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It is important to note that the LIMS qualifies samples for Method Blank failures when the amount in the blank is greater than the sample's listed PQL.

A Laboratory Control Spike and Laboratory Control Spike Duplicate (LCS/LCSD) are reagent blanks, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst-specific precision and bias or to assess the performance of all or a portion of the measurement system. Guidelines are outlined in each SOP for the frequency and pass fail requirements for LCS and LCSDs. These limits can be set utilizing control charts as discussed below.

Surrogates are utilized when dictated by method and are substances with properties that mimic the analytes of interest. The surrogate is an analyte that is unlikely to be found in environmental samples. Refer to the appropriate Method and SOP for guidelines on pass/fail requirements for surrogates.

Internal Standards are utilized when dictated by the method and are known amounts of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method. Refer to the appropriate Method and SOP for guidelines on pass/fail requirements for Internal Standards.

Proficiency Test (PT) Samples are samples provided by an unbiased third party. They are typically analyzed twice a year, between five and seven months apart, or at any other interval as defined in the method SOP. They contain a pre-determined concentration of the target compound, which is unknown to HEAL. HEAL's management and all analysts shall ensure that all PT samples are handled in the same manner as real environmental samples utilizing the same staff, methods, procedures, equipment, facilities and frequency of analysis as used for routine analysis of that analyte. When analyzing a PT, HEAL shall employ the same calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates and other procedures as used when analyzing routine samples. PT results are reported as normal samples, within the working range of the associated calibration curve. In the event an analyte concentration is less than the PQL, the result shall be reported as less than the PQL.

With regards to analyzing PT Samples HEAL shall not send any PT sample, or portion of a PT sample, to another laboratory for any analysis for which we seek accreditation, or are accredited. HEAL shall not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks accreditation, or is accredited. Laboratory management or staff will not communicate with any individual at another laboratory concerning the PT sample. Laboratory management or staff shall not attempt to obtain the assigned value of any PT sample from the PT Provider.

Upon receiving a Not Acceptable PT result for any analyte, a root cause analysis is conducted and the cause of the failure determined and corrected. As defined by TNI, two

out of the past three PTs must be acceptable to maintain accreditation for any given analyte. If this requirement is not met, a successful history will be reestablished by the analysis of an additional PT sample. For accredited tests, the PT provider will be notified, when the PT is for corrective action purposes. The analysis dates of successive PT samples for the same TNI accredited analyte shall be at least fifteen days apart.

Calibration standards are standards run to calibrate. Once the calibration is established the same standards can be analyzed as Continuing Calibration Verifications (CCV), used to confirm the consistency of the instrumentation. Calibration standards can be utilized at the beginning and end of each batch, or more frequently as required. Typically Continuing Calibration Blanks (CCB) are run in conjunction with CCVs. Refer to the current method SOP for frequency and pass/fail requirements of CCVs and CCBs.

Control Limits are limits of acceptable ranges of the values of quality control checks. The control limits approximate a 99% confidence interval around the mean recovery. Any matrix spike, surrogate, or LCS results outside of the control limits require further evaluation and assessment. This should begin with the comparison of the results from the samples or matrix spike with the LCS results. If the recoveries of the analytes in the LCS are outside of the control limits, then the problem may lie with the application of the extraction, with cleanup procedures, or with the chromatographic procedure. Once the problem has been identified and addressed, corrective action may include reanalysis of samples or re-extraction followed by reanalysis. When the LCS results are within the control limits, the issue may be related to the sample matrix or to the use of an inappropriate extraction, cleanup, and/or determinative method for the matrix. If the results are to be used for regulatory compliance monitoring, then steps must be taken to demonstrate that the analytes of concern can be determined in the sample matrix at the levels of interest. Data generated with laboratory control samples that fall outside of the established control limits are judged to be generated during an "out-of-control" situation. These data are considered suspect and shall be repeated or reported with qualifiers.

