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**QUALITY ASSURANCE PROJECT PLAN (QAPJP)
COMMENTS**

08/23/91

**USEPA/DOE-FSO
12
LETTER**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
230 SOUTH DEARBORN ST.
CHICAGO, ILLINOIS 60604

2151

AUG 23 1991

REPLY TO ATTENTION OF:

Mr. Jack R. Craig
United States Department of Energy
Feed Materials Production Center
P.O. Box 398705
Cincinnati, Ohio 45239-8705

5HR-12

RE: Quality Assurance Project Plan
(QAPjP) comments

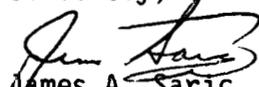
Dear Mr. Craig:

The United States Environmental Protection Agency (U.S. EPA) has completed its review of the Quality Assurance Project Plan (QAPjP) Document Change Requests (DCR) for the Feed Materials Production Center in Fernald, Ohio.

Enclosed are U.S. EPA comments on the DCRs. Also enclosed are U.S. EPA comments on the Data Validation Program of the QAPjP. Although the Data Validation Program is satisfactory, the execution of this program is not described with sufficient clarity or detail.

If there are any questions regarding the above matters please contact me at (FTS/312) 886-0992.

Sincerely,


James A. Saric
Remedial Project Manager

Enclosure

cc: Graham Mitchell, OEPA-SWDO
Pat Whitfield, U.S. DOE-HDQ

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- DCR No. 7: This DCR can be approved because it is apparent that this change will not have a significant impact on the quality of the data collected or in meeting the objectives of the RI/FS.
- DCR No. 8: This DCR can not be approved. It appears that data from the surface water, ground-water, or sediment samples are not affected by this DCR; however, data from subsurface soil samples are significantly affected. Also it is not clear why only soil samples from the facility testing program (FTP) are affected and not those from the RI. It is recommended that field rinsate blanks be collected at a frequency of 1 per 20 (or fraction there of) investigative samples as originally presented in the approved QAPP. The quality of the data collected in accordance with DCR No.8 must be accessed in detail prior to determining its validity and usefulness in contributing to the RI/FS.
- DCR No. 11: This DCR can not be approved at this time. An extensive review of the quality assurance documents (considered proprietary and available only through WMCO) concerning equipment calibration and analytical procedures for the Special Analysis, Santa Clara Valley, Cerritos, Austin, PEI, and Edison laboratories must be conducted.
- DCR No. 12: This DCR can be approved because it is apparent that this change will not have a significant impact on the quality of the data collected or in meeting the objectives of the RI/FS. However, it is recommended that ground-water temperature be measures in the field and recorded on these field sheet.
- DCR No. 15: This DCR can be approved because it is apparent that this change will not have a significant impact on the quality of the data collected or in meeting the objectives of the RI/FS.
- DCR No. 15: This DCR can be approved because it is apparent that this change will not have a significant impact on the quality of the data collected or in meeting the objectives of the RI/FS.
- DCR No. 17: This DCR can be approved because it is apparent that this change will not have a significant impact on the quality of the data collected or in meeting the objectives of the RI/FS.
- DCR No. 20: This DCR can not be approved because it was not provided to EPA for review.
- DCR No. 23: This DCR can be approved because it is apparent that this change will not have a significant impact on the quality of the data collected or in meeting the objectives of the RI/FS.
- DCR No. 25: This DCR can be approved because it is apparent that this change will not have a significant impact on the quality of the data collected or in meeting the objectives of the RI/FS.
- DCR No. 26: This DCR can be approved because it is apparent that this change will not have a significant impact on the quality of the data collected or in meeting the objectives of the RI/FS.
- DCR No. 28: This DCR can be approved because it is apparent that this change will not have a significant impact on the quality of the data collected or in meeting the objectives of the RI/FS.
- DCR No. 45: This DCR can be approved because it is apparent that this change will not have a significant impact on the quality of the data collected or in meeting the objectives of the RI/FS.
- DCR No. 49: This DCR can be approved because it is apparent that this change will not have a significant impact on the quality of the data collected or in meeting the objectives of the RI/FS.

