

in the lot then be rejected by inclusion or would this trigger the validation of 100% of the data in such a lot to determine exactly which would be rejected? This issue must be addressed prior to approval of a data validation plan.

Specific Comments

Page 1, last sentence: Redefining "100% validation" is misleading and inappropriate; instead this definition should only be applied to the term "graded validation".

Page 3, second sentence: Only one example is given here for highly sensitive projects that would continue to be 100% validated. A more complete list of such projects must be included either here, or as an attachment to this document.

Page 3, Section 4.5: This section states that some data will not be validated, but is vague about the non-historical types of data to which this applies. A more specific list of these data types must be included. In addition, this section must more clearly state whether there would be any validation at all of these types of data.

Page 4, Section 4.8, third sentence: It is stated here that "lots" will be randomly selected every month, but this does not agree with the definition of a lot and the number of required inspections shown in Table 1. The sentence makes sense if "lots" is replaced with "SDGs". In addition, this sentence and Table 1 must be corrected so that the basis for numbers of SDGs selected is the number of SDGs output by a lab in a month rather than the number of SDGs submitted to the lab in a month.

Page 4, Section 4.8: The IAG does not mandate a 30-working day turnaround for validation activities, it mandates a 21-working day turnaround for validation. It also lists a 63-working day time limit for laboratory turnaround regardless of whether it is radiochemistry or general chemistry. Therefore, the statement that this plan will allow a 90-day turnaround for validated radiochemical data from time of shipment to completion of validation is only acceptable if this means 90 calendar days. This must be clarified and approval can only be granted for a plan that will allow for 21-working days for validation activities and a total of 84-working days from time of shipment of samples from the site to completion of validation.

Page 4, Section 4.9: A rationale is needed to support the statement that if 25% of a laboratory's SDGs are validated, the other 75% is considered validated.

Page 5, Section 4.12: In going from normal to reduced inspection

levels, is past performance considered at all or is three consecutive accepted batches the only criteria? Going from a tightened level to a normal level on the basis of one accepted batch seems to be too lenient.

Page 5, Section 4.14: This should be clarified to state that all SDGs at the same inspection level must be equally likely to be inspected.

Page 9, Attachment 1: It is recommended that the following be added to the checklist: 1) Failure to follow the holding time, and 2) Deviation from proper method.

Pages 10-19, Attachments 2-4: There is no mention of the chains-of-custody (COCs) in these checklists. These documents must be included, as they describe what analytical method was requested by DOE, and are also legally binding documents.

Page 14, Inspection Checklist for Inorganics: There is no mention about laboratory control samples.

In summary, EPA encourages DOE to provide the additional information cited above and make the necessary changes to this document so that data validation can be made more efficient and less costly, without sacrificing quality assurance and quality control. If you have any questions regarding these matters, please contact Gary Kleeman of my staff at 294-1071.

Sincerely,



Martin Hestmark, Manager
Rocky Flats Project

cc: Norma Castaneda, DOE
Gary Baughman, CDH