Compliance Decision Flowchart

This flowchart may be printed and used during the on-site inspection to guide you through the process of determining compliance/non-compliance.

START HERE

Is there a policy/procedure (P/P) that addresses the intent of the checklist item?

Yes → Is there a lab practice that supports the intent of the checklist item?

No → Is there a lab practice that supports the intent of the checklist item?

Left branch (P/P exists)

Is there a lab practice that supports the intent of the checklist item?

Yes → Does the practice match the P/P as written?

No → **Non-compliant**. Cite a deficiency. Lab is only in paper compliance. Cannot be corrected on-site.

Does the practice match the P/P as written?

No → Is there documentation that supports the lab practice?

Yes → Is there documentation that supports the lab practice?

Is there documentation that supports the lab practice? (No branch)

No → **Non-compliant**. Cite a deficiency. Practice is not documented and does not match written P/P. Cannot be corrected on-site. Revise P/P and communicate/train staff.

Yes → **Non-compliant**. Cite a deficiency for practice not matching written P/P. Can possibly be corrected on-site. Revise P/P.

Is there documentation that supports the lab practice? (Yes branch)

No → **Non-compliant**. Cite a deficiency for no or incomplete documentation. Cannot be corrected on-site. Need on-going documentation.

Yes → **Lab is compliant**, move on. Write a recommendation if process can be improved.

Right branch (No P/P)

Is there a lab practice that supports the intent of the checklist item?

No → **Non-compliant**. Cite a deficiency. Nothing is in place. Cannot be corrected on-site.

Yes → Is there documentation that supports the lab practice?

Is there documentation that supports the lab practice?

Yes → **Non-compliant**. Cite a deficiency for no P/P to address issue. Can possibly be corrected on-site if a P/P is written/approved.*

No → **Non-compliant**. Cite a deficiency. Cannot be corrected on-site. Need P/P written/approved and on-going documentation.

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