HRS Training:
Updates in Use of Qualified Data in HRS Evaluations

September 28, 2023

Overview

→ Original 1996 Fact Sheet

→ Revised 2022 Fact Sheet

→ Default Adjustment Factor

→ UJ Data

→ Possible Future Updates

Qualified Data Fact Sheet Limitation

ONLY APPLIES TO HRS SCORING EVALUATIONS

The HRS is:

- Hazard Ranking System.
- Numeric scoring system using info from initial limited site investigations.
- Primary tool that EPA uses to determine if site warrants placement on the National Priorities List (Superfund).

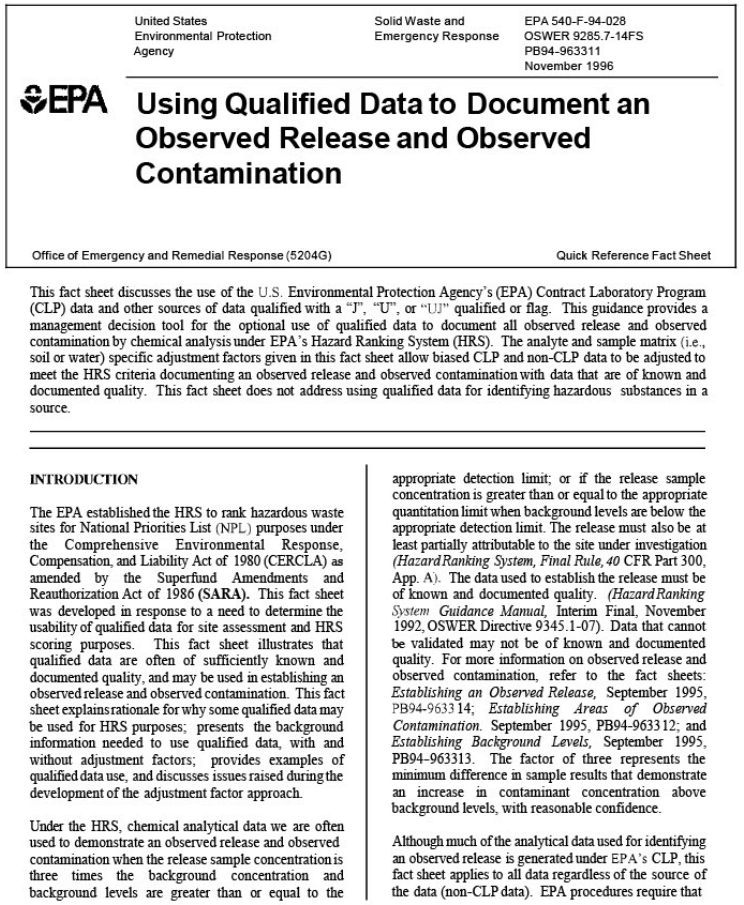
How Does the HRS Work?

The VERY rough and oversimplified workings of the HRS:

- Evaluates point-based scoring factors to produce a site score.
- If the score exceeds a threshold, the site is eligible for Superfund.
- Scoring factors are assigned points based on various site characteristics:
  - How many humans or sensitive environments may be affected?
  - How much waste in sources of contamination at a site?
  - How toxic/mobile/persistent/etc. are the contaminants?
  - Has contamination escaped into the environment (into water, soil, air)?
- Last factor above is documented by documenting an "observed release."
  - Includes comparison of background results to release/contaminated results.
  - If there is a significant difference → observed release.

Original 1996 Fact Sheet

- Used by EPA Regions as an approach to treat qualified analytical data in HRS site evaluations.
- Cited as a reference to support use of qualified data in HRS scoring package.
- Applied to qualified data from CLP and non-CLP labs in HRS evaluations (background and observed release samples in water and soil).



