



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

REPLY TO THE ATTENTION OF:

Date: May 8, 1998

Subject: Region 5 Policy and Guidance Regarding Historical Data Usage in the RCRA Facility Investigation

From: Norman R. Niedergang, Director
Waste, Pesticides and Toxics Division

To: All Staff Managing Corrective Action Projects

A RCRA facility investigation (RFI) is a process where data is generated and evaluated in order to determine the nature and extent of releases of hazardous constituents at a facility subject to RCRA corrective action. Facilities often propose utilization of sampling data which was obtained prior to the RFI work plan being finalized to meet some (or all) of the RFI objectives. It is Region 5's policy to utilize such "historical data" in meeting RFI objectives to the extent the quality of the data permits its use.

The purpose of this memo is to provide a policy on the acceptability and use of historical data relative to corrective action decision making. [For purposes of this memo, historical data is defined as any analytical data obtained and/or analyzed under conditions other than specified in an approved RFI quality assurance project plan (QAPP).] The attached guidance must be given to the facility, and it must be utilized by the U.S. EPA corrective action project manager in evaluating historical data.

If you have any questions regarding this policy and/or guidance, please contact:

Gale Hruska	(312) 886-0989	(Permitting)
Allen Debus	(312) 886-6186	(Permitting)
Brian Freeman	(312) 353-2720	(Enforcement)

GUIDANCE REGARDING HISTORICAL DATA USAGE IN RCRA FACILITY INVESTIGATIONS IN REGION 5

Introduction

Both the Region and the facility can benefit from the decreased costs that result when historical data is used to provided some (or all) of the required RFI data. The corrective action process will also be expedited because less sampling will be required. In many situations, the utilization of historical data may result in either a move directly to a corrective measures study, the direct implementation of corrective measures, or the determination that no further action is needed.

If a facility wants to incorporate historical data into the RFI, it must first be discussed with the project manager and the QAPP reviewer, and be approved before submission of the RFI work plan. This discussion can also incorporate a pre-assessment of the data package. The submission of “unapproved” data at any later point in the RFI process (e.g. at the time of an initial QAPP submission or in a final report) could trigger additional sampling to replace any “unapproved” data. This would result in significant time delays and added costs.

Historical Analytical Data as a Continuum

Historical data cannot be categorized simply as either clearly acceptable or clearly unacceptable. Much historical data will fall somewhere in between the two extremes. “Clearly acceptable historical data” is defined to be data which has been adequately documented to be of known and acceptable quality, and for which the sampling plan, data objectives, and analytical requirements are known to be compatible with the RFI data needs. “Clearly unacceptable historical data” could be seriously deficient in one or in all of the elements identified above. Intermediate quality data will demonstrate some of the required qualities, and be deficient in others. The following guidance is intended to assist the project manager in evaluating the usefulness and acceptability of such data.

Project Objectives

The RFI data objectives need to be initially well-defined. Only when they are known will the quality assurance (QA) staff be able, during the pre-QAPP meeting, to identify the criteria which must be met before the historical data can be determined to be acceptable for use in the RFI. Then the facility needs to apply these criteria to determine whether or not its historical data actually satisfies the RFI data objectives and whether the data should be submitted. This process will simplify and speed up the Agency’s subsequent review of the QAPP, since the QA staff will only have to review historical data which matches the RFI data needs.

Requirements to Be Met Prior to Facility Submission of the Historical Data Package

Prior to the facility submitting a historical data package, the facility must submit the following information:

- A detailed description of what information the facility intends to submit.
- A rationale as to what purpose(s) the data is intended to serve, and why the facility believes the data can meet these objectives.
- A detailed discussion of all activities, releases, and/or other changes at the facility that have (or could have) affected the location, nature, and/or concentration of hazardous constituents at the SWMU(s) under consideration, from the date the historical data was generated until the present. If the facility does not know of any changes in facility conditions that could have altered the release situation, a statement to this effect must be included.
- A certification, as specified in 40 CFR 270.11(d) must be submitted.

The purpose of the above information is to prevent the submission of obviously unusable data and/or data that is not relevant because of changes in the facility condition that have resulted in the historical data being no longer applicable. The project manager must make a decision as to whether or not the Agency will accept the data for review.

Review of the Historical Data Package

An initial review of the historical data package should be done by the facility or its consultant before the package is submitted to the Agency to ensure that it meets Regional requirements. After the historical data is submitted, the QA staff and the project manager should work together on the Agency review. There are many components to address in a data package review. Some of the more important ones are:

- Identification of specific dates, locations, and depths of samples in all media.
- Sampling techniques utilized, including well construction information.
- Sample collection, preservation, and transportation practices.
- Identification of all constituents for which the samples were analyzed.
- QC samples and results.
- Laboratory acceptability (including any audits, certifications, etc.).
- Analytical method documentation.
- Original analytical laboratory-submitted data package.
- Data package quality control report.
- Data reporting (including reporting limits, treatment of non-detects, etc.)