**TECHNICAL REVIEW COMMENTS
DATA VALIDATION PROGRAM (DVP)**

1.0 INTRODUCTION

The basic Data Validation Program (DVP) presented in Appendix A of the draft QAPP is satisfactory. However, the execution detailed in the appendices attached to the DVP is unacceptable. The approach should be logical and complete enough that a relatively inexperienced person could apply the process without reference to additional documents and without clarification. Some portions of the text are so unclear that even an experienced data validator could not determine what is intended.

Appendix A-II seems to oscillate between two separate processes defined on page 1 of the main text of the DVP. "Verification" is done inside the laboratory and involves a large number of qualifiers used to define possible problems. However, the appendix is supposed to cover "validation" done outside the laboratory. Validation normally involves only the qualifiers "present," "absent," "estimated," or "don't know." (The usual symbols are no symbol, "U," "J," and "R," respectively).

Because of these deficiencies, the DVP should be revised and resubmitted to EPA. Because several sections are currently extremely unclear, PRC may find additional, specific problems in the revised version.

Sections 2.0 and 3.0 present PRC's general and specific comments on the DVP. Obvious typographical errors whose meaning is clear (such as "ph" for "pH") are not cited. Nonetheless, they detract from the overall clarity of the presentation.

2.0 GENERAL COMMENTS

The DVP should specify that all data collected for data quality levels III through V should be validated. The percentage of results subject to data validation for data quality levels I and II depends on activity-specific operations; therefore, a range of the percentages of results to be validated and examples should be presented.

The DVP generally follows EPA's Functional Guidelines for evaluating organics and inorganics analyses and acceptable data validation procedures for radiochemical, biological, and geotechnical testing.

Completed DVP checklists should be retained in the project file. It is also very important to permanently maintain original data forms and records in the project file.

Definitions of qualifier codes should be consistent throughout the text.

Appendix A should group specific validation activities with related required document reviews, general checklists to be completed, and specific checklists to be completed. An example follows:

- A. Subsurface Soil Sampling
 1. Required document review
 - a. Name/section of document
 - b. Name/section of document
 2. General checklists to be completed
 - a. Title of general checklist
 - b. Title of general checklist
 3. Specific checklists to be completed
 - a. Title of specific checklist
 - b. Title of specific checklist

Appendix A should be revised as follows:

- As required by EPA's Functional Guideline for data validation, the appendix should contain discussion of "compound quantitation and reported detection limits." This will help ensure that reported quantitation results and quantitation limits are accurate.
- Pages A-26 and A-30 mention that "detection limit results" will be the general criteria used to determine performance. Explanatory text and a checklist should be included.
- The discussion on pages A-40 through A-44 is very confusing and should be reorganized.
- The beginning of the section on page A-26 states that eight general criteria will be used to determine the performance of unstated parties, presumably the laboratory but possibly the samplers and the laboratory. However,

subsequent text does not cover all the criteria to be used. The eight general criteria should be discussed in detail, and the main requirements in the EPA guidance document should be referenced. Also, the technical approach (page 4 of the DVP) lists only seven factors with somewhat different items of data validation.

3.0 SPECIFIC COMMENTS

<u>Page</u>	<u>Section</u>	<u>Paragraph</u>	<u>Comments</u>
v, vi			<p>This list omits many items used in the appendices, including NA, NK, BNA, P/P, CRHT, ID, B/N, A, PEST, CRR, RF, %D, and IDL. Either add these items or put a separate list or lists in the appendices.</p> <p>As an addendum to the list, summarize the qualifiers to be used by validators.</p>
1	I	5	Review documentation should include information on chain-of-custody and documentation of sample transfer and storage.
2	I	1	Sample tracking procedures should be included in Item 1.
5	I	1	Clarify whether two types of interference check samples are to be used.
12	II	6	Explain the procedure to be used if discrepancies are identified with laboratory analysis. Similar detail for laboratory analysis should be provided as it was for field observations and measurements in the preceding paragraph.
13	II	12	The qualifier "R" means that data is unusable. Therefore, resampling and reanalysis are necessary for verification. The text should be revised to reflect this.

