United States Environmental Protection Agency

Solid Waste and Emergency Response

EPA 540-F-94-028
OSWER 9285.7-14FS
PB94-963311
November 1996

Using Qualified Data to Document an Observed Release and Observed Contamination

Office of Emergency and Remedial Response (5204G)

Quick Reference Fact Sheet

This fact sheet discusses the use of the U.S. Environmental Protection Agency's (EPA) Contract Laboratory Program (CLP) data and other sources of data qualified with a "J", "U", or "UJ" qualified or flag. This guidance provides a management decision tool for the optional use of qualified data to document all observed release and observed contamination by chemical analysis under EPA's Hazard Ranking System (HRS). The analyte and sample matrix (i.e., soil or water) specific adjustment factors given in this fact sheet allow biased CLP and non-CLP data to be adjusted to meet the HRS criteria documenting an observed release and observed contamination with data that are of known and documented quality. This fact sheet does not address using qualified data for identifying hazardous substances in a source.

INTRODUCTION

The EPA established the HRS to rank hazardous waste sites for National Priorities List (NPL) purposes under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) as amended by the Superfund Amendments and Reauthorization Act of 1986 **(SARA).** This fact sheet was developed in response to a need to determine the usability of qualified data for site assessment and HRS scoring purposes. This fact sheet illustrates that qualified data are often of sufficiently known and documented quality, and may be used in establishing an observed release and observed contamination. This fact sheet explains rationale for why some qualified data may be used for HRS purposes; presents the background information needed to use qualified data, with and without adjustment factors; provides examples of qualified data use, and discusses issues raised during the development of the adjustment factor approach.

Under the HRS, chemical analytical data we are often used to demonstrate an observed release and observed contamination when the release sample concentration is three times the background concentration and background levels are greater than or equal to the appropriate detection limit; or if the release sample concentration is greater than or equal to the appropriate quantitation limit when background levels are below the appropriate detection limit. The release must also be at least partially attributable to the site under investigation *(Hazard Ranking System, Final Rule, 40* CFR Part 300, App. A). The data used to establish the release must be of known and documented quality. *(Hazard Ranking System Guidance Manual,* Interim Final, November 1992, OSWER Directive 9345.1-07). Data that cannot be validated may not be of known and documented quality. For more information on observed release and observed contamination, refer to the fact sheets: *Establishing an Observed Release,* September 1995, PB94-963314; *Establishing Areas of Observed Contamination.* September 1995, PB94-963312; and *Establishing Background Levels,* September 1995, PB94-963313. The factor of three represents the minimum difference in sample results that demonstrate an increase in contaminant concentration above background levels, with reasonable confidence.

Although much of the analytical data used for identifying an observed release is generated under EPA's CLP, this fact sheet applies to all data regardless of the source of the data (non-CLP data). EPA procedures require that

CLP analytical data be reviewed, or validated by EPA or third party reviewers, to ensure the data are of known and documented quality and that the determination be discussed in a data validation report that accompanies the analytical results. Based on this data validation, CLP data are classified into three categories: (1) data for which all quality control (QC) requirements have passed contract required acceptance criteria, (2) data for which at least one QC requirement has not met acceptance criteria; and (3) data for which most or all QC requirements have not met acceptance criteria. Data in the first category typically are not qualified. Data in the second category are often qualified with a "J" qualifier and, as discussed in this fact sheet, are usually usable for HRS purposes. Data in the third category are usually qualified by an "R" qualifier and are not usable for HRS purposes.

Whether data are placed into the second or third category is determined by the amount of bias associated with. the analytical results. Data validation evaluates biases resulting from laboratory analytical deficiencies or sample matrices to determine whether the data are usable. Bias indicates that the reported concentration is either higher or lower than the am concentration, and the data validation report identifies the direction of the bias or if the bias is unknown.

The EPA CLP also sets minimum quantitation limits for all analytes; the Contract Required Quantitation Limit (CRQL) for organic analytes and the Contract Required Detection Limit (CRDL) for inorganic analytes. For HRS purposes and for this fact sheet, the term CRQL refers to both the contract required quantitation limit and am contract required detection limit. (40 CFR Part 300, App. A). The CRQLs are substance specific levels that a CLP laboratory must be able to routinely and reliably detection specific sample matrices (i.e.; soil, water. sediment). The CRQLs are usually set above most instrument detection limits (IDLs) and method detection limits (MDLs).

CONSIDERATIONS FOR NON-CLP DATA

Because various laboratories and analytical methods may be used to develop non-CLP data, the following list provides the general information, sufficient for determining whether non-CLP data are usable for HRS Purposes.

(1) Identification of the method used for analysis. Methods include RCRA methods, SW-846, EPA methods, etc.

(2) Quality control (QC) data. Check each method of analysis to determine if specific QC requirements are defined. If not, seek out another method.

(3) Instrument-generated data sheets for sample results. These data sheets would be the equivalent of Form I's in CLP data.

(4) MDLs and sample quantitation limits (SQLs). The analytical method should provide the MDL. The SQL is an adjusted MDL using sample specific measurements such as percent moisture and weight.

(5) Data validation report.

