharts

| Figure | Flowchart |
|---|---|
| 8.1 | **Summary Flowchart for Primary claim and Optional claim** |
| 8.2 | **Flowchart for Primary claim** |
| 8.3 | **Optional claim data analysis flowchart** |
| 8.4 | **Combine Data flowchart** |
| 8.5 | **Test data flowsheet for single units and combined data from three units** |

8.3.2 Data analysis for performance claim

Each statistical analyses for technology testing presented in this chapter is provided as a Statistical Analysis Worksheet (SAW)

For reviewing the **Primary Claim** the testing data is used to estimate a confidence interval for the true but unknown population mean/median removal efficiency. If the upper limit (the higher value in the range) of the confidence interval, around the mean or median, percentage removal is calculated.

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Percentage removal is used for verification based on the Canada-Wide Standard for mercury (%) removal from dental wastewater. For the **Optional Claim** the testing is used to estimate, at a level of 95% confidence, that the true but unknown population mean/median is less than the proponent-specified limit.

**8.3.2.1 Statistical Analysis Worksheets[3] for the Primary and Optional Claim:**

| | SAW Number |
|---|---|
| **Assessing normality of data** | **1** |
| **Mercury Calculation For Influent And Effluent** | **2a** |
| **Calculation of a 95% Confidence Interval For a Mean** | **2b** |
| **Calculation of the median, and confidence interval for the median** | **3** |
| **Calculation of percent mercury removal** | **4** |
| **Testing Equality of 3 Means** | **5** |
| **Testing Equality of 3 Medians** | **6** |
| **Testing equality of k variances** | **7** |

**8.3.2.2 Additional Statistical Analysis Worksheets for the Optional Claim only**

| | SAW Number |
|---|---|
| **Sample Size Calculation** | **8a,b** |
| **Testing Mean is Equal to a Specified Value (Estimate a One-Sided 95% Confidence Limit For a Mean)** | **9** |
| **Testing Median is Equal to a Specified Value (Estimate a One-Sided 95% Confidence Limit For a Median)** | **10** |

[3] The SAWs provide a limited introduction to the host of statistical tools that may be used to test a performance claim. Other methods may be substituted as per the discretion of ETV Canada Inc. or as new statistical methodologies are developed. It is the responsibility of the Verification Entity to obtain approval from ETV Canada Inc. prior to using alternative procedures.