Control limits are to be updated only by Technical Directors, Section Supervisors or the Quality Assurance Officer. Control limits should be established and updated according to the requirements of the method being utilized. When the method does not specify, and control limits are to be generated or updated for a test, the following guidelines shall be utilized.

Limits should typically be generated utilizing the most recent 20-40 data values. In order to obtain an even distribution across multiple instruments and to include more than a single day's worth of data, surrogate limits should be generated using around 100 data values. The data values used shall not reuse values that were included in the previous Control Limit update. The data values shall also be reviewed by the LIMS for any Grubbs Outliers, and if identified, the outliers must be removed prior to generating new limits. The results used to update control limits should meet all other QC criteria associated with the determinative method. For example, MS/MSD recoveries from a GC/MS procedure should be generated from samples analyzed after a valid tune and a valid initial calibration that includes all

analytes of interest. Additionally, no analyte should be reported when it is beyond the working range of the calibration currently in use. MS/MSD and surrogate limits should be generated using the same set of extraction, cleanup, and analysis procedures.

All generated limits should be evaluated for appropriateness. Where limits have been established for MS/MSD samples, the LCS/LCSD limits should fall within those limits, as the LCS/LCSD are prepared in a clean matrix. Surrogate limits should be updated using all sample types and should be evaluated to ensure that all instruments as well as a reasonable dispersion across days are represented by the data. LCS/LCSD recovery limits should be evaluated to verify that they are neither inappropriately wide nor unreasonably tight. The default LCS/LCSD acceptance limits of 70-130% and RPD of 20% (or those limits specified by the method for LCS/LCSD and/or CCV acceptability), should be used to help make this evaluation. Technical directors may choose to use warning limits when they feel their generated limits are too wide, or default LCS limits when they feel their limits have become arbitrarily tight.

Once new Control Limits have been established and updated in the LIMS, the Control Charts shall be printed and reviewed by the appropriate section supervisor and primary analyst performing the analysis for possible trends and compared to the previous Control Charts. The technical director initials the control charts, indicating that they have been reviewed and that the updated Limits have been determined to be accurate and appropriate. Any manual alterations to the limits will be documented and justified on the printed control chart. These initialed charts are then filed in the QA/QCO office.

Once established, control limits should be reviewed after every 20-30 data values and updated at least every six months, provided that there are sufficient points to do so. The limits used to evaluate results shall be those in place at the time that the sample was analyzed. Once limits are updated, those limits apply to all subsequent analyses.

When updating surrogate control limits, all data, regardless of sample/QC type, shall be updated together and assigned one set of limits for the same method/matrix.

In the event that there are insufficient data points to update limits that are over a year old, the default limits, as established in the method or SOP, shall be re-instated. Refer to the requirements in SW-846 method 8000B and 8000C for further guidance on generating control limits.

Calculated Measurement Uncertainty is calculated annually using LCSs in order to determine the laboratory specific uncertainty associated with each test method. These uncertainty values are available to our clients upon request and are utilized as a trending tool internally to determine the effectiveness of new variables introduced into the procedure over time.

Client Requested QC

Occasionally certain clients will require QC that is not defined by or covered in the SOPs. These special requests will be issued to all analysts and data reviewers in writing and the analysts and data reviewers will be provided with guidance on how to properly document the client requested deviation/QC in their preparation and analytical batches.

Precision, Accuracy, Detection Levels

Precision

The laboratory uses sample duplicates, laboratory control spike duplicates, and matrix spike duplicates to assess precision in terms of relative percent difference (RPD). HEAL requires the RPD to fall within the 99% confidence interval of established control charts or an RPD of less than 20% if control charts are not available. RPD's greater than these limits are considered out-of-control and require an appropriate response.

$$RPD = 2 \times \frac{(\text{Sample Result} - \text{Duplicate Result})}{(\text{Sample Result} + \text{Duplicate Result})} \times 100$$

Accuracy

The accuracy of an analysis refers to the difference between the calculated value and the actual value of a measurement. The accuracy of a laboratory result is evaluated by comparing the measured amount of QC reference material recovered from a sample and the known amount added. Control limits can be established for each analytical method and sample matrix. Recoveries are assessed to determine the method efficiency and/or the matrix effect.