USE OF BIASED QUALIFIED DATA

In the past, all qualified data have been inappropriately perceived by some people as data of low confidence or poor quality and have not been used for HRS evaluation. With careful assessment of the nature of the analytical biases or QC deficiencies in the data on a case-by-case basis, qualified data can represent an additional resource of data for establishing an observed release. Further, the D.C. District Court of Appeals in 1996 upheld EPA's case-by-case approach to assess data quality. In reviewing the use of qualified data to identify an observed release, the Court stated that if there are deficiencies in the data, "...the appropriate response is to review the deficiencies an a 'case-by-case basis' to determine their impact on 'usability of the data.'" The Court also stated with regards to data quality that, "...EPA does not face a standard of absolute perfection .... Rather, it is statutorily required to 'assure, to the maximum extent *feasible*,' that it 'accurately assesses the relative degree of risk' posed by sites" [*Board of Regents of the University of Washington, et al., v. EPA,* No.95-1324, slip op. at 8-10 (D.C. Cir. June 25, 1996).]

As discussed in this fact sheet, the application of adjustment factors to "J" qualified data can serve as a management decision tool to "adjust," or take into account, the analytical uncertainty in the data indicated by the qualifier, thereby making qualified data usable for HRS evaluation. The use of adjustment factors to account for the larger uncertainty in "J" qualified data is a conservative approach enabling a quantitative comparison of the data for use in documenting an observed release. It should be noted that the use of

adjustment factors only addresses analytical variability and does not take into account variabilities which may be introduced during field sampling. Some guidelines for using the adjustment factor approach are discussed in Exhibit 1.

CLP QA/QC PROCEDURES

CLP qualifiers are applied to analytical data based on the results of various Quality Assurance/Quality Control (QA/QC) procedures used at the laboratory. EPA analytical methods use a number of QA/QC mechanisms during sample analysis in order to assess qualitative and quantitative accuracy *(Contract Laboratory Program Statement of Work for Inorganic Analyses,* Document No. ILM02.0; *Contract Laboratory Program Statement of Work for Organic Analyses,* Document No. OLM1.8; *Quality Assurance/Quality Control Samples,* Environmental Response Team Quality Assurance Technical Information Bulletin; *Test Methods for Evaluating Solid Waste (SW-846): Physical and Chemical Methods,* Document No. SW-846). To assess data quality, the laboratory uses matrix spikes, matrix spike duplicates, laboratory control samples , surrogates, blanks, laboratory duplicates, and quarterly blind performance evaluation (PE) samples. The Agency assumes that if biases are found in the QA/QC samples, the field sample concentrations may also be biased.

Surrogates are chemically similar to the analytes of interest. They are added or "spiked" at a known concentration into the field samples before analysis. Also, selected target analytes are "spiked" into samples at a specified frequency to assess potential interferences from the sample matrix. These samples are called matrix spikes. Comparison of the known concentration of the surrogates and matnx spikes with their actual analytical results reflects the analytical accuracy. Because the surrogates are expected to behave similarly to the target analytes, they may indicate bias caused by interferences from the sample matrices. These type of interferences from the sample matrix are known as matrix effects *(CPL National Functional Guidelines for Inorganic Data Review,* Publication, 9240.1-05-01; *CLP National Functional Guidelines for Orgainic Data Review,* Publication 9240.1-05; *Test Methods for Evaluating Solid Waste (SW-846): Physical and Chemical Methods,* Document No. SW-846).

Laboratory control samples are zero blind samples which contain known concentrations of specific analytes and are analyzed in the same batch as field samples. Their results are used to measure laboratory accuracy. Blanks are analyzed to detect any extraneous contamination introduced either in the field or in the laboratory.

Laboratory duplicates are created when one sample undergoes two separate analyses. The duplicate results are compared to determine laboratory precision. Quarterly blind PE samples are single blind samples that evaluate the laboratory's capability of performing the specified analytical protocol.

CLP and other EPA analytical methods include specifications for acceptable analyte identification, target analytes, and minimum and maximum percent recovery of the QA/QC compounds. Data are validated according to guidelines which set performance criteria for instrument calibration, analyte identification, and identification and recovery of QA/QC compounds *(CLP Statement of Work and SW-846).* The *National Functional Guidelines for Data R*eview, EPA validation, was designed for the assessment of data generated under the CLP organic and inorganic analytical protocols *(CLP Statement of Work; National Functional Guidelines for Data Review).* The guidelines do not preclude the validation of field and other non CLP data. Thus, many EPA Regions have also adapted the *National Functional Guidelines for Data Review* to validate non-CLP data. Data which do not meet the guidelines' performance criteria are qualified to indicate bias or QA/QC deficiencies. The data validation report usually explains why the data were qualified and indicates the bias direction when it can be determined. Validated data that are not qualified are considered unbiased and can be used at their reported numerical value for HRS evaluation.

QUALIFIER DEFINITIONS

Most EPA validation guidelines use the data qualifiers presented in Exhibit 2 *(CLP National Functional Guidelines for Data Review).* Other qualifiers besides these may be used; the validation report should always be checked for the exact list of qualifiers and their meanings.