<u>Page</u>	<u>Section</u>	<u>Paragraph</u>	<u>Comments</u>
22			State whether nuclear-specific guidance documents such as ASME NQA-1 (Quality Assurance Requirements for Nuclear Facilities) were also used. Most, if not all of the DVP is compatible with these guidance documents. Also, NQA-1 is cited on page A-44.
A-6	Appendix		The order and titles of checklists listed here should be the same as the order and titles of checklists provided in the back of the appendix.
A-9	Appendix		A Biological Sampling Checklist should be included. Also, the text refers to a single Radiation Survey Sampling Checklist, but there are Radiation Measurement (Node Surveys) and Radiation Measurement (Walk Over Surveys) checklists. Clarify which of the four types of surveys uses which form.
A-26	Appendix	5	Validation review should first determine actual holding times by comparing sampling dates with dates of analysis and/or extraction. Also, sample records should be examined to determine whether samples were properly preserved.
A-28	Appendix	2	In the "Qualifier for Quantitation Limits" column of Table A-1, all R's should represent unusable data and not unreliable data. This error should also be corrected on page 13.
A-28	Appendix	3	Specify the contract-required recovery range for matrix-spike recoveries for all specific analyses.
A-28	Appendix	4	Field duplicates should be identified using EPA Sample Traffic Reports or sample field sheets. The

<u>Page</u>	<u>Section</u>	<u>Paragraph</u>	<u>Comments</u>
			reviewer should compare the results reported for each sample and should calculate RPD.
A-29	Appendix	6	Corrective action for Internal Standards Performance should follow flagging and review actions specified in EPA's Functional Guidelines for Evaluating Organics Analysis.
A-30	Appendix	5	The definition of qualifiers should be consistent throughout the text (e.g., see R, page 13).
A-31	Appendix	1	According to EPA Functional Guidelines, the evaluation procedure for holding times should also include examining sample records to determine whether samples were properly preserved.
A-31	Appendix		Information in the holding times table should be more clearly presented.
A-32, A-33	Appendix		Clarify whether "A" as a column heading in the upper part of the page means the same as "A" in the surrogate actions table below.
A-35	Appendix		Instructions should be provided on how to use this form to validate field precision results, and field precision should be defined.
A-37	Appendix	2	The method for determining the qualified sample result is different from the method described in EPA guidelines (IV D). Clarify why changes (deleting less than contract-required detection limits case, adding an approximation range) were made.
A-38	Appendix	6	The acceptable level of reference factor for continuing calibration should be greater than 0.05, not less than 0.05.

<u>Page</u>	<u>Section</u>	<u>Paragraph</u>	<u>Comments</u>
A-38, A-39	Appendix		Clarify whether the plus signs in the headings of the table at the bottom of the page are defined in the "Note" at the top of the next page. If so, specify who will make the decision about what guidelines will be used.
A-40	Appendix		Pages A-40 through A-42 should be clarified and reorganized. It is not clear how three of the C subsections are categorized and what the lines between the paragraphs represent. Also, the phrase "verified positive results by GC/MS when greater than 10 µg/µL" should be clarified.
A-43, A-44	Appendix		Clarify what section of the appendix these pages belong to.
A-45	Appendix	5	Add the phrase "If the criteria for holding times and preservation are not met," to be beginning of the sentence, "Qualify all results greater than IDL as"
A-45	Appendix	5	The paragraph on calibration should be clarified.
A-46	Appendix	4	The text should cover how to qualify sample results if the ICV or CCV %R falls outside acceptance windows. (Professional judgment or an EPA guidance should be used.)
A-46	Appendix		In the third paragraph under "Blanks," "<IDL" should be "IDL."
A-47	Appendix	10	Change "usable (R)" to "unusable (R)."
A-48	Appendix		The cited table in the 7/87 SOW should be included in this appendix.

<u>Page</u>	<u>Section</u>	<u>Paragraph</u>	<u>Comments</u>
A-49	Appendix		"Field Precision Valuation," whatever that means, should be discussed here, following the order of the list on page A-45.
A-49	Appendix	3	"IDL" should be "<IDL."
A-50	Appendix		Under "Action to be taken," the first four items are for aqueous samples only and the last three for solid samples only. Clarify. In the last paragraph on that page, what are the "EPA control limits?"
A-51	Appendix	6	The referenced scheme should be included in this document.
A-51	Appendix		"Detection Limit Results" should be discussed here, for the same reason.
A-53	Appendix	2	Missing heading, <u>Sample Result Verification</u> .
A-53	Appendix		"Contract required detection limit (CRDL) results" should be discussed here, for the same reason. If this item is really "field precision analysis" or "field duplicate analysis," delete repetition and standardize terminology.
A-53	Appendix		In Item 4, ">5 x ICP" should be ">5xICPIDL."
A-54	Appendix		Suggest to replace this form, using the form "Inorganic Regional Data Assessment" in EPA Data Validation Functional Guidelines document.
A-54	Appendix		The order and designation of topics in the preceding discussion and on the following form should be the same.