United States Environmental Protection Agency | Solid Waste and Emergency Response | EPA 540-F-94-028 OSWER 9285.7-14FS PB94-963311 November 1996

EPA

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

Original 1996 Fact Sheet

Recap on basics:

- Factors used to adjust qualified results.
- Adjustment factors listed in fact sheet.
  - Analyte-specific.
  - Matrix-specific (currently soil, water).
- Used where release/contaminated results compared to background.

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

Original 1996 Fact Sheet

Recap on basics - adjustment factors general information:

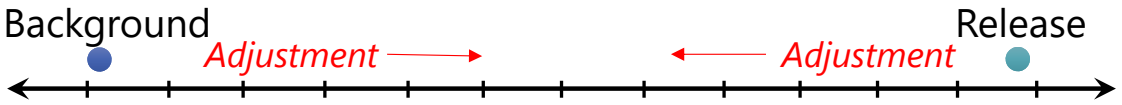
- Developed for high, low, and unknown biased data.
- Developed as **management tool to address analytical uncertainty** in data indicated by analytical data qualifier.
- Developed using the **percent recovery range** of matrix spikes, surrogates, and laboratory control samples from a large CLP data set.
- **Represent ratio of upper and lower bounds of anticipated QA/QC performance** for each analyte, based on range of quality control % recovery data used to generate them.

Original 1996 Fact Sheet

Recap on basics:

- Adjustments only in direction reducing gap between background and release:
  - Low biased background results adjusted up.
  - High biased release results adjusted down.

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



Original 1996 Fact Sheet

Recap on basics:

- Dividing high biased release result by adjustment factor deflates it from high end of performance bounds toward low end.
  - →Projected minimum release result
- Multiplying low biased background concentration by adjustment factor inflates it from low end of bounds toward high end.
  - → Projected maximum background result

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

Original 1996 Fact Sheet

Recap on basics:

- Used where J-flagged data involves quantitative comparison of contaminated sample result to background level, for:
  - observed release
  - observed contamination
  - source data (if compared to background to show relative increase)

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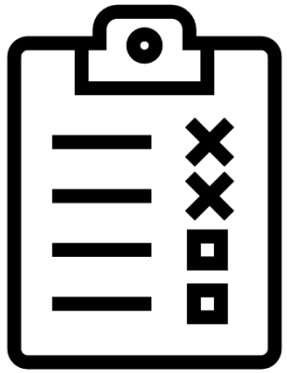
	Low Bias	None: Use concentration without factor
	High Bias	Divide concentration by factor
	Unknown Bias	Divide concentration by factor

Original 1996 Fact Sheet

Knowledge check example 1:

- Background soil sample TCE value: 12 µg/kg J+ high bias.
- Release soil sample TCE value: 40 µg/kg J- low bias.



? Should results be adjusted?

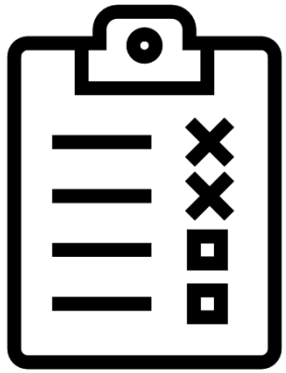
X Background is already biased high, no adjustment needed

X Release is already biased low, no adjustment needed

Original 1996 Fact Sheet

Knowledge check example 2:

- Background soil sample TCE value: 12 µg/kg J- low bias.
- Release soil sample TCE value: 30 µg/kg no bias.



? Should results be adjusted?

TCE soil adjustment factor

Estimated maximum

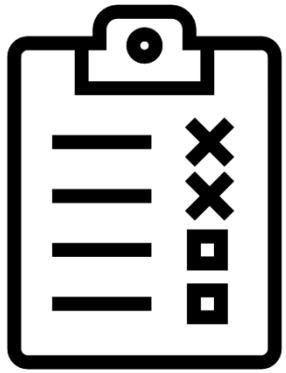
✔ Background is low biased, adjustment needed 12µg/kg × 2.11 = 25.32µg/kg

✗ Release is not biased, no adjustment needed

Original 1996 Fact Sheet

Knowledge check example 3:

- Background water sample TCE value: 15 µg/L no bias.
- Release water sample value: 70 µg/L J+ high bias.