### 8.3.1 Flowcharts

**Figure 8.1 Summary Flowchart for Primary claim and Optional claim**

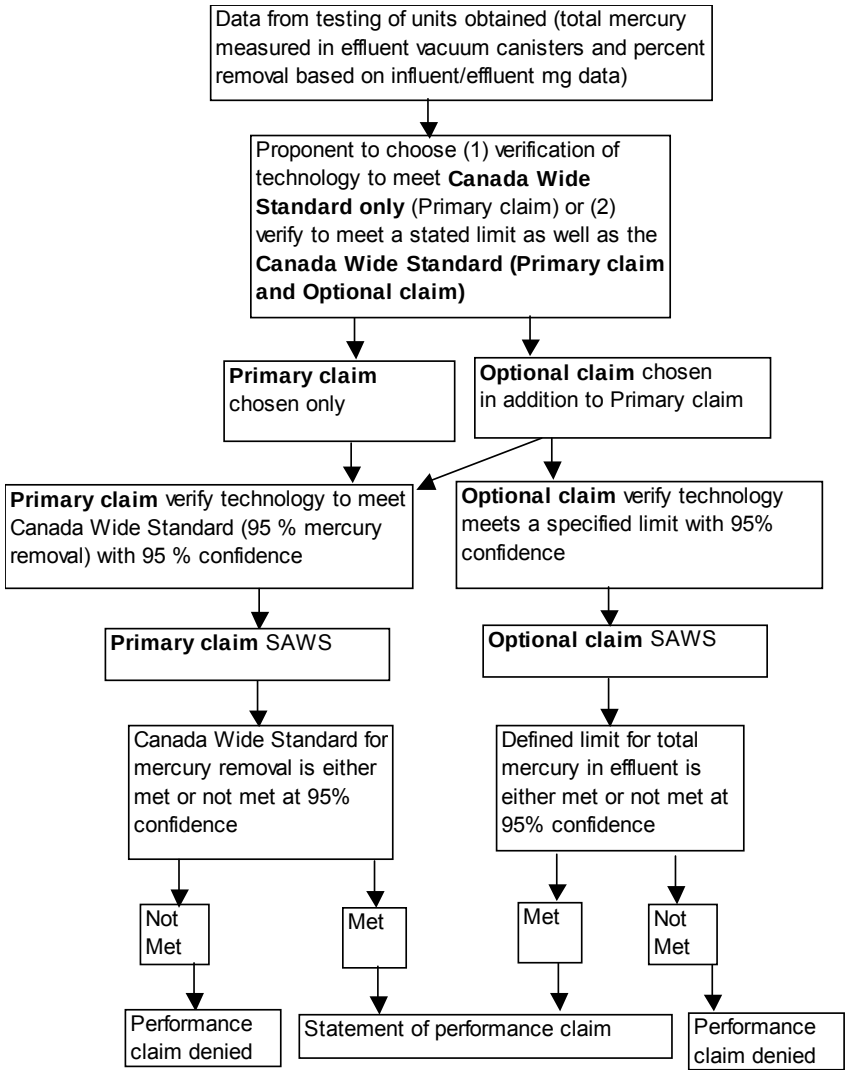


**Figure 8.2 Flowchart for Primary claim**

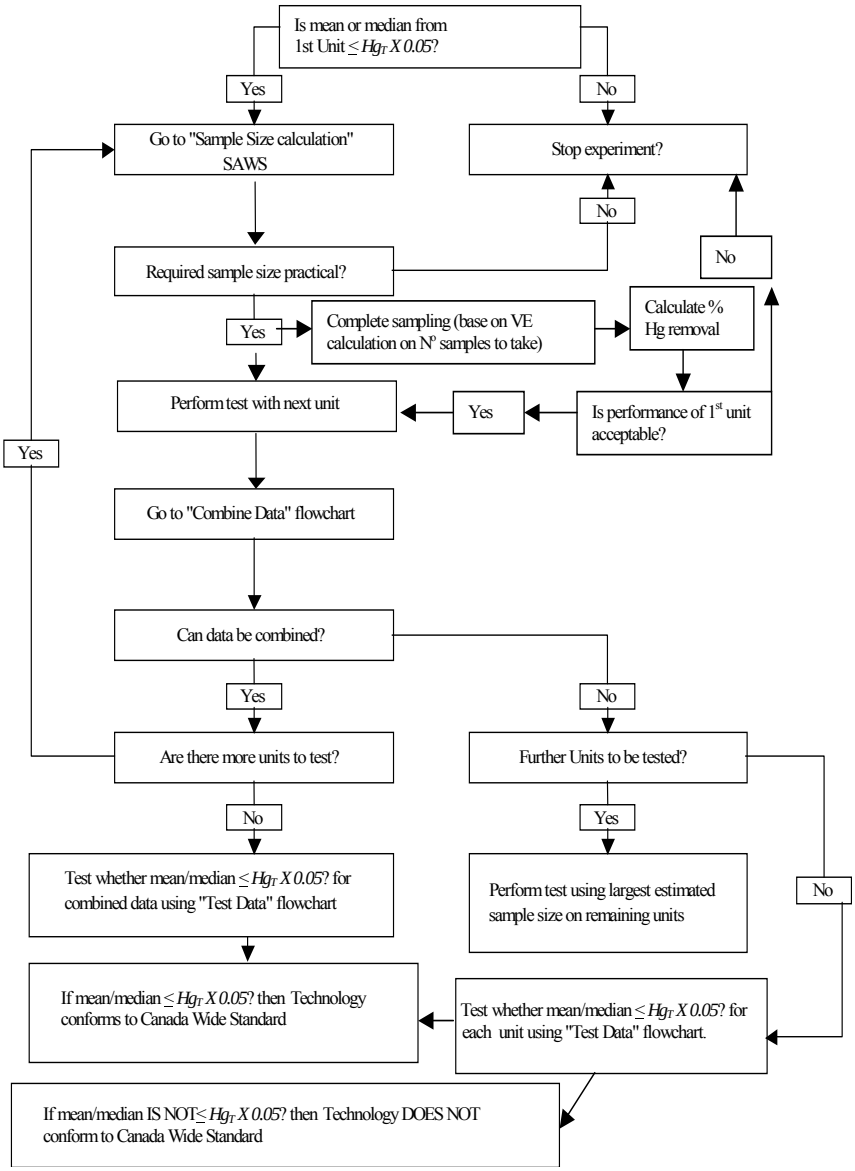


**Figure 8.3 Optional claim data analysis flowchart**

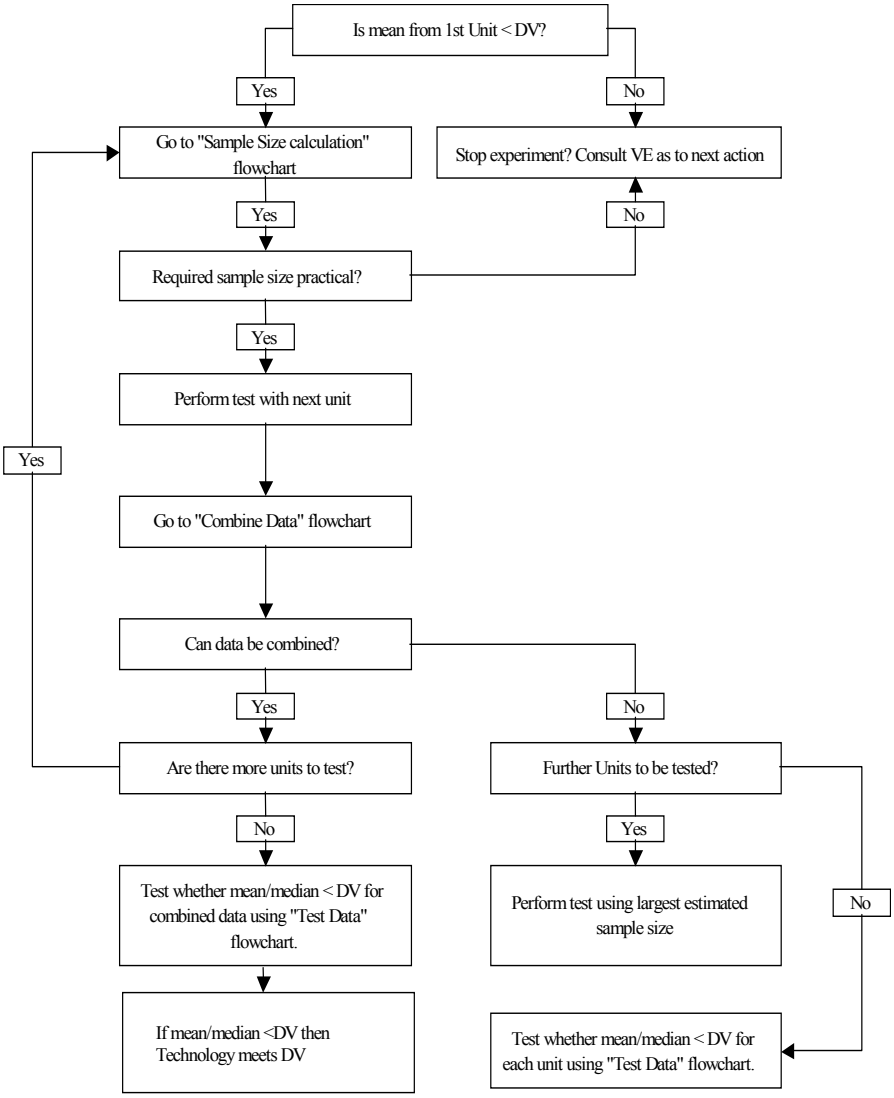


**Figure 8.4 Combine Data flowchart**

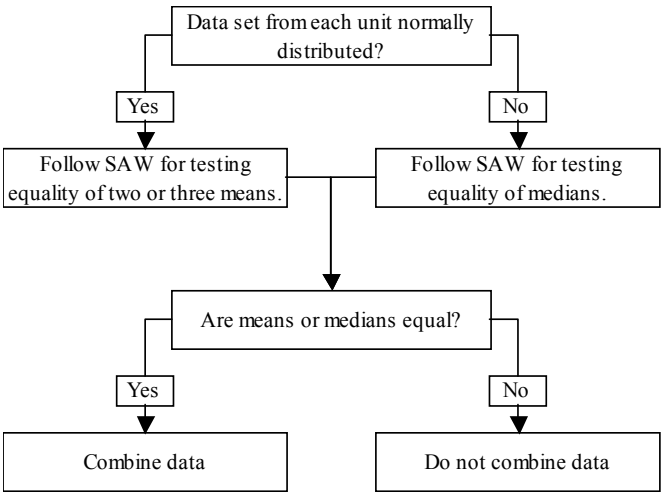
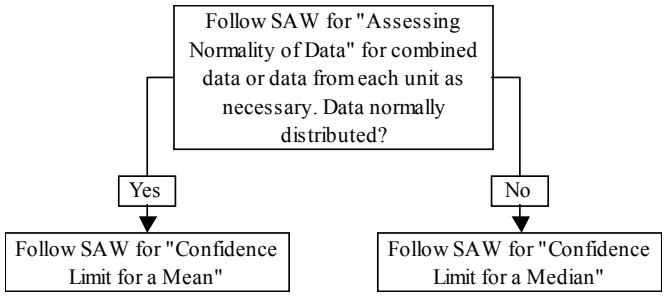


**Figure 8.5 Test data flowsheet for single units and combined data from three units**



8.3.2 Data Analysis for Performance Claim : Statistical Analysis Worksheets (SAWS)

## SAW 1 : Assessing Normality of Data

*This procedure is used to determine if the data variable is normally distributed or log-normally distributed. This is important as the assumption of normality is often invoked in subsequent calculations.*

***Assumptions:***
*The $x_i$ observations constituting the data set are independent*[4].

| **Data Description** | |
|---|---|
| Parameter: | Units: |
| Data Location | ☐ attached page |
| Filename and Location | ☐ electronic database |

| **Determining Potential Normality of Distribution** | |
|---|---|
| Data points may be any real number and the range of possible values is infinite. This is often not the case for a measured value such as a concentration, which cannot be negative. In this case it is sufficient that the majority (95%) of the points lie within 3 standard deviations[5] of the mean of the measured points. | ☐ True |
| The data points are not proportions[6], rates or frequencies. | ☐ True |
| The data points are not counts. | ☐ True |
| Is the mean approximately the same as the median?<br>median = mean = | ☐ True |
| Based on guidelines above, the sample is potentially normally distributed. | ☐ True ☐ False |
| If the sampling distribution is potentially normal, and there are more than 10 data points, prepare a normal probability plot of the raw data | |

| **Preparation of Normal Probability Plot** | |
|---|---|
| Order the data ($x_i$) from smallest to largest. Subsequent calculations use the ordered data. | |
| Sample size: | n: |

[4] A non-rigorous definition of independence is : ***Independence of data sets*** Data sets are independent of one another when the data generating process is independent from data set to data set. For example, a data set generated by a specific technology unit is independent of a data set generated by another technology unit. Note that data sets collected at different times using the same technology unit are not independent.
[5] ***Standard deviation*** is a measure of the spread of the data defined as the square root of the variance.
[6] Proportions, rates and frequencies are variously defined. We use these terms to describe a set of numbers that may take on any value between 0 and 1, inclusively

| | |
|---|---|
| Calculate "Blom" coefficients. $p_i = \frac{i - 3/8}{n + 1/4}$, for i = 1 … n. | $p_i$: unnecessary to present the n coefficients here. Attach a table or spreadsheet. |
| Convert "Blom" coefficients to $y_i$. $y_i = \sqrt{-\ln(4p_i(1-p_i))}$, for i = 1 … n. | $y_i$: unnecessary to present the n coefficients here. Attach a table or spreadsheet. |
| Calculate normal scores. $z_i = sign(p_i - 1/2) \bullet 1.238 \bullet y_i \bullet (1 + 0.0262 y_i)$, for i = 1 … n, where *sign* $(p_i\text{-}1/2)$= -1, for $(p_i\text{-}1/2)<0$, $sign(p_i\text{-}1/2)$= +1 for $(p_i\text{-}1/2)>0$, and $sign(p_i\text{-}1/2)=0$ for $(p_i\text{-}1/2)=0$. | $z_i$: unnecessary to present the n coefficients here. |
| Plot the normal score data against the ordered data. | |

$Q_1$. Do the data appear to fall on a straight line? ☐ Yes ☐ No

If yes, proceed to formal test of normality.
If no and "tails" of distribution fall off the straight-line, log-transform the data and re-plot.

