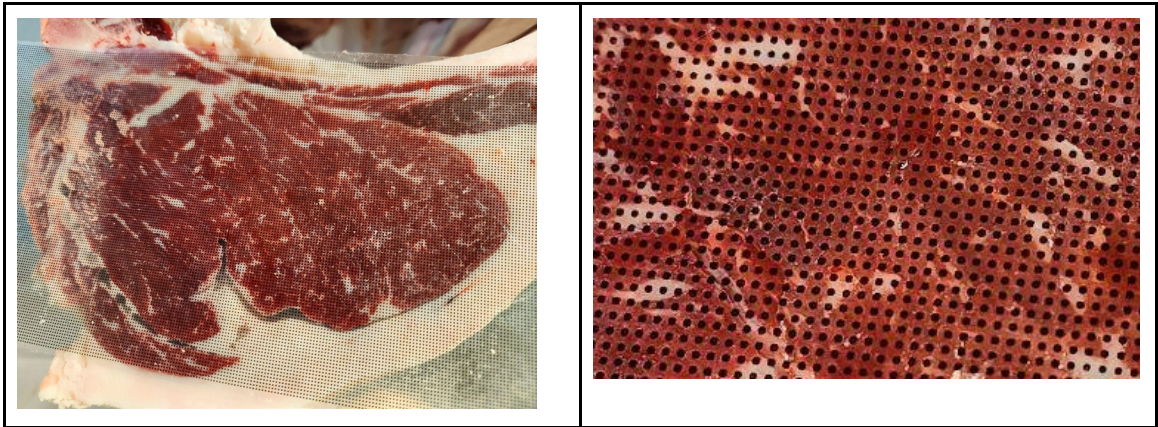


## USDA Trial Document Questions

1. The *Instrument Installation Process* document is stricter than the *approval process* document?
  - Many of the requirements for an install seem to be significantly stricter than the actual approval process as per *Instrument Approval Process*?
  - Excel file comparing the two documents is attached
2. How is every trait calculated?
  - Is there some documentation used by the Gold Standard graders which we could review to get more information about their process?
3. 95% within 20 marbling units seems like a very tight requirement, given the full range is 1000 (is this correct?) units. How consistently does a USDA gold-standard human grader meet this requirement (say, vs. the average of two other independent human graders)?
  - Is there scope to loosen parameters if it is shown that the three gold standard graders aren't able to meet the parameters?
4. Regarding the performance requirements for ribeye area
  - What formula is R2
  - Is this intended to be invariant to linear transformation?
  - The document references correlation and regression, could you elaborate?
5. What are the costs associated with an approval trial, how often is it reasonable to run one? This is to get an idea of whether it makes sense to use the trials themselves as the means of getting training data and testing/refining the camera system. Expert data is extremely valuable to us, so if we can reasonably pay for and use the trials as a basis for iterating on the product then that would allow us to develop more rapidly and with a greater degree of confidence. Is there a maximum number of trials allowed?
6. We are concerned about practical and IP implications of section 12.1 VERIFICATION OF APPROVED EQUATIONS that suggests that the instrument manufacturer must allow LP personnel access to the unencrypted software coding for an instrument immediately upon request.
  - Is it sufficient to provide the APK (install file) we are submitting for approval along with its SHA-1 hash?
  - This would allow the regulator to use standard tools to confirm categorically that the installed version of the application is exactly identical to the provided/installed version.
  - We can assist with finding an expert to validate the application

7. *Instrument Approval Process* specifies: “The technology provider will provide LP with a copy of the prediction equation used as well as the values for each variable in the prediction equation for each of the predicted marbling scores” (section 5.3.1.3)
- The primary components of our prediction systems are convolutional neural networks that operate on entire images. These algorithms use millions of parameters so a rolled out equation is nonsensical to a human
  - Could you elaborate on what is the intended purpose of this rule so we can find a way to meet the intent of it?
8. Does our current data capturing method (video) comply with the Triple replacement and trigger method specified for data collection?
9. From section 5.3.1.4 – Quality control of images and data collected. “LP will review all data and images to determine if the data and images from the selected carcasses were accurately obtained. Technology providers must submit to LP the original image and the processed display screen image or thumbnail for each carcass in the test so that images can be reviewed to determine if proper image capture occurred.”
- Does this mean we need to send the video for the test images and the segmentation mask for each carcass?
  - Will USDA be removing the ones that might be of bad quality and not considering them?
10. Regarding 5.3.1.2 – Procedure for determining the Official Marbling Score, could we clarify how the process of splitting into calibration and test works?
- “Carcasses will be ranked by the final Official Marbling Score in ascending order by trial location and then every other carcass will be assigned to a calibration data set”.
11. What about updates to the handset’s software environment that aren’t at all involved with the data capture or prediction systems? Would that need to go through the update approval process? Scenarios including:
- Updating the Android operating system (important for security reasons; but involves proprietary Samsung/Google code we have no control over)
  - Installing unrelated applications for user convenience or testing (less important but can be nice to have access to)
    - Gmail, WhatsApp etc
  - Updating the secondary application that handles barcode scanning, user login etc, perhaps to support a new type of barcode or enable better detection. Or the integration with a new processor.

12. There is no exclusion criterion for Ribeye Area, Rib fat, or Yield? In our experience we have seen significant variation in Gold Standard grades for these measures.
- Is it possible to include an exclusion criteria to ensure that the gold standard grades are accurate?
13. Can we collect gold standard data for the purpose of training models before the 60 day period is over?
14. Can we take images with a micro grid to prove ribeye and rib fat if there are discrepancies? Example image below.



15. Why does the *Installation Document* reference *Instrument Grading Systems for Beef Carcasses* but in *Approval Process* it's stated that it replaces *Instrument Grading Systems*?