After the data package is reviewed, the QA reviewer and the project manager will make a decision as to the next step. Three basic options exist: (1) Accept all (or some) of the data and incorporate it into the RFI; (2) Require confirmatory sampling prior to making the decision to reject or accept the data; or (3) Reject the data and continue on with the full RFI. (It should be noted that the age

of the historical data may or may not be a factor in assessing data acceptability. There is no automatic cut-off as to when historical data lose relevance. Specific site factors and project objectives must be used in making this determination.)

There are no absolute criteria for the acceptance or rejection of a data package, or for the imposition of confirmatory sampling. The choice of which of the three options is appropriate is dependent on the intended use of the historical data. Some examples of situations where the intended use of the historical data determines whether the data is acceptable or not are:

- In choosing locations for RFI sampling, even relatively poor quality data can be of use. Such data will not be acceptable in determining the absence of contamination or in eliminating locations to be sampled, but if the historical data did detect releases, some (or all) of those locations should be chosen for required sampling in the RFI.
- If historical data are to be important factors in making critical decisions, such as playing a significant role in the determination of human risk, then only trustworthy data should be used.
- If there is an acceptable historical data package, but there are reasons to believe that it may possibly not reflect present conditions (for example, because of possible new releases subsequent to the original sampling, chemical reactions with the matrix, migration of a plume, etc;), then confirmatory sampling could be used to determine whether the historical package may be accepted as defining the present situation.

Confirmatory Sampling

The first consideration to be addressed before proposing confirmatory sampling is whether the quality of the historical data is sufficient to warrant confirmatory sampling. If the sampling methodology or the analytical procedures are unknown, or are known to be clearly unacceptable, confirmatory sampling is not an option. Unacceptable historical data cannot be legitimized by re-sampling, even if the confirmatory and historical sampling results turn out to be consistent with each other.

If the RFI work plan reviewers determine that confirmatory sampling is needed before making a decision on the acceptability of the historical data, then care must be taken to assure that the confirmatory data is of sufficient quality to act as a standard for comparison with the historical data. In particular:

- The confirmatory sampling plan must contain data objectives that are coordinated with the full RFI project objectives.
- Sampling and analytical methods appropriate to the site specific circumstances must be used.

- Confirmatory sampling and analysis must be performed under an approved work plan and QAPP. However, it may also be acceptable to perform a field investigation under an approved mini-QAPP. Guidance on the use of field methods can be found in the July 20, 1997 memo The Use of Field Methods to Support RFI Streamlining (from Norman R. Niedergang to all staff managing corrective action projects).

A number of decisions must be made in specifying the confirmatory sampling parameters. In particular:

- Location of Samples. Confirmatory samples must be taken at the same location as the historical data samples. The actual locations to be sampled should be specified prior to sampling, together with the justification for choosing those particular locations. If new locations also need to be sampled, these should be addressed in the full RFI work plan, and not as confirmatory sampling.
- Number of Samples. The number of confirmatory samples to be taken will be dependent on a number of parameters, such as the homogeneity of the SWMU geology, the stability of the hazardous constituents in the SWMU matrix, the number of historical data samples submitted, and the uniformity of the historical data. A reasonable rule of thumb for most situations would be to sample 25% of the historical data locations, with a minimum of 3 confirmatory samples. This number is not carved in stone, but could be revised either upward or downward, if warranted by site-specific considerations.
- Constituents for Analysis. Confirmatory sample analysis must be done for all constituents identified in the full RFI. Sometimes historical data contain analyses for constituents that have not been identified as being constituents of concern in the RFI. Since such data will not be used for decision making purposes, they do not have to be confirmed.

Analysis of Confirmatory Data

After the results of the confirmatory sampling event are received, the Region will make a decision as to whether the historical data has been confirmed or rejected. While there are no standard or Agency approved methods applicable to the determination of whether or not confirmatory sampling supports historical data, Region 5 has developed a simple empirical method which provides a reasonable measure of the degree of confirmation. This method is presented in the appendix to this memo. The utilization of this method is Regional guidance; however, the use of other methods is not precluded where adequate justification is provided.

If it can be assumed that the analytical variability between the historical data and the confirmatory data caused by differences in laboratories, sampling plans, and laboratories is small (i.e. there are no significant quality assurance problems), there are three scenarios which can be expected to result from the evaluation of the sample data. The scenarios and the response to them are as follows:

- Historical data and confirmatory data correlate well. In this situation, both sets of data will either indicate the presence of contamination, or both will fail to detect contamination. If contamination is detected in both sets of data, and the concentrations of constituents are similar, the historical data should be utilized in decision making. If no significant contamination is detected in either set of data, then the consideration of eliminating the SWMU from further corrective action would normally be appropriate.
- Historical data identifies significant releases, but the confirmatory data do not. This would be a puzzling situation. Further investigation may be needed to address the discrepancy. Potential explanations are: natural remediation corrected the situation during the time between sampling events; the original contamination was caused by a one-time release which subsequently degraded or migrated out of the area; or, the choice of confirmatory sampling locations was inadequate.
- Historical data identifies no significant releases, but the confirmatory data do. This situation brings into question the use of the historical data for purposes of making corrective action decisions. The historical data could be reevaluated by the facility to resolve the discrepancy. However, it is unlikely that anything but a full RFI will be appropriate.