$Q_2$. Do the log-transformed data appear to fall on a straight line? ☐ Yes ☐ No

If yes, proceed to formal test of normality.
If no, use a test that does not assume normality.

| **Test of Normality** | |
|---|---|
| Estimate the Test Statistic | |
| $SS_{xz} = \sum_{i=1}^{n} x_i z_i - \left[ \left( \sum_{i=1}^{n} x_i \right) \left( \sum_{i=1}^{n} z_i \right) / n \right]$ | $SS_{xz}$: |
| $SS_x = \sum_{i=1}^{n} x_i^2 - \left[ \left( \sum_{i=1}^{n} x_i \right)^2 / n \right]$ | $SS_x$: |
| $SS_z = \sum_{i=1}^{n} z_i^2 - \left[ \left( \sum_{i=1}^{n} z_i \right)^2 / n \right]$ | $SS_z$: |
| Estimate Shapiro-Francia W. $W = \frac{SS_{xz}^2}{SS_x SS_z}$ | W: |
| Apply Box-Cox Transformation | |
| u = ln(n) | u: |
| v = ln (u) | v: |
| $\hat{\mu} = -1.2725 + 1.0521(v - u)$ | $\hat{\mu}$: |
| $\hat{\sigma} = 1.0308 - 0.26758(v + 2/u)$ | $\hat{\sigma}$: |

| | |
|---|---|
| Transform W to Z′.<br>$Z' = \frac{\ln(1-W) - \hat{\mu}}{\hat{\sigma}}$ | $Z'$: |
| If $Z'$ > 1.645 we reject the null hypothesis that the data are normally distributed at the 95% level of confidence. The data are not normally distributed. | |

$Q_3$. Do the data pass a goodness of fit test[7] for normality? ☐ Yes ☐ No

If answers to questions $Q_1$ or $Q_2$ and $Q_3$ are yes, the raw (or log-transformed) data are normally distributed. The raw or log-transformed data may be used in SAWs assuming normality.

**The raw data are Normally Distributed?** ☐ Yes ☐ No
**The log-transformed data are Normally Distributed?** ☐ Yes ☐ No

You can now proceed to the next appropriate SAW.

[7] Recommended test of normality for manual calculations is the Royston modification of the Shapiro-Francia test. Users with access to statistical software are advised to use the Shapiro-Wilks test.

## Sample Calculations: SAW # 1

For Unit 1 of Mercury amalgam unit (1st 10 data points)

## Assessing Normality of Data

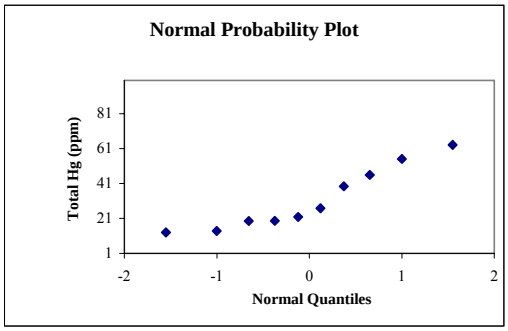
**Preparation of Normal Probability Plot and Test of Normality (Shapiro-Francia Calculations)**

User Notes: only those values required for calculations are presented below
worksheets may be printed in landscape mode

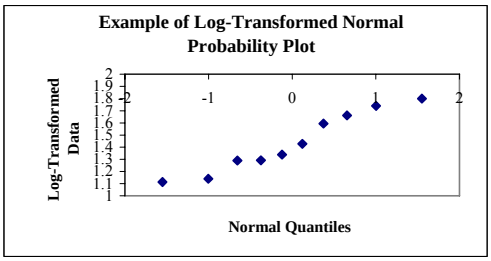
**Common Calculations**

| Index | unit 1 Total Hg (ppm) | Sorted Treatment 1 | Squared, Sorted Treatment 1 | Log-transformed, Sorted Treatment 1 | Blom Coefficient | Converted Coefficient | Normal Score | Squared Normal Scores | Cross-Products |
|---|---|---|---|---|---|---|---|---|---|
| i | x | x_i | x_i^2 | log(x_i) | p_i | y_i | z_i | z_i^2 | x_i*z_i |
| 1 | 21.8 | 13 | 169 | 1.11394 | 0.06098 | 1.21404 | -1.55079 | 2.40496 | -20.1603 |
| 2 | 19.6 | 13.8 | 190.44 | 1.13988 | 0.15854 | 0.79252 | -1.00151 | 1.00303 | -13.8209 |
| 3 | 26.8 | 19.5 | 380.25 | 1.29003 | 0.2561 | 0.52129 | -0.65418 | 0.42795 | -12.7564 |
| 4 | 13 | 19.6 | 384.16 | 1.29226 | 0.35366 | 0.29926 | -0.37339 | 0.13942 | -7.31841 |
| 5 | 39.3 | 21.8 | 475.24 | 1.33846 | 0.45122 | 0.09779 | -0.12138 | 0.01473 | -2.64607 |
| 6 | 19.5 | 26.8 | 718.24 | 1.42813 | 0.54878 | 0.09779 | 0.12138 | 0.01473 | 3.25297 |
| 7 | 55 | 39.3 | 1544.49 | 1.59439 | 0.64634 | 0.29926 | 0.37339 | 0.13942 | 14.6742 |
| 8 | 63 | 45.9 | 2106.81 | 1.66181 | 0.7439 | 0.52129 | 0.65418 | 0.42795 | 30.0267 |
| 9 | 13.8 | 55 | 3025 | 1.74036 | 0.84146 | 0.79252 | 1.00151 | 1.00303 | 55.0832 |
| 10 | 45.9 | 63 | 3969 | 1.79934 | 0.93902 | 1.21404 | 1.55079 | 2.40496 | 97.6999 |
| Sample size | n | 10 | | | | | | | |
| Mean | x.bar | 31.77 | | | | | | | |
| Median | | 24.3 | | | | | | | |
| Sum | | 317.7 | | | | | 0 | | 144.035 |
| Sum of squares | | | 12962.6 | | | | | 7.98017 | |

**$Q_1$**: Data appear to fall on a straight line.
Can proceed to Test of Normality.



**Note**: Since the answer to $Q_1$ is "Yes", log-transformation of data is not required. This chart is presented as an example of sample calculations.




**Formal Test of Normality: Shapiro-Francia Calculations**

| | | |
|---|---|---|
| Test Statistics | SSxz = | 144.035 |
| | SSx = | 2869.3 |
| | SSz = | 7.98017 |
| Shapiro-Francia | W= | 0.90604 |
| | | |
| Box-Cox Transformation | u = | 2.30259 |
| | v = | 0.83403 |
| | mu.hat = | -2.81756 |
| | sigma.hat = | 0.57521 |
| | Z.prime = | 0.78699 |

Since Z.prime is less than 1.645, we consider the data to be normally distributed.

**$Q_3$**: Data pass a goodness of fit test for normality.

**Conclusion:** Since the answers to questions **$Q_1$** and **$Q_3$** are "Yes", the raw data are normally distributed.

## SAW 2a: MERCURY CALCULATION FOR INFLUENT AND EFFLUENT:

(a) Influent Mercury Mass Per Test:

| Determining mean mercury influent | | |
|---|---|---|
| | | Units |
| Mass of 10 restored teeth (TAm) | TAm | mg |
| Mass of 10 teeth without amalgam (T) | T | mg |
| Mass of amalgam (from 10 teeth) removed by chairside trap (ChAm) | ChAm | mg |
| **Influent amalgam weight to unit (InfAm)** | InfAm = TAm - T - ChAm | mg |
| **Influent mercury to unit (InfHg)** Weight of amalgam into unit (InfAm) x % mercury content in solid amalgams analysed by analytical laboratory from batch (Hg%) | InfHg = InfAm x Hg% | mg |
| **Average influent mercury (AveInfHg)** Sum of all tests (ΣInfHg)/ number of tests (n) | AveInfHg = (ΣInfHg)/n | mg |