<u>Page</u>	<u>Section</u>	<u>Paragraph</u>	<u>Comments</u>
A-60	Appendix	1	Change "ICAP" to "ICP."
A-62	Appendix		Under actions, add that alternate action limits for soils are \pm twice the contract-required detection limit.
A-62	Appendix		Add that reported detection limits should be determined no more than 3 months before the date of the assays.
A-64	Appendix	1	Define "W" and "E." The statements do not agree with the associated text on page A-51.
A-69, A-75	Appendix		The contract-required detection limit is required for validation of data; therefore, CRDL for parameters like TKN, chloride, and phenol should be presented.
A-70	Appendix	2	Instrument calibration should be listed as a general criterion for determining performance.
A-71	Appendix	1	The holding time is the number of days from the time of sample collection to the time of sample extraction or analysis (depending on compounds); therefore, replace "Date samples received" with "Date samples collected."
A-72 to A-74	Appendix		This form should be revised to clearly show the action level and results.
A-74	Appendix	1	Change "IDLS" to "IDLs" or "IDL."
A-78	Appendix		Define the procedures used to calculate %R, %RD, and RPD. Also, specify whether "A" and "B" refer to "SSR" and "SSRD" or "SSR-SR" and "SSRD-SR."

<u>Page</u>	<u>Section</u>	<u>Paragraph</u>	<u>Comments</u>
A-80	Appendix		Explain how duplicate sample results will be used to calculate a standard deviation with one degree of freedom. Also, discuss instrument calibration (which <u>does</u> involve control charts); ITAS/Oak Ridge has a sophisticated calibration analysis system that is ignored here. Define the various control limits cited, so the validator can conclusively identify them. Clarify whether water blanks (field and laboratory method) will be used for soil samples.
A-80	Appendix	2	Specify control limits for the material analyzed and the method used.
A-80	Appendix		Add text discussing data validation for sample preparation and instrument calibration for the Radiological Laboratory Analysis.
A-83	Appendix		Explain how the lower limit of background uranium (item D.1) can be 0.5 pCi/g if the laboratory detection limit is 0.6 pCi/g for each isotope.
A-86	Appendix		The checklist should include such items as instrument calibration and sample preparation (if needed).
A-86	Appendix		Specify whether the third checklist item refers to the "background count rate," "blank gross count rate," or "blank net count rate."
A-88	Appendix		Clarify the location of the Specific Validation Checklist for Macroinvertebrate Surveys cited in 1.0A. Clarify whether it is the "Biological Resources Sampling Ecological Field Survey Collection Log Checklist, which is otherwise

<u>Page</u>	<u>Section</u>	<u>Paragraph</u>	<u>Comments</u>
			unexplained. Clarify the location of the Field Log cited in 1.0C.
A-89	Appendix		Item G should be corrected.. The reference is probably intended to be "ASTM D-4557, Standard Practice for Collecting Benthic Macroinvertebrates with Surber and Related Type Samplers," found in Section 11.04 (page 104) of the 1990 Annual Book of ASTM Standards. The current citation is a paper presented at a symposium, not an ASTM Standard Practice. Item H should specify statistical tests to be used.
A-90	Appendix		Clarify whether Item 2.0A refers to the Biological Resources Acute and Chronic Checklist.
A-91	Appendix		Clarify whether the checklist on page A-95 is to be used for Wetlands Delineation validation. If not, define the checklist to be used. Critical factors should include identifying soil and plants and statistically analyzing plant prevalences.
A-91	Appendix		Clarify whether the checklist on page A-96 is to be used for Bioaccumulation Study validation. Many data cited in Item E on page A-92 are omitted.
A-92	Appendix		A checklist for Soils and Sediments Toxicity Testing should be presented.
A-101	Appendix		Prepare a specific validation checklist for each type of geotechnical test to be conducted.
A-101	Appendix		"NBS" should be "NIST." This form and the text on page I-99 should agree.