TCE water adjustment factor

Estimated minimum

? Should results be adjusted?

✔ Release is high biased, adjustment needed 70µg/L ÷ 1.66 = 42.16µg/L

✗ Background is not biased, no adjustment needed

Original 1996 Fact Sheet

Adjustment factor limitations:

- ✓ Blunt tool to roughly compensate for bias in sample results.
- ✓ Intended to generate projected ESTIMATED minimum release/maximum background value for HRS scoring.
- ✓ Apply to identifying observed release/contamination/exposure or source contamination.
- ! Not correction of qualified result to “true” value.
- ! Adjusted value not a new “final” value or replacement for laboratory result. Exists only in HRS documentation record.
- ! Do not apply outside of an HRS evaluation.

Revised 2022 Fact Sheet

Revised 2022 Fact Sheet Technical/editorial Changes to Factsheet

- Updated reference citations
- Updated qualified data flag definitions
- Technical statement corrections
  - Detections below CRQL
  - Adjustment factors
- Approach clarification
  - Default of 10
  - UJ qualified data

Using Qualified Data to Document an Observed Release and Observed Contamination

EPA

Directive 9285.7-89FS | Office of Superfund Remediation and Technology Innovation | November 2022

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" qualifier or flag. This new fact sheet supersedes the existing 1996 fact sheet, Using Qualified Data to Document an Observed Release and Observed Contamination (OSWER 9285.7-14FS). This guidance provides a management decision tool for the optional use of qualified data to document observed release and observed contamination by chemical analysis under EPA's Hazard Ranking System (HRS)[1]. 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. Hereafter, throughout the fact sheet, "observed release" will generally refer to both observed release and observed contamination.[2]

INTRODUCTION

The EPA established the HRS to rank hazardous waste sites for National Priorities List 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. This fact sheet explains the 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 are often used to demonstrate an observed release 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; *Establishing Areas of Observed Contamination*. September 1995; and *Establishing Background Levels,* September 1995. The factor of three represents the minimum difference in sample results that demonstrate an increase in contaminant concentration above background levels, with reasonable confidence.

Revised 2022 Fact Sheet

- **Updates**: Out-of-date reference citations (e.g., CLP methods and national functional guidelines).
- **Updates**: Qualified data flag definitions based on current CLP guidelines.
- **Correction**: Results detected between DL and QL are usable (typically as background).
- **Clarification**: Results qualified only due to result between DL and QL = no-bias situations.
- **Clarification**: Adjustment factors may be used for results qualified due to field QC failure.
- **Clarification**: Adjustment factors can be applied to source data if compared to background to show relative increase in site-related contaminants.

Default Adjustment Factor

Default of 10

Default Adjustment Factor – Original Fact Sheet

In the original fact sheet:

- Historical % recovery data used to determine each factor.
- Default adjustment factor of 10 used for analytes when percent recovery data unavailable.
  - 10 generally considered conservative value.
  - 10 listed in factor tables for specific substances.
- Instructed using default factor 10 when analyte-specific adjustment factor not available.

→But, other cases not clear.

Default Adjustment Factor – Revised Fact Sheet

Revised fact sheet approach:

- Default 10 may be applied where analyte-specific adjustment factor not available in fact sheet tables.
- Can be used for:
  - Analytes not listed (e.g., dioxins/furans, PFAS)
  - Analytical methods not covered (e.g., methods other than CLP methods used to develop adjustment factors)
  - Matrices not listed (e.g., gaseous/air samples)

UJ Data

Useable UJs!

UJ Data – UJ Refresher

- **Typical** UJ (**under CLP/NFG**) is a prospective background sample result.
- Typical UJs begin as non-detect (<DL).
- Lab reports result as U-flagged with SQL.
- QC failures imply low bias may be associated with result.
- Validator changes U to UJ to reflect issue.
- In rare cases, UJ flag can have other meanings.