Analytical accuracy is expressed as the Percent Recovery (%R) of an analyte or parameter. A known amount of analyte is added to an environmental sample before the sample is prepared and subsequently analyzed. The equation used to calculate percent recovery is:

$$\%Recovery = \{(concentration^* \text{ recovered})/(concentration^* \text{ added})\} \times 100$$

*or amount

HEAL requires that the Percent Recovery to fall within the 99 % confidence interval of established control limits. A value that falls outside of the confidence interval requires a warning and process evaluation. The confidence intervals are calculated by determining the mean and sample standard deviation. If control limits are not available, the range of 80 to 120% is used unless the specific method dictates

otherwise. Percent Recoveries outside of this range mandate additional action such as analyses by Method of Standard Additions, additional sample preparation(s) where applicable, method changes, and out-of-control action or data qualification.

Detection Limit

Current practices at HEAL define the Detection Limit (DL) as the smallest amount that can be detected above the baseline noise in a procedure within a stated confidence level.

HEAL presently utilizes a Method Detection Limit (MDL), and a Practical Quantitation Limit (PQL).

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The MDL is a measure of the sensitivity of an analytical method. MDL studies are required annually for each quality system matrix, technology and analyte, unless indicated otherwise in the referenced method. An MDL determination (as required in 40CFR part 136 Appendix B) consists of replicate spiked samples carried through all necessary preparation steps. The spike concentration is three times the standard deviation of three replicates of spikes. At least seven replicates are spiked and analyzed and their standard deviation(s) calculated. Routine variability is critical in passing the 10 times rule and is best achieved by running the MDLs over different days and when possible over several calibration events. Standard Methods and those methods used for drinking water analysis must have MDL studies that are performed over a period of at least three days in order to include day to day variations. The method detection limit (MDL) can be calculated using the standard deviation according to the formula:

$$MDL = s * t\ (99\%),$$

where t (99%) is the Student's t-value for the 99% confidence interval. The t-value depends on the number of trials used in calculating the sample standard deviation, so choose the appropriate value according to the number of trials.

Number of Trials	t(99%)
6	3.36
7	3.14
8	3.00
9	2.90

The calculated MDL must not be less than 10 times the spiked amount or the study must be performed again with a lower concentration.

Where there are multiple MDL values for the same test method in the LIMS the highest MDL value is utilized.

The PQL is significant because different laboratories can produce different MDLs although they may employ the same analytical procedures, instruments and sample matrices. The PQL is about two to five times the MDL and represents a practical, and routinely achievable, reporting level with a good certainty that the reported value is reliable. It is often determined by regulatory limits. The reported PQL for a sample is dependent on the dilution factor utilized during sample analysis.

In the event that an analyte will not be reported less than the PQL, an MDL study is not required and a PQL check shall be done, at least annually, in place of the MDL study. The PQL check shall consist of a QC sample spiked at or below the PQL. All sample-processing and analysis steps of the analytical method shall be included in the PQL check and shall be done for each quality system matrix, technology, and analyte. A successful check is one where the recovery of each analyte is within the established method acceptance criteria. When this criterion is not defined by the method or SOP, a default limit of +/-50% shall be utilized.

Quality Control Parameter Calculations

Mean

The sample mean is also known as the arithmetic average. It can be calculated by adding all of the appropriate values together, and dividing this sum by the number of values.

$$\text{Average} = (\Sigma x_l) / n$$

x_l = the value x in the l^{th} trial
n = the number of trials

Standard Deviation

The sample standard deviation, represented by s, is a measure of dispersion. The dispersion is considered to be the difference between the average and each of the values x_i. The variance, s^2, can be calculated by summing the squares of the differences and dividing by the number of differences. The sample standard deviation, s, can be found by taking the square root of the variance.