Data Generated Under Voluntary Corrective Action Activities or Under Other Governmental Authority Activities

Sometimes analytical data may be generated during the course of voluntary corrective action activities, preliminary site assessments, or as the result of sampling activities required and approved by other governmental authorities. This data meets the definition of “historical data” regardless of the reason why it was generated. The quality of this data must be evaluated in accordance with this policy before it can be used in a Region 5 RCRA RFI. There are presently no defined criteria as to what would make this type of data automatically acceptable to the Region. If it is determined that this data is unacceptable for RFI purposes, then the sampling must be repeated under the full RFI. If the data has been determined to be acceptable, then data packages can be selected for use in the RFI.

The Reporting of Historical Data and Its Use in Making Corrective Action Decisions

Historical data can be reported as a stand-alone submission, as part of the RFI final report, or both ways. If it is a stand-alone report, it must be complete, formatted in a clear and concise manner, and clearly demonstrate that it satisfies the RFI project objectives.

If the historical data has been determined to be acceptable, the project manager must utilize the data in making corrective action decisions; it should not be ignored. (For example, if the data is sufficient, it can be used to eliminate locations from full RFI sampling, or it can be used trigger a SWMU into a corrective measures study without further sampling under a full RFI.)

Appendix: A Method for Comparing Historical Data and Confirmatory Sampling Data

This is a simple empirical method for comparing confirmatory data with historical data, and drawing conclusions about the degree of confirmation observed. It assumes that the confirmatory data were taken in the same locations, depths, etc: as was the historical data, so as to rule out any site variability. Its purpose is to determine if there is significant variability in the laboratory data reporting limits and in the sample concentrations. The variability in the laboratory data reporting limits are first addressed, and if determined to be acceptable, then the variability in the data itself is addressed.

Laboratory Method Reporting Limits Comparability

This test is designed to compare the laboratory method reporting limits (MRLs) of historical and confirmatory data. (It is assumed that both sets of data provide this information on an individual sampling location basis.) It compares the ratio of the MRLs of the historical data with that of the confirmatory data. If the historical data MRLs are significantly higher than the confirmatory MRLs, then the quality of the historical data needs to be reassessed.

Step 1. For each hazardous constituent of concern at a sample location, calculate the ratio:

$$R = (\text{MRL for historical data}) / (\text{MRL for confirmatory data})$$

Step 2. If $R > 2$ then assign the index "0" to the location/constituent.
If $R \leq 2$ then assign the index "1" to the location/constituent

Step 3. Compare the number of locations/constituents having an index of 1 to those having an index of 0. If there are 80% (or more) of the 1 values, then conclude that both sets of data have basically the same method detection limits. If there are less than 80% of 1 values, then the historical data has a trend of higher MDLs than the confirmatory data, and the data quality either needs to be reassessed, or the data must be rejected.

[Note: This test is not a replacement for the historical data package review. It is only designed to flag the historical data quality and alert the project manager to situations where high reporting limits could mask significant releases identified by the confirmatory sampling. In other words, a lot of non-detects in the historical data could indicate that there were no releases, but it could also indicate that the historical data quality was insufficient to be able to confidently compare it to the confirmatory data. Also, if the targeted action levels are much greater than both the historical and confirmatory MRLs, then this test will not be relevant, and can be ignored, i.e., differences in reporting limits are not significant if the levels that trigger corrective action decisions are significantly higher.]

Data Comparability and Confirmation

This test is designed to compare the reported hazardous constituent concentrations obtained in the historical data to those in the confirmatory data. (It assumes that the MRLs for the historical data and confirmatory data addressed in the preceding test are acceptable.) It specifically compares the ratio of the concentration of a hazardous constituent reported in the historical data with that reported in the confirmatory data. If too many of the constituent concentrations are more than an order of magnitude different than the confirmatory concentrations, then the data is determined not to be confirmed.

Step 1. For each hazardous constituent of concern and each sampling depth at the sampling location, calculate the ratio:

$$R = (\text{Concentration from historical data}) / (\text{Concentration from confirmatory data})$$

[Note: Use the reporting limit if the constituent is not detected.]

Step 2. If $0.1 \leq R \leq 10$, then assign the index "1" to the location.
If either $R > 10$ or $R < 0.1$, then assign the index "0" to the location.

Step 3. Compare the number of location/constituents having an index of 1 to those having an index of 0. If less than 75% of the points have an index of 0, then conclude that the data have not been confirmed.

Step 4. On a map of the sampling locations, plot each index number. By doing this it may be possible to observe whether the non-confirmed data exhibit any patterns which could segregate out the non-confirming locations from conforming ones.

[Note: This test assumes that there is a sufficient number of data points. If there are only a few, the comparisons in Step 3 may not make sense.]