

Definitions:

- **Reference Material:**
 - A standard of known concentration provided by a Manufacturer Accredited to ISO Guide 34. In Potency, these are limited to 1 mL of 1000 ppm.
 - These come with a Certificate of Analysis and an expiration date. The expiration date should apply to any solutions made with this reference material and contained in the records and on the vial. The CofA should be available and the standards used should be traceable to each result. .
- **Calibration Curve**
 - A set of serial dilutions of the reference material showing a linear graph of instrument response versus known concentrations. The calibration curve, once verified, only needs be run when the instrument shows itself to be out of calibration. If choosing a quadratic fit, you're required to run at least 5 standards. Linear requires only 3 but more are recommended. You cannot force your curve through zero or run a blank as one of your points. Average Response Factor is recommended as an additional evaluation to R² as it takes into account your lower points.
- **Initial Calibration Verification (ICV)**
 - A reference material from a different manufacturer or different lot than your primary standard, usually diluted to the middle curve point. This only needs to be run with calibration and should have % recovery control limits from 80% to 120%. Your ongoing CCV can be from your primary curve after the ICV passes. Lack of an ICV to check your calibration curve will result in an immediate finding.
- **Continuing Calibration Verification**
 - This should bracket your run (beginning and end) and be analyzed at a minimum of 1 per 20 samples with the same control limits as the ICV. If your instrument is stable, you can run a CCV to start your analytical batch each day. You do not have to recalibrate until a CCV fails. If a CCV fails, it demonstrates your instrument is out of calibration and any bracketed samples must be reanalyzed. Due to the risk of re-analyzing so many samples, many labs choose to run these 1 in 10.
- **Characterized Material**
 - Potency only-Due to the low concentration of the reference materials compared to the high concentration of products, labs are producing mixes of the 4 required cannabinoids from existing products. These mixes must be "characterized" by a documented procedure that demonstrates its homogeneity, stability (with expiration date) and established concentration.
- **Method Blank**
 - A blank (preferably matrix matched) taken through extraction to show that contamination is not introduced in your extraction through your reagents, solvents, air, equipment, etc. Several labs have demonstrated that pesticide-free cannabis is possible to be used for pesticides. A solvent or plant blank without interference is currently acceptable for potency.
- **Laboratory Control Sample/Blank Spike**
 - A blank (preferably matrix matched) spiked with a known concentration of the Reference Material (in pesticides) or characterized material (only allowed in potency) to show %recovery of extraction
- **Sample Duplicate**
 - A sample prepped and analyzed twice (primary and duplicate) with precision control limits (+/- 20%). This is the preferred duplicate in analyses like Potency where hits are expected
- **Matrix Spike**
 - A sample duplicate that is spiked with the characterized material to show matrix interference with % recovery limits either standardized at 70%-130% or control chart established limits.
- **Matrix Spike Duplicate**
 - A third preparation that is spiked exactly as the matrix spike is. The RPD criteria is usually <30%. This is the preferred duplicate if you don't expect hits such as pesticides.

-ORELAP understands that running matrix spikes and blank spike/LCS with reference materials (which is normally the requirement) is prohibitively expensive. Until the reference material concentrations change, our policy on allowable Batch QC is as follows:

- Flower:
 - Method blank-Should contain all reagents and solvents used on samples with a result of < LOQ
 - Blank Spike
 - PTs are sometimes considered reference materials. ORELAP is requiring 3 analyses of an extra Phenova In-Matrix PT as an LCS study to prove that their extraction procedure is providing effective recovery (80%-120% of known value as dry weight). Phenova has agreed to sell these leftover vials. There are 26 vials between 2 lot of known value and Phenova will supply a Certificate of Analysis.
 - After this, since there is not an appropriate blank matrix, the policy will be to spike your characterized material into your solvents.
- Extracts
 - Method Blank
 - Safflower oil should be carried through extraction with your reagents and solvents and analyzed at <LOQ
 - Blank Spike
 - The lab must use the same amount as a sample. The characterized material should be spiked on safflower oil for recovery within defined limits. Any other blank matrix must be approved by ORELAP.
- Edibles/Products
 - Method Blank
 - If at all possible (ORELAP is assured that this is possible in most situations), you must obtain a non-medicated version of the product and use the same amount you would use for a sample with the same reagents and solvents you would use for your sample with a result of <LOQ.
 - Blank Spike
 - If at all possible (ORELAP is assured that this is possible in most situations), you must obtain a non-medicated version of the product and use the same amount you would use for a sample. This should be spiked with characterized material for %recovery within defined limits.

ORELAP Policy on Extraction QC when the extracts are subcontracted to a lab for analysis:

- The lab performing the extraction must:
 - Always submit a MB, LCS, MS, and MSD for every batch of 20 samples. If this is not submitted to the analysis lab, they must reject your samples and ask for a re-extraction.
 - If your Method Blank or LCS fails, the analysis lab may request a re-extraction depending on the professional judgment of both labs as to the reason of the failure.
 - These must be submitted with PT samples and process validation batches as well as any client samples.
 - This is the policy that ORELAP sent out earlier this year on the topic:
 - **Pesticide Sub-contracting**
 - As has been occurring in the industry, we are aware that not everyone will have pesticide capability immediately and the turnaround time needs might necessitate labs doing their own extractions and sending them to labs for analysis. ORELAP is drafting a policy on this right now but to summarize:
 - 1) You must follow all ODOT regulations regarding solvent volumes.
 - 2) Both the analysis lab and the extraction lab must successfully pass a PT for pesticide analysis.
 - 3) If the analysis lab and extraction lab are analyzing the same lot of PT, the analysis lab must report their own data to the PT company before analyzing PTs from their extraction labs to eliminate the risk of the analysis lab being able to "check their result".
 - 4) If using control charts to set limits for preparation batch QC such as LCS, Duplicates, and Matrix spikes, the lab must control chart each extraction lab data separately and use the limits from extraction group that are the most stringent. If the QC sample does not meet these limits, the extraction lab must re-extract.
 - 5) Both the analysis lab and the extraction lab must perform DOC and an LOQ verification independently.