**No other calculation required for influent**

(b) Concentration and mass per test of effluent mercury

| Determining mean mercury effluent | | |
|---|---|---|
| | | Units |
| Concentration of mercury in 1 vacuum canister (10 amalgam removals) before rinsing vacuum canister (CanHg) | CanHg | mg/l |
| Volume of effluent collected in 1 vacuum canister (CanVol) | CanVol | ml |
| Concentration of residual mercury in emptied canister (acid rinsate and water rinse at analytical laboratory (rinsing of emptied vacuum canister)) (RinsHg) | RinsHg | mg/l |
| Volume of acid and water rinsates used to clean emptied vacuum canister (RinsVol) | RinsVol | ml |
| Total concentration of mercury in 1 vacuum canister (10 amalgam removals) (TotCanHg) | TotCanHg= [(CanHg x CanVol] + [(RinsHg x RinsVol)/Can Vol + Rins Vol] | mg/l |
| Mean effluent mercury concentration (MeEffHg) Sum of all tests ((ΣTotCanHg) / number of tests (n)) | MeEffHg = (ΣTotCanHg) / n | mg/l |

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| Determining mean mercury total mass in effluent | | |
|---|---|---|
| | | Units |
| Concentration of mercury in 1 vacuum canister (10 amalgam removals) (CanHg) | CanHg | mg/l |
| Volume of effluent in 1 vacuum canister (CanVol) | CanVol | ml |
| Concentration of mercury in acid rinsate and water rinse (at analytical laboratory (rinsing of emptied vacuum canister) (RinsHg) | RinsHg | mg/l |
| Volume of acid and water rinsates used to clean vacuum canister (RinsVol) | RinsVol | ml |
| Total mass of mercury in 1 vacuum canister (10 amalgam removals) (**MasHgCan**) | **MasHgCan** = [(CanHg X CanVol) / 1000] + [RinsHg X RinsVol]) / 1000] | mg |
| **Mean effluent mercury mass (HgEffMas)** Sum of all tests ((ΣMasHgCan) / number of tests (n) | **HgEffMas** = (ΣMasHgCan) / n | mg |

SAW 2b is now used for data on effluent mercury concentration

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## SAW 2b: Calculation of a 95% Confidence Interval For a Mean

*This test is used to determine at a level of 95% confidence that the true but unknown population mean lies within the constructed interval.*

***Assumptions:***

- *The data set is normally distributed.*
- The $x_i$ observations constituting the data set are independent[8].

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| **Data Description and Tests of Assumptions** | |
|---|---|
| Parameter | Units: mass (mg) |
| Data Location | ☐ attached page |
| Filename and Location | ☐ electronic database |
| Based on SAW #1, the data set is normally distributed. | ☐ Yes |

| **Common Calculations** | |
|---|---|
| Estimate of μ | $\bar{x}$: |
| Total sample size n | n: |
| Estimate of $\sigma^2$<br>$s^2 = \frac{1}{n-1}\left[\sum_{i=1}^{n} x_i^2 - \frac{\left(\sum_{i=1}^{n} x_i\right)^2}{n}\right]$ | $s^2$: |
| If $n \geq 30$[9] | |
| Obtain $Z_{0.975}$ from Table C1, Appendix C, ETV Canada General Verification Protocol June 2002. | $Z_{0.975}$: 1.96 |
| Lower Confidence Limit:<br>$LCL = \bar{x} - Z_{0.975}\, s/\sqrt{n}$ | LCL: |
| Upper Confidence Limit<br>$UCL = \bar{x} + Z_{0.975}\, s/\sqrt{n}$ | UCL: |
| If n <30 | |
| Obtain $t_{0.975,\ n-1}$ from Table C2, Appendix C, ETV Canada General Verification Protocol June 2002. | $t_{0.975,\ n-1}$: |

[8] A non-rigorous definition of independence is : Data sets are independent of one another when the data generating process is independent from data set to data set. For example, a data set generated by a specific technology unit is independent of a data set generated by another technology unit. Note that data sets collected at different times using the same technology unit are not independent

[9] This sequence may be required for combined data

| **Common Calculations** | |
|---|---|
| Lower Confidence Limit<br>LCL = $\bar{x} - t_{0.975,\ n-1}\ s/\sqrt{n}$ | LCL: |
| Upper Confidence Limit<br>UCL = $\bar{x} + t_{0.975,\ n-1}\ s/\sqrt{n}$ | UCL: |

The 95% confidence interval for the mean $\bar{x}$ is: (LCL, UCL).

**SAW 3: MEDIAN MERCURY MASS IN EFFLUENT:**

## Calculation of a 95% Confidence Interval For a Median

*This test is used to determine at a level of at least[10] 95% confidence that the true but unknown population median lies within the constructed interval.*

***Assumptions:***

- The $x_i$ observations constituting the data set are independent[11].
- The measurement scale for the $x_i$ observations is at least ordinal.

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| Data Description and Tests of Assumptions | |
|---|---|
| Parameter | Units: mass (mg) |
| Data Location | ☐ attached page |
| Filename and Location | ☐ electronic database |
| Based on SAW #1, the data set is not normally distributed. | ☐ Yes |

| Common Calculations | |
|---|---|
| Sort the $x_i$ from smallest to largest. | |
| Total sample size n | |
| For the sample size n, choose the lower rank value from table SAW3 a. | LRV: |
| For the sample size n, choose the upper rank value from table SAW3 a. | URV: |
| From the ordered data choose the observation corresponding to the LRV. | $x_{LCL}$: |
| From the ordered data choose the observation corresponding to the URV. | $x_{UCL}$: |

The 95%[10] confidence interval for the median is: ($x_{LCL}$, $x_{UCL}$).

[10] Due to the discrete nature of the binomial distribution exact levels of significance cannot usually be obtained for a specific desired level of significance. Levels of significance are at least those stated.

[11] A non-rigorous definition of independence is : Data sets are independent of one another when the data generating process is independent from data set to data set. For example, a data set generated by a specific technology unit is independent of a data set generated by another technology unit. Note that data sets collected at different times using the same technology unit are not independent.

## SAW 3 for Primary Claim SAW Table 3a

| | Lower rank | Upper rank |
|---|---|---|
| n | LRV | URV |
| 1 | 0 | 1 |
| 2 | 0 | 2 |
| 3 | 0 | 3 |
| 4 | 0 | 4 |
| 5 | 0 | 5 |
| 6 | 1 | 5 |
| 7 | 1 | 6 |
| 8 | 1 | 7 |
| 9 | 2 | 7 |
| 10 | 2 | 8 |
| 11 | 2 | 9 |
| 12 | 3 | 9 |
| 13 | 3 | 10 |
| 14 | 3 | 11 |
| 15 | 4 | 11 |
| 16 | 4 | 12 |
| 17 | 5 | 12 |
| 18 | 5 | 13 |
| 19 | 5 | 14 |
| 20 | 6 | 14 |
| 21 | 6 | 15 |
| 22 | 6 | 16 |
| 23 | 7 | 16 |
| 24 | 7 | 17 |
| 25 | 8 | 17 |
| 26 | 8 | 18 |
| 27 | 8 | 19 |
| 28 | 9 | 19 |
| 29 | 9 | 20 |
| 30 | 10 | 20 |
| 31 | 10 | 21 |
| 32 | 10 | 22 |
| 33 | 11 | 22 |
| 34 | 11 | 23 |
| 35 | 12 | 23 |
| 36 | 12 | 24 |
| 37 | 13 | 24 |
| 38 | 13 | 25 |
| 39 | 13 | 26 |
| 40 | 14 | 26 |
| 41 | 14 | 27 |
| 42 | 15 | 27 |
| 43 | 15 | 28 |
| 44 | 16 | 28 |
| 45 | 16 | 29 |
| 46 | 16 | 30 |

| | | |
|---|---|---|
| 47 | 17 | 30 |
| 48 | 17 | 31 |
| 49 | 18 | 31 |
| 50 | 18 | 32 |
| 51 | 19 | 32 |
| 52 | 19 | 33 |
| 53 | 19 | 34 |
| 54 | 20 | 34 |
| 55 | 20 | 35 |
| 56 | 21 | 35 |
| 57 | 21 | 36 |
| 58 | 22 | 36 |
| 59 | 22 | 37 |
| 60 | 22 | 38 |
| 61 | 23 | 38 |
| 62 | 23 | 39 |
| 63 | 24 | 39 |
| 64 | 24 | 40 |
| 65 | 25 | 40 |
| 66 | 25 | 41 |
| 67 | 26 | 41 |
| 68 | 26 | 42 |
| 69 | 26 | 43 |
| 70 | 27 | 43 |
| 71 | 27 | 44 |
| 72 | 28 | 44 |
| 73 | 28 | 45 |
| 74 | 29 | 45 |
| 75 | 29 | 46 |
| 76 | 29 | 47 |
| 77 | 30 | 47 |
| 78 | 30 | 48 |
| 79 | 31 | 48 |
| 80 | 31 | 49 |
| 81 | 32 | 49 |
| 82 | 32 | 50 |
| 83 | 33 | 50 |
| 84 | 33 | 51 |
| 85 | 33 | 52 |
| 86 | 34 | 52 |
| 87 | 34 | 53 |
| 88 | 35 | 53 |
| 89 | 35 | 54 |
| 90 | 36 | 54 |
| 91 | 36 | 55 |
| 92 | 37 | 55 |
| 93 | 37 | 56 |
| 94 | 38 | 56 |
| 95 | 38 | 57 |
| 96 | 38 | 58 |
| 97 | 39 | 58 |

