

Cases for Discussion

1. The analytical portion of a Magnitude of the Residue study on Green Bean (string bean) is being transferred by the Sponsor to your facility from the original, contract laboratory (ORI Lab). This decision was made on November 3rd.

Your facility (Nex-Lab, Inc.) where the test substance is manufactured, will also prepare the final report and archive all of the raw data, according to the protocol amendment.

The field portion of the project was conducted at multiple sites to represent growing regions of the northeast and the south. ORI Lab had already received the crop samples at various times from August 1 to October 16th. The samples have been assigned ID numbers. They have been stored, intact, in Freezer ID# 4587. ORI Lab shipped all of the samples on dry ice via FedEx on the morning of Nov. 10th.

All of the samples arrived at your facility, Nex-Lab, at 3 pm on Nov. 11th.

A. What documents should be provided by ORI Lab for the study file because of this change and the transfer of the samples? [The group will call them out to the Scribe for recording on the flip-chart after the case is reviewed]

- Documentation I would expect to find -

1. B.

Now change the circumstance – assume that processing (the beans were chopped and ground finely with dry ice) of some sites' samples had already occurred at ORI Lab by the time the Sponsor authorized the transfer.

What would you add to your list of documents?

[We'll record these the same way, after review time]

2.A. During validation of the published method listed for use in the study protocol, the lead technician finds that several changes to equipment or solvents will be necessary to accomplish reliable for analysis of the green beans. At your facility, how is this kind of circumstance:

1. communicated?

2. documented?

3. approved for use in the study?

2. B.

How does your QAU SOP on selection of study critical phase inspections guide you react to protocol amendments?

- Are there any directions that you would like to suggest to the group?

If there is presently no written guidance in your SOP, did our brief study of the FDA GLP Preambles trigger any ideas for improving the procedure? Refer to 160.35 (c) – “**The responsibilities (what QA does) and procedures applicable to the quality assurance unit (how the QAU carries out those responsibilities) ...**” “**shall be in writing and shall be maintained.**”

Presenter/Team Guidance for Case Discussion Period

Examples of Documentation Expected for Case 1. A

- ✓ The complete protocol to-date, and the specific change amendment in GLP-compliant format. [Trick question! The QAU should have been notified already – when was the protocol etc. provided to Nex-Lab QA by the Sponsor and its QAU – or is there some other arrangement?]
- ✓ Records of the original sample receipt from each site
- ✓ Personnel names to ID initials in data
- ✓ Any assignment of unique identification of the samples at first lab
- ✓ Records of sample placement (inventory) in Frzr.# 4587
- ✓ Temperatures from at least Aug. 1 until transfer date
- ✓ Any applicable records related to Frzr.# 4587 cleaning or maintenance/repair during the holding period
- ✓ Records detailing the transfer of the samples from ORI-Lab to your laboratory, include shipping instruction in the protocol amendment (or elsewhere in protocol)
- ✓ Receiving records of Nex-Lab, to verify receipt of all samples
 - Was a new ID given?
- ✓ Placement of samples in your facility's freezer and its ID. **Starts chain of custody at Nex-Lab.**

For Case 1.B

Records detailing the transfer of the samples from storage to processing

Information on the actual procedure - SOPs, equipment records, tech initials

Return of the processed material to the original freezer or placement into a different one? That would require a set of temperature records for the second unit.

** What will you put into your final report for the analytical phase of the study when/if original documentation cannot be obtained? [new EPA Guidance] Has the communication asking for the material being properly recorded and added to the study file?

2.A. During validation of the published method listed for use in the study protocol, the lead technician finds that several changes to equipment or solvents will be necessary to accomplish reliable for analysis of the green beans. At your facility, how is this kind of circumstance:

1. communicated?

Documented?

Approved for use in a study?

2. B.

How does your QAU SOP on selection of study critical phase inspections guide you react to protocol amendments? **You need to have SOPs directing how phases will be selected, how the CPI will be performed, scheduling any follow-up inspections, etc.**

- Are there any directions that you would like to suggest to the group?

If there is presently no written guidance in your SOP, did our brief study of the FDA GLP Preambles trigger any ideas for improving the procedure?