UJ Data – Original Fact Sheet

In the original factsheet:

- UJ results not generally usable or adjustable.
- UJ **only** usable if all apply:
  - Confidence that UJ background concentration not detectable above CRQL.
  - UJ background concentration biased high.
  - Sample measurement establishing observed release equals or exceeds CRQL.

→ But, typical UJ results always fail 2nd criterion (and 1st criterion vague).

→ Lack of UJ usability caused issues in past, sometimes eliminating too many prospective background results from consideration.

UJ Data – Revised Fact Sheet

Revised fact sheet approach:

- Language added to describe typical UJ.
- Allows unadjusted use of typical UJ result.
- Rationale: Though some low bias may be associated with original measurement, non-detected result represents measurement below DL; there is typically a significant spread between DL and QL (often factor of 3 or more).
- Therefore, treat UJ result as non-detect for HRS purposes.

UJ Data – Revised Fact Sheet

Revised fact sheet application:

- UJ-qualified data should be used as part of data pool considered for establishing background levels.
- **If QL available** (SQL, or CRQL for CLP data):
  - Treat UJ qualified result as normal non-detected result.
  - Use QL in determining observed release criteria.
- **If QL not available**:
  - Use DL (e.g., sample-specific MDL).
  - Multiply DL x 3 to generate surrogate QL for use in determining observed release criteria.

UJ Data – UJ Presentation in HRS Documentation Record

- In data table footnotes:
  - Define UJ qualifier.
  - Define associated bias.
  - Ensure associated limit defined as QL or DL.

UJ Data – UJ Presentation in HRS Documentation Record

- In data tables, present original result with post-fact sheet result in parentheses. E.g.:
  - If original result “3 UJ”, and 3 is SQL,

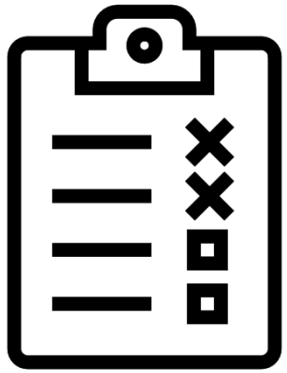
    →present “3 UJ (3 U)”.
  - If original result “3 UJ”, 3 is DL (SQL not available),

    →present “3 UJ (9 U)”.

UJ Data – Revised Fact Sheet

Knowledge check example 4:

- Background sample value: 12 µg/kg UJ.
  - Low bias.
  - SQL = 12 µg/kg.
- Release sample value: 30 µg/kg no bias.



? How should the UJ be treated?

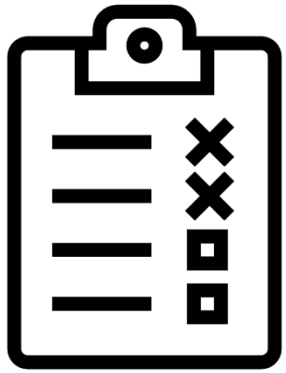
✔ Typical low-bias UJ, therefore UJ treated as non-detect

✔ SQL is available, result presented as 12µg/kg UJ (12µg/kg U)

UJ Data – Revised Fact Sheet

Knowledge check example 5:

- Background sample value: 3 µg/kg UJ.
  - Low bias.
  - MDL = 3 µg/kg.
- Release sample value: 30 µg/kg no bias.



? How should the UJ be treated?

✔ Typical low-bias UJ, therefore UJ treated as non-detect

✔ SQL not available, result presented as 3µg/kg UJ (9µg/kg U)

Possible Future Updates

Possible Future Updates

- Gaseous/air matrix.
  - Currently available default 10 is conservative.
  - Gaseous/air-specific adjustment factors may be developed.
- Soil and water matrices.
  - Existing adjustment factors may be reevaluated based on more current lab data.
  - May or may not result in changes to analyte-specific adjustment factors.