| | | |
|---|---|---|
| 98 | 39 | 59 |
| 99 | 40 | 59 |
| 100 | 40 | 60 |

## SAW 4 : Calculation of percent removal based on the individual tests
**(Tests 1 to 5, for example)**

There are five[12] samples, and from this data the mean or median value, and its confidence interval, is calculated. The CWS target is 95% removal; therefore the value of total mercury entering the amalgam removal unit is needed, so the percent removal can be calculated. The method for calculating influent mercury mass for each test is given in SAW 2a. The weights of total mercury going into each sampling sequence are known and are used to estimate an average influent total Hg that is treated as a fixed value in subsequent calculations[13].

In addition, SAW 2a provides the method for calculating the value of the mass of mercury in the effluent from each individual test. Then the mean value of the five samples can be calculated. This gives an estimate of the value of μ, the true value of the mean. Using SAW 2b, the confidence interval is found. Therefore the value of the Lower Confidence Limit (LCL) and the Upper Confidence Limit (UCL) is available. If the data is not normally distributed (SAW 1), then an analogous procedure is carried out to find the confidence interval for the median, and this is outlined in SAW 3.

The procedure for finding percent removal is below, and uses the same notation as SAW 2a.

| Determining percent removal | | |
|---|---|---|
| | | Units |
| Average mass of influent mercury | (AveInfHg) | mg |
| Average mass of effluent mercury (or median mass) | HgEffMas | mg |
| Lower Confidence Interval for effluent mercury | LCL | mg |
| Upper Confidence Interval for effluent mercury | UCL | mg |
| **Percent removal, based on the mean or median = [1 – HgEffMas/AveInfHg] * 100** | Ave%HgRem | |

[12] At least five samples are acquired during the test procedure described in this protocol. Depending on the specific requirements, as noted in the proponent's TSTP, and depending on whether the optional claim is desired, more samples may be taken. All available data should be used for calculating the percent removal. Data may be used from all 3 units if it can be combined following SAW 4 and SAW 5

[13] The pragmatic decision to treat influent total Hg as a fixed value is made primarily to allow non-statisticians to use reasonably simple statistical tools involving a mean or median. This decision also follows dialogue regarding the limited extent of variation in influent total Hg observations and the likelihood that removal efficiencies will be at least 98%. In the unlikely event that the estimated removal efficiency is between 94 and 96% verification entities **must** acknowledge the variability in the influent total Hg. The requisite calculations are more sophisticated and beyond the scope of the available SAWs. Verification Entities will likely need to consult a statistician.

[15] A non-rigorous definition of independence is : Data sets are independent of one another when the data generating process is independent from data set to data set. For example, a data set generated by a specific technology unit is independent of a data set generated by another technology unit. Note that data sets collected at different times using the same technology unit are not independent.

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Deleted: , and therefore 5 values of the weight of total mercury can be averaged. This number is calculated, and not subjected to a statistical test for confidence interval, because the variation[14] in this value will not cause a significant difference to the end calculation of percentage removal.

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| | | |
|---|---|---|
| Percent removal, based on the Lower Confidence Limit for mean or median = [1 – (LCL)/AveInfHg]* 100 | LCL%HgRem | |
| Percent removal, based on the Upper Confidence Limit = [1 – (UCL)/AveInfHg]* 100 | UCL%HgRem | |

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The values of Q and R can then be used to determine whether the technology meets the verification criteria of passing the Canada-Wide Standard.

**The Performance Claim for the Canada-Wide Standard**

Recalling the null and alternate hypotheses $H_o$ and $H_a$, given in section 8.2, we seek to use the Confidence Interval to produce the finding that the alternate hypothesis is accepted. The Upper Confidence Limit for the mean gives the worst case for Hg removal, and therefore if the UCL is less than or equal to AveInfHg * .05, the alternate hypothesis is accepted at the 95% confidence level.

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We wish to express this finding in terms of percent removal. Therefore, inspection of the above calculation will show that the least value of percent removal is the one based on the Upper Confidence Limit. For a successful claim, the least value of percent removal must be 95% or greater. Therefore the Performance Claim that the tested technology conforms to the CWS is based on the value of **UCL%HgRem, in the table above. UCL%HgRem must be greater than or equal to 95%(but note footnote 12).** The claim would therefore be similar to the following text:

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> "When operated according to the procedures in the test protocol, Technology ABC removes at least 95% of total mercury, with 95% confidence, and is in compliance with the Canada-Wide Standard on mercury from dental amalgam wastes"

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However, the calculation in SAW 4 only applies to the test of one unit, so to complete the evaluation necessary to make the claim for the technology units generally, it is necessary to complete the examination of the data and apply SAW 5 or SAW 6, and then the Performance Claim is made on the basis of testing and evaluation of multiple examples of the technology unit.

Note: Not all individual units for a technology may pass the Canada-Wide Standard. For example one could fail to achieve 95% mercury removal whilst the other 2 units may achieve more than 95% mercury removal. The end result is that the Verification Entity must try and identify the factors that caused unit failure and determine how the performance claim is worded.

## SAW 5: Testing equality of 3 Means

From Statistical Analysis Worksheet No. 11 ETV Canada General Verification Protocol 2002 Appendix B

Testing Equality of k Means

**$H_o$: $\mu_1 = \mu_2 = \ldots \mu_k$**

This test is used to test the equality of k means at a level of 95% confidence. The k samples represent different technology units. The formulae presented below are applicable when the k data sets are equal or unequal in number. The test presented is the known as analysis of variance or ANOVA.

***Assumptions:***

- *All k data sets are normally distributed.*
- *The $x_{ij}$ observations constituting the data set are independent*[15].
- *The variances estimated from the k data sets are equal*

| **Data Description and Tests of Assumptions** | | |
|---|---|---|
| Parameter: | Units: mass (mg) | |
| Data Location | ☐ attached page | |
| Filename and Location | ☐ electronic database | |
| Based on SAW#1,the data sets are normally distributed. | ☐ Yes | |
| Based on SAW #7, the variances are equal. | ☐ Yes | ☐ No, obtain assistance from a statistician |

| **Common Calculations** | |
|---|---|
| Sample sizes $n_1, n_2 \ldots n_k$ | $n_1, n_2 \ldots n_k$: |
| Total sample size $n = n_1 + n_2 + \ldots n_k$ | n: |
| Total replicate units k | k: |
| Calculate C<br>$C = \frac{\left(\sum_{j=1}^{k}\sum_{i=1}^{n_j} x_{ij}\right)^2}{n}$ | C: |
| Calculate sum of observations within each unit<br>$T_j = \sum_{i=1}^{n_j} x_{ij}$ , for j = 1 …k | $T_1, T_2 \ldots T_j$: |
| Calculate the degrees of freedom $\nu_1$<br>$\nu_1 = k - 1$ | $\nu_1$: |

| **Common Calculations** | |
|---|---|
| Calculate the degrees of freedom $\nu_2$<br>$\nu_2 = n - k$ | $\nu_2$: |
| Calculate total sum of squares TSS<br>$TSS = \left( \sum_{j=1}^{k} \sum_{i=1}^{n_j} x_{ij}^2 \right) - C$ | TSS: |
| Calculate sum of squares due to treatment SST<br>$SST = \left( \sum_{j=1}^{k} \frac{T_j^2}{n_j} \right) - C$ | SST: |
| Calculate SSE<br>**SSE = TSS - SST** | SSE: |
| Calculate test statistic F<br>$F = \frac{SST / \nu_1}{SSE / \nu_2}$ | F: |
| $\alpha$ = | $\alpha$: 0.05 |
| **Calculations Case - $H_a$: At least one: $\mu_s \neq \mu_r$ for s ≠r** | |
| Obtain $F_{0.95, \nu1, \nu2}$ from Table C3, Appendix C, ETV Canada General Verification Protocol 2002. | critical value: |

Decision Rule

**If the test statistic F ≥ the critical value we reject the null hypothesis and accept the alternative hypothesis.**

**Null Hypothesis $\mu_1 = \mu_2 = \ldots \mu_k$: ☐ Not Rejected ☐ Rejected**
**Alternative Hypothesis: ☐ Accepted ☐ Not Accepted**

## SAW 6: Testing equality of 3 medians

From ETV Canada General Verification Protocol Appendix B Sep 11 2002 Statistical Analysis Worksheet No. 12

### $H_o$: $median_1 = median_2 = \ldots median_k$

This test is used to test the equality of k medians at a level of 95% confidence. The k samples represent different technology units. The formulae presented below are applicable when the k data sets are equal or unequal in number. The test presented is the Kruskal Wallis test.