Standard deviation = s = $[\Sigma (x_i - \text{average})^2 / (n - 1)]^{1/2}$

Percent Recovery (LCS and LCSD)

$$\text{Percent Recovery} = \frac{\text{(Spike Sample Result)}}{\text{(Spike Added)}} \times 100$$

Percent Recovery (MS, MSD)

$$\text{Percent Recovery} = \frac{\text{(Spike Sample Result – Sample Result)}}{\text{(Spike Added)}} \times 100$$

Control Limits

Control Limits are calculated by the LIMS using the average percent recovery (x), and the standard deviation (s).

Upper Control Limit = x + 3s
Lower Control Limit = x – 3s

These control limits approximate a 99% confidence interval around the mean recovery.

Grubbs Outliers

Grubbs Outliers are calculated by the LIMS during the generation of control limits and uncertainties. An outlier is an observation that appears to deviate markedly from other observations in the sample set and are removed, unless documented otherwise.

Identify both the lowest and highest values in the sample set. Use the following equations to determine the T values.

$$T = \frac{x_{max} - x_{mean}}{sd} \quad \text{(for the largest value)}$$

$$T = \frac{x_{mean} - x_{min}}{sd} \quad \text{(for the smallest value)}$$

Compare the T values to the Grubbs' critical value table. If either value of T is greater than the critical value (assuming a 5% risk) for the sample size, the point(s) must be dropped then the calculation repeated for both the lowest and highest value using the new mean and standard deviation.
The Grubbs test is repeated until there are no longer any outliers detected. Keep in mind you must have at least 20 data points available to generate your limits.

RPD (Relative Percent Difference)

Analytical precision is expressed as a percentage of the difference between the results of duplicate samples for a given analyst. Relative percent difference (RPD) is calculated as follows:

$$RPD = 2 \times \frac{(\text{Sample Result} - \text{Duplicate Result})}{(\text{Sample Result} + \text{Duplicate Result})} \times 100$$

Uncertainty Measurements

Uncertainty, as defined by ISO, is the parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurement. Ultimately, uncertainty measurements are used to state how good a test result is and to allow the end user of the data to properly interpret their reported data. All procedures allow for some uncertainty. For most analyses, the components and estimates of uncertainty are reduced by following well-established test methods. To further reduce uncertainty, results generally are not reported below the lowest calibration point (PQL) or above the highest calibration point (UQL). Understanding that there are many influential quantities affecting a measurement result, so many in fact that it is impossible to identify all of them, HEAL calculates measurement uncertainty at least annually using LCSs. These estimations of measurement uncertainty are kept on file in the method folders in the QA/QC office.

Measurement Uncertainty contributors are those that may be determined statistically. These shall be generated by estimating the overall uncertainty in the entire analytical process by measuring the dispersion of values obtained from laboratory control samples over time. At least 20 of the most recent LCS data points are gathered. The standard deviation(s) is calculated using these LCS data points. Since it can be assumed that the possible estimated values of the spikes are approximately normally distributed with approximate standard deviation(s), the unknown value of the spike is believed to lie in 95% confidence interval, corresponding to an uncertainty range of +/- 2(s).

Calculate standard deviation (s) and 95% confidence interval according to the following formulae:

$$s = \sqrt{\frac{\sum (x - \bar{x})^2}{(n-1)}}$$

Where: s = standard deviation
x = number in series
$\bar{x}$ = calculated mean of series
n = number of samples taken

$95\%\ confidence = 2 \times s$

Example: Assuming that after gathering 20 of the most recent LCS results for Bromide, we have calculated the standard deviations of the values and achieved a result of 0.0326, our measurement of uncertainty for Bromide (at 95% confidence = 2 x s) is 0.0652.