It should be emphasized that not meeting one or some of the contract required QA/QC acceptance criteria is often an indication that the sample was difficult to analyze, not that there is low confidence in the analysis (i.e., the

EXHIBIT 1 GUIDELINES FOR THE USE OF ADJUSTMENT FACTORS
• The use of adjustment factors identified in this fact sheet is a management tool for the optional use of "J" qualified data generated under CLP or other sources of data to document an observed release.
• Adjustment qualified data should be used with non-qualified data whenever possible.
• EPA maintains a "worst sites first" policy for placing sites on the NPL (*Additional Guidance on "Worst Sites" and "NPL Caliber Sites" to assist in SACM Implementation,* OSWER Directive 9320.2-07).
• EPA Regions should use adjustment factors with discretion on a case-by-case basis and should always carefully consider the use of qualified data in borderline cases.
• Resampling and/or reanalysis may be warranted if qualified data do not appear adequate to document an observed release.
• EPA Regions may substitute higher adjustment factors based on documented, justifiable reasons but may never use a lower adjustment factor value.
• The adjustment factors should only be applied to analytes listed in the tables. These adjustment factors should not be interpolated or extrapolated to develop factors for analytes not listed in the tables.
• The adjustment factors apply only to "J" qualified data above the CRQL.
• Detection below the CRQL is treated as non-quantifiable for HRS purposes.
• "UJ" data may be used under strict circumstances as explained in this fact sheet.
• The adjustment factors only apply to biased "J" qualified data, not to other "J" qualified data.
• The adjustment factors do not apply to "N", "NJ", or "R" qualified data. These data can not be used to document an observed release for HRS purposes.

analysis is "under control" and can be adequate for HRS decision making). Often "J", "U", and "UJ" qualified data fall into this category.

There are instances when qualified data cannot be used since the uncertainty of the results is unknown. For example, violations of laboratory instrument calibration and tuning requirements, and gross violations of holding times reflect the possibility that the results are of unknown quality (i.e., the analysis is "out of control"). Most often these data would be qualified with an "R" or an "N" (not usable for HRS purposes).

USING "U" QUALIFIED DATA

The "U" qualifier simply means that the reported concentration of the analyte was at or below the CRQL-- there can be confidence that the true concentration is at or below the quantitation limit. Therefore, "U" qualified data can be used for establishing background levels. If the release sample concentration is above this level, as specified in the HRS, an observed release can be established. The quantitation limit for that analyte could be used as a maximum background concentration if a more conservative background level seems appropriate.

USING "J" QUALIFIED DATA

As discussed previously, some "J" qualified data can be used in establishing an observed release if the uncertainty in the reported values is documented. Qualified data should always be carefully examined by the Regions to determine the reasons for qualification before use in HRS evaluation. Resampling and/or reanalysis may be warranted if qualified data only marginally document an observed release. Whenever possible, qualified data should be used in conjunction with non-qualified data.

As described in Exhibit 2, "J" qualified data indicates that bias has been detected in the sample analysis and although the analyte is definitively present, the reported concentration is an estimate. Depending on the reasons and the direction of bias, with the use of adjustment factors, "J" qualified data can represent data of known and documented quality sufficient for use in establishing an observed release and observed contamination under the HRS.

USING "UJ" QUALIFIED DATA

A combination of the "U" and "J" qualifiers indicates that the reported value may not accurately represent the concentration necessary to positively detect the analyte in the sample. Under limited conditions, "UJ" qualified data can be used to represent background concentrations for establishing an observed release. These conditions are: instances when there is confidence that the background concentration is not detectable above the CRQL, the background concentration is biased high, and the sample measurement establishing the observed release equals or exceeds the CRQL.

DIRECTION OF BIAS IN "J" QUALIFIED DATA

It is important to understand the direction of bias associated with "J" qualified data before using the data to document an observed release. Qualified data may have high, low, or unknown bias. A low bias means that the reported concentration is likely an underestimate of the true concentration. For example, data may be biased low when sample holding times for volatile organic compounds (VOCs) are moderately exceeded or when recovery of QA/QC compounds is significantly less than the amount introduced into the sample. Low surrogate recovery would also indicate a low bias. A high bias means the reported concentration, is likely an overestimate of the true concentration. For example, data may be biased high when recovery of QA/QC compounds is significantly higher than the amount in the sample. A bias is unknown when it is impossible to ascertain whether the concentration is an overestimate or an underestimate. For example, an unknown bias could result when surrogate recoveries exceed method recovery criteria and matrix spike/matrix spike duplicate compounds below method recovery criteria fail the relative percent difference (RPD) criteria in the same sample.

Despite the bias, certain qualified data may be used without application of adjustment factors for determining an observed release under certain circumstances. The following examples are of using "J" qualified data without adjustment factors:

- Low bias release samples are likely to be underestimates of true concentrations. If the reported concentration of a low bias release sample is three times above unbiased background levels, these release samples would still meet the HRS criteria. The true concentrations would still be three times above the background level.

- High bias background samples are likely to be overestimates of true concentrations. If the reported concentration of unbiased release samples are three times above the reported background concentration, they would still meet the HRS observed release criteria because they would still be three times above the true background concentration.

The above examples show that both low bias "J" qualified release samples at their reported concentrations and high bias "J" qualified background samples may be used at their reported concentrations in these situations.

High bias release samples may not be used at their reported concentrations because they are an overestimate of true concentrations in this situation; resampling and/or re-analysis of the release samples should be considered. The true difference in the background and release concentration may be less than the HRS criteria for establishing an observed release. The reported concentration for low bias background concentrations may not be compared to release samples because it is most likely an underestimate of background level; the release sample concentration may not significantly exceed the true background concentration. However, in lieu of re-sampling and/or re-analysis, high bias release data and low bias background data may be used with adjustment factors which compensate for the probable uncertainty in the analyses.