***Assumptions:***

- *The $x_{ij}$ observations constituting the data set are independent*[16].
- *The variances estimated from the k data sets are equal*

| **Data Description and Tests of Assumptions** | | |
|---|---|---|
| Parameter: | Units: mass (mg) | |
| Data Location | ☐ attached page | |
| Filename and Location | ☐ electronic database | |
| Based on SAW #7, the variances are equal. | ☐ Yes | ☐ No, obtain assistance from a statistician |

| **Common Calculations** | |
|---|---|
| Sample sizes $n_1, n_2 \ldots n_k$ | $n_1, n_2 \ldots n_k$: |
| Total sample size $n = n_1 + n_2 + \ldots n_k$ | n: |
| Total replicate units k | k: |
| Rank all n observations from smallest (rank = 1) to largest (rank = n). In the event of a tie, the average rank is assigned to the observation. For example, if the 5th and 6th smallest observations are tied, each observation would receive the rank 5.5. | |
| Calculate the sum of the ranks ($R_j$) within each unit. $R_j = \sum_{i=1}^{n_j} R(X_{ij})$ for j = 1 … k. | $R_1, R_2, \ldots R_k$: |

[16] A non-rigorous definition of independence is : Data sets are independent of one another when the data generating process is independent from data set to data set. For example, a data set generated by a specific technology unit is independent of a data set generated by another technology unit. Note that data sets collected at different times using the same technology unit are not independent.

| **Common Calculations** | |
|---|---|
| Calculate $S^2$<br>$S^2 = \left(\frac{1}{n-1}\right)\left(\sum_{j=1}^{k}\sum_{i=1}^{nj} R(X_{ij})^2 - \frac{n(n+1)^2}{4}\right)$ | $S^2$: |
| Calculate the test statistic T<br>$T = \frac{1}{S^2}\left(\sum_{j=1}^{k}\frac{R_j^2}{n_j} - \frac{n(n+1)^2}{4}\right)$ | T: |
| **Calculations Case - $H_a$: At least one: $median_s \neq median_r$ for s ≠r** | |
| Obtain $X^2_{0.95,\ k-1}$ from Table C6, Appendix C, ETV Canada General Verification Protocol 2002. | critical value: |

Decision Rule

**If the test statistic T ≥ the critical value we reject the null hypothesis and accept the alternative hypothesis.**

**Null Hypothesis $median_1 = median_2 = \ldots median_k$:** ☐ **Not Rejected** ☐ **Rejected**

**Alternative Hypothesis:** ☐ **Accepted** ☐ **Not Accepted**

## SAW 7 : Testing equality of k variances

From ETV Canada General Verification Protocol 2002 Appendix B Statistical Analysis Worksheet No. 13

$\mathbf{H_0}: \sigma_1^2 = \sigma_2^2 = \ldots = \sigma_k^2$

This test is used to test the equality of k variances at a level of 95% confidence. The k samples represent different technology units. The formulae presented below are applicable when the k data sets are equal or unequal in number. The test presented is known as Levene's test.

***Assumptions:***

- *All k data sets are normally distributed.*
- *The $x_{ij}$ observations constituting the data set are independent*[17].

| **Data Description and Tests of Assumptions** | |
|---|---|
| Parameter: | Units: mass (mg) |
| Data Location | ☐ attached page |
| Filename and Location | ☐ electronic database |
| Based on SAW#1,the data sets are normally distributed. | ☐ Yes |

| **Common Calculations** | |
|---|---|
| Sample sizes $n_1, n_2 \ldots n_k$ | $n_1, n_2 \ldots n_k$: |
| Total sample size $n = n_1 + n_2 + \ldots n_k$ | n: |
| Total replicate units k | k: |
| Treatment means $\overline{T}_j = \frac{\sum_{i=1}^{n_j} x_j}{n_j}$ for j = 1 … k | |
| Adjust data using: $y_{ij} = \lvert x_{ij} - \overline{T}_j \rvert$ for i = 1 … $n_j$, j = 1… k | |
| Perform analysis of variance on adjusted values $y_{ij}$, using SAW # 5 | |
| **Calculations Case - $H_a$: At least one pair of variances are unequal.** | |
| Test statistic F from SAW # 5 | F: |
| Critical value $F_{0.95, k-1, \nu 2}$ from SAW # 5 | critical value: |

[17] A non-rigorous definition of independence : Data sets are independent of one another when the data generating process is independent from data set to data set. For example, a data set generated by a specific technology unit is independent of a data set generated by another technology unit. Note that data sets collected at different times using the same technology unit are not independent.

Decision Rule

**If the test statistic F ≥ the critical value we reject the null hypothesis and accept the alternative hypothesis.**

**Null Hypothesis $\sigma_1^2 = \sigma_2^2 = \ldots = \sigma_k^2$:** ☐ **Not Rejected** ☐ **Rejected**
**Alternative Hypothesis:** ☐ **Accepted** ☐ **Not Accepted**

Recall, the hypotheses for the Optional claim (the mean or median **effluent Hg concentration** is less than a desired value) are:

*Ho: The mean or median value of total mercury is >$Hg_T$ X 0.95 with 95% confidence.*

*Ha: The mean or median value of total mercury is ≤$Hg_T$ X 0.95 with 95% confidence.*

Deleted: (for technology to meet a proponent chosen concentration value

Deleted: $M_T$

Deleted: $M_T$

If the observations are normally distributed, the one-sided mean test (t-test) of hypothesis shall be employed in the analysis, while a one-sided median test shall be used for observations that do not follow the normal distribution. The hypothesis testing requires calculating the test statistics and comparing them with the critical values. The critical values depend on the desired confidence and degree of freedom.

If the observed mean or median removal efficiency of total mercury is greater than 95% with 95% confidence, then the next replicate of the technology shall be tested and the analyst can proceed to replicate data analysis.

### 8.3.3 Statistical Analysis For Optional Claim

#### 8.3.3.1 Statistical Analysis for Optional Claim. Data Analysis Overview for Technology Testing

The following analyses are designed to be used by a non-statistician. The analysis is relatively simple and easy to understand. However, this method may suffer from lack of power, and may fail to meet the stated level of confidence over the group of tests conducted.[18] In this case, a more rigorous statistical method than either than those used for the Primary claim and Optional claim may be chosen by the proponent

[18] As many tests are conducted, some by chance alone will be significant. Adjustments to the type 1 error (refer to glossary) rate are necessary to ensure that the type 1 error rate for the entire experiment is not increased. The interested reader is referred to the multiple-comparisons section of an introductory statistics textbook for further information (1,2).

**Note: The following Statistical Analysis Worksheets are used for the Optional claim only**

# SAW 8a: Sample size calculation for mean

Purpose: The purpose is to estimate the sample size required to achieve pre-specified type I and type II error rates when comparing the mean to a pre-specified desired value using a one-sample t-test.

The alternative hypothesis is that the mean effluent Hg concentration is < the desired value. For this example, the desired value is 30 μg/L.

Data Set: Five hypothetical observations from the first Hg removal unit tested.

User Notes:
Type I error = 5%
Type II error = 10%
Only those values required for calculations are presented below
Worksheet may be printed in landscape mode

Steps:

1 Square all observations.
2 Sum the observations.
3 Sum the squared observations.
4 Estimate the mean of the observations.
5 Estimate the sample variance and take square root to obtain sample standard deviation.
6 Estimate "D" as follows:

D = (desired value-observed mean)/sample standard deviation

7 Look up sample size in table below.

Example: D = (30-20.4)/4.96185
D = 1.93476 (highlighted in table below)

Interpretation:

We require at least 4 samples to ensure a type I error not greater than 5% and a type II error not greater than 10% when testing the hypotheses described above.