Total Nitrogen

Total nitrogen is calculated as follows:

Total Nitrogen = TKN + NO_2 + NO_3

Langelier Saturation Index

The Langelier Saturation Index (LSI) is calculated as follows:

Solids Factor (SF) =(Log10[TDS] - 1) / 10
Ca Hardness Factor (HF) = Log10([Ca] x 2.497) - 0.4
Alkalinity Factor (AF) = Log10[Alkalinity]
Temp. Factor (TF) = -13.12 x Log10(°C + 273) + 34.55
pHs (pH @ saturation) =(9.3 + SF + TF) - (HF + AF)
LSI = pH - pH_s

Calibration Calculations

1. Response Factor or Calibration Factor:

$RF = ((A_x)(C_{is}))/((A_{is})(C_x))$ $CF=(A_x)/(C_x)$

a. Average RF or CF

$RF_{AVE} = \Sigma RF_i / n$

b. Standard Deviation

$s = SQRT \{ [\Sigma (RF_i - RF_{AVE})^2] / (n-1) \}$

c. Relative Standard Deviation

$RSD = s / RF_{AVE}$

Where:
A_x = Area of the compound
C_x = Concentration of the compound
A_{is} = Area of the internal standard
C_{is} = Concentration of the internal standard
n = number of pairs of data
RF_i = Response Factor (or other determined value)
RF_{AVE} = Average of all the response factors
Σ = the sum of all the individual values

2. Linear Regression

$y=mx+b$

a. Slope (m)

$m =(n\Sigma x_i y_i - (n\Sigma x_i)*(n\Sigma y_i)) / (n\Sigma x_i^2 - (\Sigma x_i)^2)$

b. Intercept (b)

$b = y_{AVE} - m*(x_{AVE})$

c. Correlation Coefficient (cc)

$$CC\ (r) = \{ \Sigma((x_i - x_{ave}) * (y_i - y_{ave})) \} / \{ SQRT((\Sigma(x_i - x_{ave})^2) * (\Sigma(y_i - y_{ave})^2)) \}$$

Or

$$CC\ (r) = [(\Sigma w * \Sigma wxy) - (\Sigma wx * \Sigma wy)] / (sqrt(([(\Sigma w * \Sigma wx^2) - (\Sigma wx * \Sigma wx)] * [(\Sigma w * \Sigma wy^2) - (\Sigma wy * \Sigma wy)])))]$$

d. Coefficient of Determination

$$COD\ (r^2) = CC * CC$$

Where:
y = Response (Area) Ratio A_x/A_{is}
x = Concentration Ratio C_x/C_{is}
m = slope
b = intercept
n = number of replicate x,y pairs
x_i = individual values for independent variable
y_i = individual values for dependent variable
Σ = the sum of all the individual values
x_{ave} = average of the x values
y_{ave} = average of the y values
w = weighting factor, for equal weighting w=1

3. Quadratic Regression

$$y = ax^2 + bx + c$$

a. Coefficient of Determination

$$COD\ (r^2) = (\Sigma(y_i - y_{ave})^2 - \{[(n-1)/(n-p)] * [\Sigma(y_i - Y_i)^2]\}) / \Sigma(y_i - y_{ave})^2$$

Where:
y = Response (Area) Ratio A_x/A_{is}
x = Concentration Ratio C_x/C_{is}
a = x^2 coefficient
b = x coefficient
c = intercept
y_i = individual values for each dependent variable
x_i = individual values for each independent variable
y_{ave} = average of the y values
n = number of pairs of data
p = number of parameters in the polynomial equation (I.e., 3 for third order, 2 for second order)