ADJUSTMENT FACTORS FOR BIASED "J" QUALIFIED DATA

Applying adjustment factors to "J" qualified data will enable EPA to be more confident that the increase in contaminant concentrations between the background and

EXHIBIT 2 EPA CLP DATA QUALIFIERS AND THEIR USABILITY FOR DOCUMENTING AN OBSERVED RELEASE	
Usable*	**Not Usable**
"U" The substance or analyte was analyzed for, but no quantifiable concentration was found at or above the CRQL *(CLP National Functional Guidelines for Data Review).*	**"N"** The analysis indicates the presence of an analyte for which there is presumptive evidence to make a "tentative identification" *(CLP National Functional Guidelines for Data Review).*
"J" The analyte was positively identified-the associated numerical value is the approximate concentration of the analyte in the sample. The "J" qualifier indicates that one or more QA/QC requirements have not met contact required acceptance criteria but the instrumentation was functioning properly during the analysis. For example, a "J" qualifier may indicate that the sample was difficult to analyze or that the value may lay near the low end of the linear range of the instrument. "J" data are considered biased, but provide definitive analyte identification *(CLP National Functional Guidelines for Data Review).*	**"R"** The sample results are rejected due to serious deficiencies in the ability to analyze the sample and meet QC criteria. The presence or absence of the analyte can not be verified and the result has been rejected. A sample result may be qualified with an "R" qualifier when the instrument did not remain "in control" or the stability or sensitivity of the instrument were not maintained during the analysis *(CLP National Functional Guidelines for Data Review).*
"UJ" The analyte was not quantifiable at or above the CRQL. In addition to not being quantifiable, one or more QA/QC requirements have not met contract acceptance criteria *(CLP Functional Guidelines for Data Review).*	**"NJ"** The analysis indicates the presence of the analyte that has een "tentatively identified" and the associated numerical value represents it's approximate concentration (CLP *National Functional Guidelines for Data Review).*

* Usable under certain circumstances as explained in this fact sheet.

release samples is due to a release. The adjustment factors are applied as "safety factors" to compensate for analytical uncertainty, allowing biased data to be used for determining an observed release. Dividing the high bias result by an adjustment factor deflates it from the high end of the acceptable range towards a low bias value. Multiplying a low bias concentration by an adjustment factor inflates it to the high end of the acceptable range.

Tables 1 through 4 (pages 11 - 18) present analyte and matrix-specific adjustment factors to address the analytical uncertainty when determining an observed release using high bias release samples and low bias background data. The factors am derived from percent recoveries of matrix spikes, surrogates, and laboratory control samples in the CLP Analytical. Results Database (CARD) from January 1991 to March 1996. A total of 32,447 samples were reviewed for volatile organic analytes; 32,913 samples for semivolatile organic analytes; 59,508 samples for pesticides/PCB analytes; and 5,954 samples for inorganic analytes.

The range of CARD data for each analyte includes 97 percent of all percent recoveries in the database, discarding outliers. The adjustment factors are ratios of percent recovery values at the 98.5 and 1.5 percentiles. The ratios generally show a consistent pattern.

Adjustment factors have been determined for all analytes in the CLP Target Compound List (organic analytes) and Target Analyte List (inorganic analytes). A tiered approach was used to derive the organic adjustment factors. Percent recoveries for surrogates were

examined first, followed by matrix spike recoveries. When both matrix spike and surrogate data were available for the same analyte, the larger adjustment factor (representing more extreme high and low percent recoveries) was used. Laboratory control samples were used to calculate the inorganic adjustment factors. Quarterly blind sample data were not used to determine adjustment factors because of the small data set available. A default adjustment factor of 10 was used for analytes when percent recovery data were unavailable.

Adjustment factors do not correct the biased sample concentration to its true value, as such "correction" is not possible. CARD data do not differentiate and quantify individual sources of variation. Instead, the ratio of percentile used to develop adjustment factors represent a "worst-case" scenario. Adjustment factors either inflate background values to the high end of the range or deflate release data to the low end. Therefore, adjustment factors compensate or adjust for the apparent analytical variability when comparing a high bias value to a low bias value (see Exhibit 3).

USING THE ADJUSTMENT FACTORS

This section of the fact sheet demonstrates how adjustment factors can be used with "J" qualified data for HRS scoring purposes, including documentation and detection limit issues.

Documentation Requirements for Using Qualified Data

In using "J" qualified data to determine an observed release, include a discussion of "J" qualifiers from the data validation report and cite it as a reference in the site assessment report or HRS documentation record. If adjustment factors are applied to "J" qualified data, reference and cite this fact sheet. These steps will ensure that the direction of bias is documented and will demonstrate how biases have been adjusted.

Detection Limit Restrictions

Adjustment factors may only be applied to "J" qualified data with concentrations above the CLP CRQL for organics or CRDL for inorganics. "J" qualified data with concentrations below the CRQL can not be used to document an observed release except as specified in the previous section entitled "Using "UJ" Qualified Data."

Application of Factors

Exhibit 3 shows how to apply the factors to "J" qualified data. Multiply low bias background sample results by the analyte-specific adjustment factor or the default factor 10 when analyte-specific adjustment factor is not available. The resulting new background value effective becomes a high bias value that may be used to determine an observed release. Divide high bias release sample data by the analyte-specific adjustment factor or the default factor of 10 when an analyte-specific adjustment factor is not available. The resulting new release sample value effectively becomes a low bias value that may be used to determine an observed release.

Note: High bias background data, low bias release data, and unbiased data may be used at their reported concentrations.