Common Calculations

| | 1st Set of Effluent Hg(μg/L) | Squared Cycle 4 Effluent Hg |
|---|---|---|
| | 21.8 | 475.24 |
| | 19.6 | 384.16 |
| | 20.8 | 432.64 |
| | 26.8 | 718.24 |
| | 13 | 169 |
| sum | 102 | 2179.28 |

| | |
|---|---|
| n | 5 |
| mean | 20.4 |
| sample variance | 24.62 |
| sample standard deviation | 4.96185 |
| desired value | 30 |
| D | 1.93476 |

Table for Estimating Sample Size for One-Sample Mean Test
(Type I error rate set to 5% and Type II error rate set to 10%)

| D | n |
|---|---|
| 0.05 | 3484 |
| 0.1 | 872 |
| 0.15 | 388 |
| 0.2 | 219 |
| 0.25 | 141 |
| 0.3 | 98 |
| 0.35 | 73 |
| 0.4 | 56 |
| 0.45 | 44 |
| 0.5 | 36 |
| 0.55 | 30 |
| 0.6 | 26 |
| 0.65 | 22 |
| 0.7 | 19 |
| 0.75 | 17 |
| 0.8 | 15 |
| 0.85 | 14 |
| 0.9 | 12 |
| 0.95 | 11 |
| 1 | 10 |
| 1.05 | 9 |
| 1.1 | 9 |
| 1.15 | 8 |
| 1.2 | 8 |
| 1.25 | 7 |
| 1.3 | 7 |
| 1.35 | 6 |
| 1.4 | 6 |
| 1.45 | 6 |
| 1.5 | 5 |
| 1.55 | 5 |
| 1.6 | 5 |
| 1.65 | 5 |
| 1.7 | 5 |
| 1.75 | 4 |
| 1.8 | 4 |
| 1.85 | 4 |
| 1.9 | 4 |
| 1.95 | 4 |
| 2 | 4 |
| 2.05 | 4 |

| | |
|---|---|
| 2.1 | 3 |
| 2.15 | 3 |
| 2.2 | 3 |
| 2.25 | 3 |
| 2.3 | 3 |
| 2.35 | 3 |
| 2.4 | 3 |
| 2.45 | 3 |
| 2.5 | 3 |
| 2.55 | 3 |
| 2.6 | 3 |
| 2.65 | 3 |
| 2.7 | 3 |
| 2.75 | 3 |
| 2.8 | 3 |
| 2.85 | 3 |
| 2.9 | 3 |
| 2.95 | 3 |
| 3 | 2 |
| 3.05 | 2 |
| 3.1 | 2 |
| 3.15 | 2 |
| 3.2 | 2 |
| 3.25 | 2 |
| 3.3 | 2 |
| 3.35 | 2 |
| 3.4 | 2 |
| 3.45 | 2 |
| 3.5 | 2 |
| 3.55 | 2 |
| 3.6 | 2 |
| 3.65 | 2 |
| 3.7 | 2 |
| 3.75 | 2 |
| 3.8 | 2 |
| 3.85 | 2 |
| 3.9 | 2 |
| 3.95 | 2 |
| 4 | 2 |

## SAW 8b: Sample size calculation for median

Purpose: This analysis is used to estimate the sample size required to achieve pre-specified type I and type II error rates when comparing a median to a pre-specified value using the one-sample Wilcoxon signed ranks procedure.

The alternative hypothesis is that the mean effluent Hg concentration is < the desired value. For this example, the desired value is 30 µg/L.

Data Set: Five hypothetical observations from the first Hg removal unit tested.

User Notes: Type I error = 5%
Type II error = 10%
Theory described below.

Steps:

1 Conduct sample size calculations assuming normal distribution.
2 Multiply the required sample size by 1/0.864.

Example: From sample size calculation worksheet, n = 4 to ensure a type I error not greater than 5% and a type II error not greater than 10%.

Multiply 4 * 1/0.864 to obtain 4.630

Interpretation:

We require at least 5 samples to ensure a type I error not greater than 5% and a type II error not greater than 10%.

Theory: The sample size calculation uses the worst asymptotic relative efficiency of the Wilcoxon signed ranks test, relative to the normal theory test. Hodges and Lehman estimated this value as 0.864.

Hodges, J. L. Jr. and E. L. Lehman. 1956. The efficiency of some nonparametric competitors of the t-test. Ann. Math. Stat. 27:324-335.

## SAW 9 : Estimate a One-Sided 95% Confidence Limit For a Mean

*This test is used to estimate at a level of 95% confidence that the true but unknown population mean is less than the estimated limit.*

***Assumptions:***

- *The data set is normally distributed.*
- The $x_i$ observations constituting the data set are independent[19].

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| Data Description and Tests of Assumptions | |
|---|---|
| Parameter | Units: Hg concentration (mg/l) |
| Data Location | ☐ attached page |
| Filename and Location | ☐ electronic database |
| Based on SAW #1, the data set is normally distributed. | ☐ Yes |

| Common Calculations | |
|---|---|
| Estimate of μ | $\bar{x}$: |
| Total sample size n | n: |
| Estimate of $\sigma^2$<br>$s^2 = \frac{1}{n-1}\left[\sum_{i=1}^{n} x_i^2 - \frac{\left(\sum_{i=1}^{n} x_i\right)^2}{n}\right]$ | $s^2$: |
| If n ≥ 30 | |
| Obtain $Z_{0.95}$ from Table C1, Appendix C, ETV Canada General Verification Protocol. June 2002 | $Z_{0.95}$: 1.645 |
| Upper Confidence Limit<br>$UCL = \bar{x} + Z_{0.975}\, s/\sqrt{n}$ | UCL: |
| If n <30 | |
| Obtain $t_{0.95,\ n-1}$ from Table C2, Appendix C, ETV Canada General Verification Protocol. June 2002. | $t_{0.95,\ n-1}$: |
| Upper Confidence Limit<br>$UCL = \bar{x} + t_{0.95,\ n-1}\, s/\sqrt{n}$ | UCL: |

[19] A non-rigorous definition of ***Independence of data sets:*** Data sets are independent of one another when the data generating process is independent from data set to data set. For example, a data set generated by a specific technology unit is independent of a data set generated by another technology unit. Note that data sets collected at different times using the same technology unit are not independent.

We are at least 95% confident that the true but unknown population mean Hg concentration is less than UCL.

## SAW 10 : Estimate a One-Sided 95% Confidence Limit For a Median

*This test is used to estimate at a level of at least[20] 95% confidence that the true but unknown population median is less than the estimated limit.*

***Assumptions:***

- The $x_i$ observations constituting the data set are independent[21].
- The measurement scale for the $x_i$ observations is at least ordinal.

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| Data Description and Tests of Assumptions | |
|---|---|
| Parameter | Units: Hg concentration (mg/l) |
| Data Location | ☐ attached page |
| Filename and Location | ☐ electronic database |
| Based on SAW #1, the data set is not normally distributed. | ☐ Yes |

| Common Calculations | |
|---|---|
| Sort the $x_i$ from smallest to largest. | |
| Total sample size n | |
| For the sample size n, choose the upper rank value from table Optional claim SAW Table 10a. | URV: |
| From the ordered data choose the observation corresponding to the URV. | $x_{UCL}$: |

We are at least 95% confident that the true but unknown population median Hg concentration is less than $x_{UCL}$.

[20] Due to the discrete nature of the binomial distribution exact levels of significance cannot usually be obtained for a specific desired level of significance. Levels of significance are at least those stated.

[21] A non-rigorous definition of independence is : Data sets are independent of one another when the data generating process is independent from data set to data set. For example, a data set generated by a specific technology unit is independent of a data set generated by another technology unit. Note that data sets collected at different times using the same technology unit are not independent.

