



IR-4 Advisory #2018-01

- Title:** Test substance characterization results versus nominal formulation concentration
- Issue/Question:** The EPA inspectorate has asked if IR-4 Testing Facility Management (TFM) has a policy on how the active ingredient concentration of test substances is verified to the Certificate of Analysis. The nominal concentration of formulated materials has always been used for application calculations of test substances in IR-4 studies.
- Background:** GLP requirements in 40CFR 160.105(a) specify: “The identity, strength, purity and composition or other characteristics which will appropriately define the test, control or reference substance shall be determined for each batch and shall be documented before its use in a study.” The IR-4 Project relies on registrants to provide GLP-characterized test substances for use in IR-4 GLP residue studies. The Certificates of Analysis provided by registrants have always been used as evidence of the suitability of the use of the test substances in the studies. If the registrant analyzed the batch and released it for use, they are indicating its acceptability.
- Resolution:** TFM will accept Certificates of Analysis results issued by the registrant/entity responsible for the testing as meeting the acceptance criteria for using test substances. The nominal formulation concentration will be used for all study calculations.

If you have any questions, please contact your Regional/ARS Field Coordinator, the appropriate Study Director or Headquarters Management for further guidance.