Note: Adjusted release and background values must still meet HRS criteria (e.g., release concentration must be at, least three times above background level) to determine an observed release.

Examples Using Trichloroethene in Soil and Water

1. *Release water sample is unbiased, background water sample is unbiased but all data are qualified with a "J" due to an contractual laboratory error no: analytical error.*

Background sample value: 12 μg/L (J) *no bias*
Release sample value: 40 μg/L (J) *no bias*

The CRQL for trichloroethene is 10 μg/Kg for soil and 10 μg/L for water.

In this example, the qualification of the data is not related to bias in the reported concentrations. Thus, using adjustment factors is not needed and an observed release is established if all other criteria are met.

2. *Release soil sample data is biased low, background soil sample data is biased high.*

Background sample value: 12 μg/Kg (J) high bias
Release sample value: 40 μg/Kg (J) low bias

In this example, the direction of bias indicates that the. true release value may be higher and the true background value may be lower than reported values. The release sample concentration still exceeds background by more than three times, so an observed release is established, provided all other HRS criteria are met. Using adjustment factors is not needed.

EXHIBIT 3 USE OF ADJUSTMENT FACTORS FOR "J" QUALIFIED DATA		
Type of Sample	**Type of Bias**	**Action Required**
Background Sample	No Bias	None: Use concentration without factor
	Low Bias	Multiply concentration by factor
	High Bias	None: Use concentration without factor
	Unknown Bias	Multiply concentration by factor
Release Sample	No Bias	None: Use concentration without factor
	Low Bias	None: Use concentration without factor
	High Bias	Divide concentration by factor
	Unknown Bias	Divide concentration by factor

3. *Release soil sample data is unbiased, background soil sample is biased low.*

Background sample value: 12 μg/Kg (J) *low bias*
Release sample value: 30 μg/Kg *no bias*

In this example, the true background value is assumed to be less than the reported value; however, an observed release may still be possible. To use the data to establish an observed release, multiply the background sample data value by the adjustment factor given for trichloroethene in soil (2.11). No adjustment factor is needed for the release sample.

New background sample value:
(12 μg/Kg) x (2.11) = 25.32 μg/Kg (J) *high bias*

The release sample concentration does not meet or exceed the new background level by three time, so an observed release is not established.

4. *Release water sample data is biased high, background water sample data is unbiased.*

Background sample value: 15 μg/L *no bias*
Release sample value: 70 μg/L (J) *high bias*

In this example, the true release value may be lower than the reported value; however, an observed release may still be possible. To use the data to establish an observed release divide the release sample by the adjustment factor for trichloroethene in water (1.66). No adjustment factor is needed for the background sample.

New release sample value:
(70 μg/L) ÷ (1.66) = 42.17 μg/L (J) *low bias*

The new release sample concentration does not meet or exceed the background level by three times, so an observed release is not established.

5. *Release soil sample data has unknown bias; background soil sample data has unknown bias.*

The following example is the most conservative approach to using adjustment factors with qualified data.

Background sample value: 20 μg/Kg (J) *unknown bias*
Release sample value: 325 μg/Kg (J) *unknown bias*

In this example, it is not possible to determine from the reported values if an observed release is possible. To use the data to establish an observed release, divide the release sample value and multiply the background sample value by the adjustment factor given for trichloroethene in soil (2.11).

New release sample value:
(325 μg/Kg) ÷ (2.11) = 154.03 μg/Kg (J) *low bias*

New background sample value:
(20 μg/Kg) x (2. 11) = 42.2 μg/Kg (J) *high bias*

The new release sample is at least three times the new background concentration, so an observed release is established, provided all other HRS criteria are met.

ISSUES WITH USING ADJUSTMENT FACTOR APPROACH

Some issues were raised regarding the application of adjustment factors to qualified data during the Agency's internal review process.

One issue is that "J" qualifiers are added to analytical results for many reasons that may or may not affect the accuracy and precision of the analytical result. The application of an adjustment factor to "J" qualified data in which bias is not affected could be considered overly conservative.

All qualified data should be carefully evaluated to determine if the data are biased. Based on the reasons for bias, the use of an adjustment factor should only be considered as a management tool that provides a quick screening of the data for site assessment, not a means for correcting the biased value to a true value. Application of adjustment factors are intended for use with qualified data reported at or above the CRQL and may not be applicable to data which are qualified but technically sound. As stated previously, qualified data should always be carefully reviewed on a case-by-case basis prior to use in HRS evaluation.

Another issue is the validity of "10" as a default adjustment factor. A default adjustment factor of 10 was a policy decision based on the range of adjustment factors and an industry approach. The default was chosen in order to account for the maximum variability regardless of the direction of the bias. Therefore, the default value of 10 is generally considered to be a conservative adjustment factor. EPA reviewed the use of the default value of 10 and determined that this value was conservative.

Even if using adjustment factors is sometimes overly conservative, this approach is preferable to not using the data at all. EPA maintains a "worst sites first" policy that only the sites considered most harmful to human health and/or the environment should be listed. EPA considers the use of adjustment factors appropriate as a management decision tool. However, discretion is needed when applying adjustment factors. The use of adjustment factors may not be appropriate in all cases.