$Yi = ((2*a*(C_x/C_{is})^2)-b^2+b+(4*a*c))/(4a)$

b. Coefficients (a,b,c) of a Quadratic Regression

$a = S_{(x2y)}S_{(xx)}-S_{(xy)}S_{(xx2)} / S_{(xx)}S_{(x2x2)}-[S_{(xx2)}]^2$

$b = S_{(xy)}S_{(x2x2)}-S_{(x2y)}S_{(xx2)} / S_{(xx)}S_{(x2x2)}-[S_{(xx2)}]^2$

$c = [(\Sigma yw)/n] - b*[(\Sigma xw)/n] - a*[\Sigma(x^2w)/n]$

Where:
n = number of replicate x,y pairs
x = x values
y = y values
$w = S^{-2} / (\Sigma S^{-2}/n)$
$S_{(xx)} = (\Sigma x^2w) - [(\Sigma xw)^2 / n]$
$S_{(xy)} = (\Sigma xyw) - [(\Sigma xw)*(\Sigma yw) / n]$
$S_{(xx2)} = (\Sigma x^3w) - [(\Sigma xw)*(\Sigma x^2w) / n]$
$S_{(x2y)} = (\Sigma x^2yw) - [(\Sigma x^2w)*(\Sigma yw) / n]$
$S_{(x2x2)} = (\Sigma x^4w) - [(\Sigma x^2w)^2 / n]$
Or If unweighted calibration, w=1
S(xx) = (Sx2) - [(Sx)2 / n]
S(xy) = (Sxy) - [(Sx)*(Sy) / n]
S(xx2) = (Sx3) - [(Sx)*(Sx2) / n]
S(x2y) = (Sx2y) - [(Sx2)*(Sy) / n]
S(x2x2) = (Sx4) - [(Sx2)2 / n]

Weighting

Weighting of 1/x or $1/x^2$ is permissible for linear calibrations. Weighting shall not be employed for quadratic calibrations. When weighting, use the above equations by substituting x for 1/x or $1/x^2$.

Concentration Calculations

On-Column Concentration for Average RRF Calibration using Internal Standard

On-Column Concentration $C_x = ((A_x)(C_{is}))/((A_{is})(RF_{AVE}))$

On-Column Concentration for Average CF Calibration using External Standard

On-Column Concentration $C_x = (A_x)/(CF_{AVE})$

On-Column Concentration for Linear Calibration

If determining an external standard, then exclude the A_{is} and C_{is} for internal standards

On-Column Concentration $C_x = ((\text{Absolute}\{[(A_x)/(A_{is})] - b\})/m) * C_{is}$

Where: m = slope
b = intercept
A_x = Area of the Sample
C_{is} = Concentration of the Internal Standard
A_{is} = Area of the Internal Standard

On-Column Concentration for Quadratic Calibration

If determining an external standard, then exclude the A_{is} and C_{is} for internal standards

On-Column Concentration $=[(+SQRT(b^2-(4*a*(c-y)))-b)/(2*a)] * C_{is}$

Where: a = x^2 coefficient
b = x coefficient
c = intercept
y = Area Ratio = A_x/A_{is}
C_{is} = Concentration of the Internal Standard

Final Concentration (Wet Weight)

$$\text{Concentration for Extracted Samples} = \frac{(\text{On-Column Conc})(\text{Dilution})(\text{Final Volume})}{(\text{Initial Amount})(\text{Injection Volume})}$$

$$\text{Concentration for Purged Samples} = \frac{(\text{On-Column Conc})(\text{Purged Amount})(\text{Dilution})}{(\text{Purged Amount})}$$

Dry Weight Concentration

$$\text{Dry Weight Concentration} = \frac{\text{Final Concentration Wet Weight} * 100}{\% \text{ Solids}}$$

Percent Difference

$$\% \text{ Difference} = \frac{\text{Absolute(Continuing Calibration RRF - Average RRF)}}{\text{Average RRF}} * 100$$

Percent Drift

$$\% \text{ Drift} = \frac{\text{Absolute(Calculated Concentration - Theoretical Concentration)}}{\text{Theoretical Concentration}} * 100$$

Dilution Factor

Dilution Factor =(Volume of Solvent + Solute) / Volume of Solute

Relative Retention Time

RRT =RT of Compound / RT of ISTD

Breakdown Percent

$$\text{Breakdown} = \frac{\text{Area of DDD + Area of DDE}}{\text{Average (DDT, DDE and DDD)}}$$

-or-

$$\frac{\text{Area of Endrin Ketone + Area of Endrin Aldehyde}}{\text{Average (Endrin, Endrin Ketone, Endrin Aldehyde)}}$$

11.0 Data Reduction, Validation, Reporting, and Record Keeping

All data reported must be of the highest possible accuracy and quality. During the processes of data reduction, validation, and report generation, all work is thoroughly checked to insure that error is minimized.