## SAW 10 for Optional claim SAW Table 10a

| n | Lower Rank | Upper Rank |
|---|---|---|
| | LRV | URV |
| 1 | 0 | 1 |
| 2 | 0 | 2 |
| 3 | 0 | 3 |
| 4 | 0 | 4 |
| 5 | 1 | 4 |
| 6 | 1 | 5 |
| 7 | 1 | 6 |
| 8 | 2 | 6 |
| 9 | 2 | 7 |
| 10 | 2 | 8 |
| 11 | 3 | 8 |
| 12 | 3 | 9 |
| 13 | 4 | 9 |
| 14 | 4 | 10 |
| 15 | 4 | 11 |
| 16 | 5 | 11 |
| 17 | 5 | 12 |
| 18 | 6 | 12 |
| 19 | 6 | 13 |
| 20 | 6 | 14 |
| 21 | 7 | 14 |
| 22 | 7 | 15 |
| 23 | 8 | 15 |
| 24 | 8 | 16 |
| 25 | 8 | 17 |
| 26 | 9 | 17 |
| 27 | 9 | 18 |
| 28 | 10 | 18 |
| 29 | 10 | 19 |
| 30 | 11 | 19 |
| 31 | 11 | 20 |
| 32 | 11 | 21 |
| 33 | 12 | 21 |
| 34 | 12 | 22 |
| 35 | 13 | 22 |
| 36 | 13 | 23 |
| 37 | 14 | 23 |
| 38 | 14 | 24 |
| 39 | 14 | 25 |
| 40 | 15 | 25 |
| 41 | 15 | 26 |
| 42 | 16 | 26 |
| 43 | 16 | 27 |
| 44 | 17 | 27 |
| 45 | 17 | 28 |
| 46 | 17 | 29 |

| | | |
|---|---|---|
| 47 | 18 | 29 |
| 48 | 18 | 30 |
| 49 | 19 | 30 |
| 50 | 19 | 31 |
| 51 | 20 | 31 |
| 52 | 20 | 32 |
| 53 | 21 | 32 |
| 54 | 21 | 33 |
| 55 | 21 | 34 |
| 56 | 22 | 34 |
| 57 | 22 | 35 |
| 58 | 23 | 35 |
| 59 | 23 | 36 |
| 60 | 24 | 36 |
| 61 | 24 | 37 |
| 62 | 25 | 37 |
| 63 | 25 | 38 |
| 64 | 25 | 39 |
| 65 | 26 | 39 |
| 66 | 26 | 40 |
| 67 | 27 | 40 |
| 68 | 27 | 41 |
| 69 | 28 | 41 |
| 70 | 28 | 42 |
| 71 | 29 | 42 |
| 72 | 29 | 43 |
| 73 | 29 | 44 |
| 74 | 30 | 44 |
| 75 | 30 | 45 |
| 76 | 31 | 45 |
| 77 | 31 | 46 |
| 78 | 32 | 46 |
| 79 | 32 | 47 |
| 80 | 33 | 47 |
| 81 | 33 | 48 |
| 82 | 34 | 48 |
| 83 | 34 | 49 |
| 84 | 34 | 50 |
| 85 | 35 | 50 |
| 86 | 35 | 51 |
| 87 | 36 | 51 |
| 88 | 36 | 52 |
| 89 | 37 | 52 |
| 90 | 37 | 53 |
| 91 | 38 | 53 |
| 92 | 38 | 54 |
| 93 | 39 | 54 |
| 94 | 39 | 55 |
| 95 | 39 | 56 |
| 96 | 40 | 56 |
| 97 | 40 | 57 |

| | | |
|---|---|---|
| 98 | 41 | 57 |
| 99 | 41 | 58 |
| 100 | 42 | 58 |

## 8.4 Outline of the Testing Report

Upon completion of the testing program and data analysis, the testing agency shall submit the testing report to the verification organization. This summary report shall contain all raw and analysed data, description of the methods used for data collection and analysis, QA/QC data and results. The recommended outline of the report is presented below. At its discretion, the testing agency may provide any additional details relevant to a particular technology.

Title Page defining the mercury amalgam removal technology being evaluated, the technology proponent, the testing agency, including the pertinent information on contact person(s) in case of questions, and report submission date.

Executive Summary with a description of technology evaluated, information on the manufacturer, objectives of the testing program, summary of the testing activities and findings, and concluding remarks on technology performance.

Table of Contents with associated page numbers.

Introduction giving detailed description of the technology. It shall contain information on the technology type and capacity (number of operatories and/or maximum flow rate), installation location in the dental facility, and type of the vacuum system (wet/dry) technology is designed for. Technology diagram, description of the parts and non-performance design features, as well as outline of the technology operation, shall be provided.

Experimental Objectives expressing the specific objectives of the Testing Program, which reflect the objectives formulated in this Protocol.

Experimental Design explaining the methodology of the experimental design, specifying analytical methods, chemicals and equipment used, and outlining quality assurance procedures followed. References can be made to the ETV Protocol for Mercury Amalgam Removal Technologies.

Results and Discussion reporting the results of the experimental program and addressing the stated objectives. This section shall include results on influent characterization, removal efficiency testing and examination of non-performance technology design features. The results should be presented in the form of tables and/or graphs as appropriate. Statistical analysis and any observations pertinent to the technology operation shall also be incorporated in this part of the report.

Data Quality Review summarizing the Data Quality Assessment(s) that has been conducted in accordance with the Quality Assurance Project Plan.
Conclusions presenting statements about the technology performance that reflect the program objectives.

Appendices containing complete set of the raw data and O&M manuals provided by the proponent.

**Example Report Format for Environmental Technology Verification – Mercury Amalgam Removal Unit Testing Reporting**

The following Table of Contents is a template that may be used to prepare a Verification Report

**Title Page**
**Approvals Page (with signatures)**

**TABLE OF CONTENTS**

**EXECUTIVE SUMMARY**



**FIGURES**
Insert figures in main body of the report, wherever possible

## References

General Verification Protocol, Environmental Technology Verification Canada Inc., 2000.

Hosmer DW and Lemshow S. Applied Logistic Regression by, J. Wiley and Sons. 2000

McClave, James T. and Sincich, Terry. 2003 9th ed. Statistics Prentice-Hall Inc., New Jersey

Snedecor, G.W. and Cochran, W.G., Statistical Methods, 7th Edition, Iowa State University Press, Ames, Iowa, 1980.

Steel, R.G., et al., Principles and Procedures of Statistics: A Biometrical Approach, McGraw-Hill Series in Probability and Statistics, New York, 1997.

## 9.0 Technology performance evaluation

### 9.1 Performance Claim

A Performance Claim is a precise statement of technology performance supported by statistical analysis of the data from the technology testing. It must be quantitative and specific to operating conditions of the experimental program. The technology must be based on sound scientific and engineering principles and, under defined operating conditions, the results must be reproducible. The Performance Claim shall describe only the mercury removal performance of the technology.

The content of the Performance Claim is directly related to success in reaching the quantifiable performance objective of the experimental program. This objective has been stated in Section 1.4 as follows:

On the basis of daily performance, to determine whether the technology can achieve an average removal efficiency of total mercury greater than 95%, expressed with 95% confidence.

The Performance Claim statement will vary depending on the actual measurements made during the testing program. To illustrate a typical Performance Claim for Option (1) verified technologies, assume that the experimental program is carried out for three replicate units of HgRem™, a fictional technology. A typical Performance Claim would be as follows:

HgRem™ was tested in accordance with the HgRem™ Test Plan of May 2002. Operation and maintenance were performed as indicated in the HgRem™ O&M Manual of October 2000. Treatment was monitored using 270 L of simulated dental wastewater. With 95% confidence, HgRem™ can remove more than 95% of total mercury.

The format of the Performance Claim must include a description of the operating conditions of the technology for which the performance data was taken. This is demonstrated in the first three sentences of the Performance Claim. In this example, the statement of the quantitative results, proven at a statistical confidence level of 95%, is given in the last sentence. The Performance Claim shall be made only on test conditions for which replicate units were tested.

### 9.2 Performance Evaluation

As a result of the experimental program, characteristic performance of the technology is tested and information is generated about operating parameters that impact the technology performance. Because this data is valuable, it shall be formally categorized as a Performance Evaluation, and shall be stated for use in conjunction with the Performance Claim.

Performance Evaluation statements are expected to include:

As applicable, statements on examination of the proper functioning of the following technology design features: warning system, alarm system for filling container, alarm system for malfunction, removal of filled collecting container, and maximum mass of filled collecting container.

Reporting on the amount of soluble mercury released into the environment in the treated water.
Performance curves showing the dependence of parameters, e.g. mercury removal efficiency versus number of amalgam fillings removed and/or placed; or, mercury removal efficiency versus cumulative wastewater flow.
Any other additional information generated with respect to technology performance.