USE OF OTHER ADJUSTMENT FACTORS

EPA Regions may substitute higher, but never lower, adjustment factor values for the ones listed in this fact sheet on a case-by-case basis when technically justified. For example, other adjustment factors may be applied to conform with site-specific Data Quality Objectives (DQOs) or with Regional Standard Operating Procedures (SOPs) *(Data Quality Objectives Process for Superfund, Publication 9355.9-01).*

SUMMARY

For site assessment purposes, EPA Regions should not automatically discard "J" qualified data. However, site-specific data usability determinations may result in the data's not being used.

Data qualified under the EPA's CLP or from other sources of validated data may be used to demonstrate an observed release if certain measures are taken to ensure that the bias of the data qualifier is adjusted using the factor approach specified in this fact sheet. (This fact sheet provides a management decision tool for making qualified data usable for documenting an observed release.) The analyte and matrix-specific adjustment factors provided in Tables 1 through 4 of this fact sheet present these adjustment factors.

The scope of this fact sheet is limited to the situations described in Exhibit 1. The use of qualified analytical data without the adjustment factors presented in this fact sheet is limited. Higher adjustment factors may be substituted by EPA Regions on a case-by-case basis when technically justified by site-specific DQOs or SOPS.

REFERENCES

1. U.S. Government Printing Office, *Federal Register,* Part 11, Environmental Protection Agency, 40 CFR Part 300, Hazard Ranking System, Final Rule, December 14, 1990.

2. U.S. Environmental Protection Agency, *Hazard Ranking System Guidance Manual*, Office of Solid Waste and Emergency Response, PB92-963377, November 1992.

3. U.S. Environmental Protection Agency, 1995. *Establishing an Observed Release.* Office of Emergency and Remedial Response. PB94-963314.

4. U.S. Environmental Protection Agency, 1995. *Establishing Areas of Observed Contamination.* Office of Emergency and Remedial Response. PB94-963312.

5. U.S. Environmental Protection Agency, 1995. *Establishing Background Levels.* Office of Emergency and Remedial Response. PB94-963313.

6. U.S. Environmental Protection Agency, 1994. *CLP National Functional Guidelines for Inorganic Data Review.* Office of Solid Waste and Emergency Response. Publication 9240.1-05.

7. U.S. Environmental Protection Agency, 1993. *CLP National Functional Guidelines for Organic Data Review.* Office of Solid Waste and Emergency Response. Publication 9240.1-05.

8. U.S. Environmental Protection Agency, 1991. *Contract Laboratory Program Statement of Work for Inorganic Analysis.* Document No. ILM02.0.

9. U.S. Environmental Protection Agency, 1991. *Contract Laboratory Program Statement of Work for Organic Analysis.* Document No. OLM1.8.

10. U.S. Environmental Protection Agency, 1993. *Additional Guidance on "Worst Sites" and "NPL Caliber Sites" to Assist in SACM Implementation.* Office of Emergency and Remedial Response. PB94-963206.

11. *Board of Regents of the University of Washington, et al., v. EPA,* No. 95-1324, slip op. at 10 (D.C. Cir. June 25, 1996). 10.

12. U.S. Environmental Protection Agency, 1991. *Guidance for Performing Preliminary Assessments Under CERCLA.* Office of Solid Waste and Emergency Response. Publication 9345.0-01-A.

13. U.S. Environmental Protection Agency, 1992. *Guidance for Performing Site Inspections Under CERCLA.* Office of Solid Waste and Emergency Response. PB92-963375.

14. U.S. Environmental Protection Agency, 1992. *Quality Assurance/Quality Control Samples.* Environmental Response Team Quality Assurance Technical Information Bulletin.

15. U.S. Environmental Protection Agency, 1986. *Test Methods for Evaluating Solid Waste (SW-846): Physical and Chemical Methods.* Office of Solid Waste and Emergency Response. Document No. SW-846.

16. U.S. Environmental Protection Agency, 1993. *Data Quality Objectives Process for Superfund.* Office of Emergency and Remedial Response Publication 9355.9-01.

TABLE 1 FACTORS FOR VOLATILE ORGANIC ANALYTES				
VOLATILE ORGANIC ANALYTES	SOIL MATRIX		WATER MATRIX	
	Number of CARD Samples Reviewed	Factor	Number of CARD Samples Reviewed	Factor
1,1,1-TRICHLOROETHANE	---	10.0	---	10.0
1,1,2,2-TETRACHLOROETHANE	---	10.0	---	10.0
1,1,2-TRICHLOROETHANE	---	10.0	---	10.0
1,1-DICHLOROETHANE	---	10.0	---	10.0
1,1-DICHLOROETHENE	7,031	2.71	5,015	2.35
1,2-DICHLOROETHANE-D4	32,446	1.52	25,516	1.38
1,2-DICLOROETHENE (TOTAL)	---	10.0	---	10.0
1,2-DICHLOROPROPANE	---	10.0	---	10.0
2-BUTANONE	---	10.0	---	10.0
2-HEXANONE	---	10.0	---	10.0
4-METHYL-2-PENTANONE	---	10.0	---	10.0
ACETONE	---	10.0	---	10.0
BENZENE	7,024	1.97	5,001	1.64
BROMODICHLOROMETHANE	---	10.0	--	10.0
BROMOFORM	---	10.0	---	10.0
BROMOFLUOROBENZENE	32,444	1.7	25,518	1.26
BROMOMETHANE	---	10.0	---	10.0
CARBON DISULFIDE	---	10.0	---	10.0