Data Reduction

The analyst who generated the data usually performs the data reduction. The calculations include evaluation of surrogate recoveries (where applicable), and other miscellaneous calculations related to the sample quantitation.

If the results are computer generated, then the formulas must be confirmed by hand calculations, at minimum, one per batch.

See the current Data Validation SOP for details regarding data reduction.

Validation

A senior analyst, most often the section supervisor, validates the data. All data undergoes peer review. If an error is detected, it is brought to the analyst's attention so that he or she can rectify the error, and perform further checks to ensure that all data for that batch is sound. Previous and/or common mistakes are stringently monitored throughout the validation process. Data is reported using appropriate significant figure criteria. In most cases, two significant digits are utilized, but three significant digits can be used in QC calculations. Significant digits are not rounded until after the last step of a sample calculation. All final reports undergo a review by the laboratory manager, the project manager, or their designee, to provide a logical review of all results before they are released to the client.

If data is to be manually transferred between media, the transcribed data is checked by a peer. This includes data typing, computer data entry, chromatographic data transfer, data table inclusion to a cover letter, or when data results are combined with other data fields.

All hand-written data from run logs, analytical standard logbooks, hand-entered data logbooks, or on instrument-generated chromatograms, are systematically archived should the need for future retrieval arise.

See the current Data Validation SOP for details regarding data validation.

Reports and Records

All records at HEAL are retained and maintained through the procedures outlined in the most recent version of the Records Control SOP.

Sample reports are compiled by the Laboratory Information Management System (LIMS). Most data is transferred directly from the instruments to the LIMS. After being processed by the analyst and reviewed by a data reviewer, final reports are approved and signed by the senior laboratory management. A comparative analysis of the data is performed at this point. For example, if TKN and NH3 are analyzed on the same sample, the NH3 result should never be greater than the TKN result. Lab results and reports are released only to appropriately designated individuals. Release of the data can be by fax, email, electronic deliverables, or mailed hard copy.

When a project is completed, the final report, chain of custody, any relevant supporting data, and the quality assurance/control worksheets are scanned as a .pdf file onto the main server. Original client folders are kept on file and are arranged by project number. Additionally, all electronic data is backed up routinely on the HEAL main server. The backup includes raw data, chromatograms, and report documents. Hard copies of chromatograms are stored separately according to the instrument and the analysis date. All records and analytical data reports are retained in a secure location as permanent records for a minimum period of five years (unless specified otherwise in a client contract). Access to archived information shall be documented with an access log. Access to archived electronic reports and data will be password protected. In the event that HEAL transfers ownership or terminates business practices, complete records will be maintained or transferred according to the client's instructions.

After issuance, the original report shall remain unchanged. If a correction to the report is necessary, then an additional document shall be issued. This document shall have a title of "Addendum to Test Report or Correction to Original Report", or equivalent. Demonstration of original report integrity comes in two forms. First, the report date is included on each page of the final report. Second, each page is numbered in sequential order, making the addition or omission of any data page(s) readily detectable.

When final Arizona Compliance work order reports contain data analyzed at sub-contracted laboratories, the final report to the client will include the sub-contracted laboratories report in its entirety. This includes but is not limited to cover sheets, qualifiers, data, chain of custodies and any included QC. All sub-contracted data is scanned into the LIMS and archived through the same process as in-house generated records.

12.0 Corrective Action

Refer to the most recent version of the Data Validation SOP for the procedure utilized in filling out a Corrective Action Report. A blank copy of the corrective action report is available in the current Document Control Logbook.

The limits that have been defined for data acceptability also form the basis for corrective action initiation. Initiation of corrective action occurs when the data generated from continuing calibration standard, sample surrogate recovery, laboratory control spike, matrix spike, or sample duplicates exceed acceptance criteria. If corrective action is necessary, the analyst or the section supervisor will coordinate to take the following guidelines into consideration in order to determine and correct the measurement system deficiency:

Check all calculations and data measurements systems (Calibrations, reagents, instrument performance checks, etc.).

Assure that proper procedures were followed.

Unforeseen problems that arise during sample preparation and/or sample analysis that lead to treating a sample differently from documented procedures shall be documented with a corrective action report. The section supervisor and laboratory manager shall be made aware of the problem at the time of the occurrence. See the appropriate SOP regarding departures from documented procedures.

Continuing calibration standards below acceptance criteria cannot be used for reporting analytical data unless method specific criteria states otherwise.

Continuing calibration standards above acceptance criteria can be used to report data as long as the failure is isolated to a single standard and the corresponding samples are non-detect for the failing analyte.

Samples with non-compliant surrogate recoveries should be reanalyzed, unless deemed un-necessary by the supervisor for matrix, historical data, or other analysis-related anomalies.

Laboratory and Matrix Spike acceptance criteria vary significantly depending on method and matrix. Analysts and supervisors meet and discuss appropriate corrective action measures as spike failures occur.

In the event that results must be reported with associated QC failures, the data must be qualified appropriately to notify the end user of the QC failure.

Sample duplicates with RPD values outside control limits require supervisor evaluation and possible reanalysis.

A second mechanism for initiation of corrective action is that resulting from Quality Assurance performance audits, system audits, inter- and intra-laboratory comparison studies. Corrective Actions initiated through this mechanism will be monitored and coordinated by the laboratory QA/QCO.

All corrective action forms are entered in the LIMS and included with the raw data for peer review, signed by the technical director of the section and included in the case narrative to the client whose samples were affected. All Corrective action forms in the LIMS are reviewed by the QA/QCO.

13.0 Quality Assurance Audits, Reports and Complaints

Internal/External Systems' Audits, Performance Evaluations, and Complaints

Several procedures are used to assess the effectiveness of the quality control system. One of these methods includes internal performance evaluations, which are conducted by the use of control samples, replicate measurements, and control charts. External performance audits, which are conducted by the use of inter-laboratory checks, such as participation in laboratory evaluation programs and performance evaluation samples available from a NELAC-accredited Proficiency Standard Vendor, are another method.

Proficiency samples will be obtained twice per year from an appropriate vendor for all tests and matrices for which we are accredited and for which PTs are available. HEAL participates in soil, waste water, drinking water, and underground storage tank PT studies. Copies of results are available upon request. HEAL's management and all analysts shall ensure that all PT samples are handled in the same manner as real environmental samples utilizing the same staff, methods, procedures, equipment, facilities, and frequency of analysis as used for routine analysis of that analyte. When analyzing a PT, HEAL shall employ the same calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates, and other procedures as used when analyzing routine samples.

With regards to analyzing PT Samples, HEAL shall not send any PT sample, or portion of a PT sample, to another laboratory for any analysis for which we seek accreditation, or are accredited. HEAL shall not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks accreditation, or is accredited. Laboratory management or staff will not communicate with any individual at another laboratory concerning the PT sample. Laboratory management or staff shall not attempt to obtain the assigned value of any PT sample from the PT Provider.

Internal Audits are performed annually by the QA/QCO in accordance with the current Internal Audit SOP. The system audit consists of a qualitative inspection of the QA system in the laboratory and an assessment of the adequacy of the physical facilities for sampling, calibration, and measurement. This audit includes a careful evaluation and review of laboratory quality control procedures. Internal audits are performed using the guidelines outlined below, which include, but are not limited to:

1. Review of staff qualifications, demonstration of capability, and personnel training programs
2. Storage and handling of reagents, standards, and samples
3. Standard preparation logbook and LIMS procedures
4. Extraction logbooks
5. Raw data logbooks
6. Analytical logbooks or batch printouts and instrument maintenance logbooks