TABLE 1 FACTORS FOR VOLATILE ORGANIC ANALYTES				
VOLATILE ORGANIC ANALYTES	SOIL MATRIX		WATER MATRIX	
	Number of CARD Samples Reviewed	Factor	Number of CARD Samples Reviewed	Factor
CARBON TETRACHLORIDE	---	10.0	---	10.0
CHLOROBENZENE	7,018	2.0	5,015	1.54
CHLOROETHANE	---	10.0	---	10.0
CHLOROFORM	---	10.0	---	10.0
CHLOROMETHANE	---	10.0	---	10.0
CIS-1,3-DICHLOROPROPENE	---	10.0	---	10.0
DIBROMOCHLOROMETHANE	---	10.0	---	10.0
ETHYLBENZENE	---	10.0	---	10.0
METHYLENE CHLORIDE	---	10.0	---	10.0
STYRENE	---	10.0	---	10.0
TETRACHLOROETHENE	---	10.0	---	10.0
TOLUENE-D8	32,447	1.63	25,526	1.21
TRANS-1,3-DICHLOROPROPENE	---	10.0	---	10.0
TRICHLOROETHENE	6,988	2.11	4,938	1.66
VINYL CHLORIDE	---	10.0	---	10.0
XYLENE (TOTAL)	---	10.0	---	10.0

TABLE 2 FACTORS FOR SEMIVOLATILE ORGANIC ANALYTES				
	SOIL MATRIX		WATER MATRIX	
SEMIVOLATILE ORGANIC ANALYTES	Number of CARD sample Reviewed	Factor	Number of CARD Samples Reviewed	Factor
1,2,4-TRICHLOROBENZENE	6,792	4.83	4,605	3.71
1,2-DICHLOROBENZENE-D4	32,848	4.22	21,506	3.0
1,3-DICHLOROBENZENE	---	10.0	---	10.0
1,4-DICHLOROBENZENE	6,796	6.0	4,599	3.85
2,2'-OXYBIS(1-CHLOROPROPANE)	---	10.0	---	10.0
2,4,6-TRIBROMOPHENOL	32,605	9.38	21,509	3.57
2,4,5-TRICHLOROPHENOL	---	10.0	---	10.0
2,4,6-TRICHLOROPHENOL	---	10.0	---	10.0
2,4-DICHLOROPHENOL	---	10.0	---	10.0
2,4-DIMEHYLPHENOL	---	10.0	---	10.0
2,4-DINITROPHENOL	---	10.0	---	10.0
2,4-DINITROTOLUENE	6,798	4.88	4,623	3.52
2,6-DINITROTOLUENE	---	10.0	---	10.0
2-CHLORONAPHTHALENE	---	10.0	---	10.0
2-CHLOROPHENOL-D4	32,798	4.08	21,506	2.92
2-FLUOROBIPHENYL	32,913	3.38	21,532	2.84
2-FLUORPHENOL	32,781	5.05	21,511	3.34
2-METHYLNAPHTHALENE	---	10.0	---	10.0
2-METHYLPHENOL	---	10.0	---	10.0
2-NITROANILINE	---	10.0	---	10.0
2-NITROPHENOL	---	10.0	---	10.0
3,3'-DICHLOROBENZIDINE	---	10.0	---	10.0
3-NITROANILINE	---	10.0	---	10.0
4,6-DINITRO-2-METHYLPHENOL	---	10.0	---	10.0
4-BROMOPHENYL-PHENYETHER	---	10.0	---	10.0

TABLE 2 FACTORS FOR SEMIVOLATILE ORGANIC ANALYTES				
	SOIL MATRIX		WATER MATRIX	
SEMIVOLATILE ORGANIC ANALYTES	Number of CARD Sample Reviewed	Factor	Number of CARD Samples Reviewed	Factor
4-CHLORO-3-METHYLPHENOL	6,715	6.26	4,609	4.46
4-CHLOROANILINE	---	10.0	---	10.0
4-CHLOROPHENYL-PHENYLETHER	---	10.0	---	10.0
4-METHYLPHENOL	---	10.0	---	10.0
4-NITROANILINE	---	10.0	---	10.0
4-NITROPHENOL	6,627	9.33	4,586	5.96
ACENAPHTHENE	6,773	4.68	4,600	3.63
ACENAPHTHYLENE	---	10.0	---	10.0
ANTHRACENE	---	10.0	---	10.0
BENZO(A)ANTHRACENE	---	10.0	---	10.0
BENZO(A)PYRENE	---	10.0	---	10.0
BENZO(B)FLUORANTHENE	---	10.0	---	10.0
BENZO(G,H,I,)PERYLENE	---	10.0	---	10.0
BENZO(K)FLUORANTHENE	---	10.0	---	10.0
BIS(2-CHLOROETHOXY)METHANE	---	10.0	---	10.0
BIS(2-CHLOROETHYL)ETHER	---	10.0	---	10.0
BIS(2-ETHYLHEXYL)PHTHALATE	---	10.0	---	10.0
BUTYLBENZYLPHTHALATE	---	10.0	---	10.0
CARBAZOLE	---	10.0	---	10.0
CHRYSENE	---	10.0	---	10.0
DI-N-BUTYLPHTHALATE	---	10.0	---	10.0
DI-N-OCTYLPHTHALATE	---	10.0	---	10.0
DIBENZ(A,H)ANTHRACENE	---	10.0	---	10.0
DIBENZOFURAN	---	10.0	---	10.0
DIETHYLPHTHALATE	---	10.0	---	10.0

TABLE 2 FACTORS FOR SEMIVOLATILE ORGANIC ANALYTES				
SEMIVOLATILE ORGANIC ANALYTES	SOIL MATRIX		WATER MATRIX	
	Number of CARD Sample Reviewed	Factor	Number of CARD Samples Reviewed	Factor
DIMETHYLPHTHALATE	—	10.0	---	10.0
FLUORANTHENE	---	10.0	---	10.0
FLUORENE	---	10.0	---	10.0
HEXACHLOROBENZENE	---	10.0	---	10.0
HEXACHLOROBUTADIENE	---	10.0	--	10.0
HEXACHLOROCYCLOPENTADIENE	---	10.0	---	10.0
HEXACHLOROETHANE	---	10.0	---	10.0
INDENO(1,2,3-CD)PYRENE	---	10.0	---	10.0
ISOPHORONE	---	10.0	---	10.0
N-NITROSO-DI-N-PROPYLAMINE	6,725	4.92	4,513	4.0
N-NITROSODIPHENYLAMINE(1)	---	10.0	---	10.0
NAPHTHALENE	---	10.0	--	10.0
NITROBENZENE-D5	32,867	3.96	21,533	2.73
PENTACHLOROPHENOL	6,597	72.5	4,550	10.12
PHENANTHRENE	---	10.0	---	10.
PHENOL-D5	32,855	3.85	21,489	3.53
PYRENE	6,543	11.86	4,612	5.67
TERPHENYL-D14	32,899	4.35	21,541	6.32

TABLE 3 FACTORS FOR PESTICIDES/PCB ANALTYES				
VOLATILE ORGANIC ANALYTES	SOIL MATRIX		WATER MATRIX	
	Number of CARD Samples Reviewed	Factor	Number of CARD Samples Reviewed	Factor
4,4'-DDD	---	10.0	---	10.0
4,4'-DDE	---	10.0	---	10.0
4,4'-DDT	5,343	12.82	3,850	7.14
ALDRIN	5,526	14.26	3,829	6.63
ALPHA-BHC	---	10.0	---	10.0
ALPHA-CHLORDANE	---	10.0	---	10.0
AROCLOR-1016	---	10.0	---	10.0
AROCLOR-1221	---	10.0	---	10.0
AROCLOR-1232	---	10.0	---	10.0
AROCLOR-1242	---	10.0	---	10.0
AROCLOR-1248	---	10.0	---	10.0
AROCLOR-1254	---	10.0	---	10.0
AROCLOR-1260	---	10.0	---	10.0
BETA-BHC	---	10.0	---	10.0
DECACHLOROBIPHENYL	57,315	17.79	33,592	10.0
DELTA-BHC	---	10.0	---	10.0
DIELDRIN	5,539	11.93	3,861	4.87

TABLE 3 FACTORS FOR PESTICIDES/PCB ANALYTES				
VOLATILE ORGANIC ANALYTES	SOIL MATRIX		WATER MATRIX	
	Number of CARD Samples Reviewed	Factor	Number of CARD Samples Reviewed	Factor
ENDOSULFAN I	—	10.0	---	10.0
ENDOSULFAN II	—	10.0	---	10.0
ENDOSULFAN SULFATE	---	10.0	---	10.0
ENDRIN	5,521	14.13	3,850	5.33
ENDRIN ALDEHYDE	---	10.0	---	10.0
ENDRIN KETONE	---	10.0	---	10.0
GAMMA-BHC (LINDANE)	5,545	11.79	3,832	10.0
GAMMA-CHLORDANE	---	10.0	---	10.0
HEPTACHLOR	5,548	7.88	3,836	5.26
HEPTACHLOR EPOXIDE	---	10.0	---	10.0
METHOXYCHLOR	---	10.0	---	10.0
TETRACHLORO-M-XYLENE	59,508	8.5	33,787	5.29
TOXAPHENE	---	10.0	---	10.0

TABLE 4 FACTORS FOR INORGANIC ANALYTES				
VOLATILE ORGANIC ANALYTES	SOIL MATRIX		WATER MATRIX	
	Number of CARD Samples Reviewed	Factor	Number of CARD Samples Reviewed	Factor
ALUMINUM	5387	1.66	6208	1.30
ANTIMONY	5392	1.98	6170	1.27
ARSENIC	5675	1.74	6303	1.35
BARIUM	5360	3.99	6201	1.25
BERYLLIUM	5399	1.28	6208	1.25
CADMIUM	5385	1.41	6166	1.29
CALCIUM	5383	1.28	6201	1.24
CHROMIUM	5389	1.29	6210	1.30
COBALT	5392	1.25	6212	1.27
COPPER	5394	1.22	6205	1.25
CYANIDE	3281	1.55	225	1.36
IRON	5391	1.34	6216	1.27
LEAD	5982	1.44	6384	1.31
MAGNESIUM	5397	1.23	6210	1.24
MANGANESE	5395	1.24	6214	1.28
MERCURY	5954	1.83	256	1.50
NICKEL	5400	1.35	6210	1.29
POTASSIUM	3874	17.49	6175	1.24
SELENIUM	5620	2.38	6278	1.14
SILVER	5392	1.74	6215	1.42
SODIUM	5024	25.43	6195	1.26
THALLIUM	5621	1.86	6253	1.37
VANADIUM	5393	1.34	6212	1.25
ZINC	5404	1.50	6224	1.29