

Standard Operating Procedure: SOP-BALL-22

Data Analysis for 8- and 24-Additional DPMO

Rev	Date	Staff Member	Purpose
Origination date: 4/21/22		Originator: D. Speranza	



<u>Purpose:</u> This SOP covered the data analysis process along with steps required when the results differ between two operators.

Data analysis and data verification for 8- and 24- ball samples

- Some steps in the ball approval and spot checks processes require 8- and 24-additional samples per the Equipment Specifications Manual to verify the model meets the allowable Defects Per Million Opportunities (DPMO). Once the data is collected on these test balls, calculate the DPMO for the group of balls. If the model has greater than 0.6% DMPO have a second operator repeats the test. Calculate the defect rate for each operator separately. Determine if the results for both operators fall within one of the categories below:
 - a. Both operators passing the model with a defect rate below 0.6%
 - b. Both operators having a defect rate between 0.6% and 5.0%
 - c. Both operators having a defect rate greater than 5.0%

If both operators are within the same category above, the test is concluded. If both operators are not in the same category above (see item 1a- 1c), then the operators should observe each conducting the test to identify any operator differences versus the SOP. If a difference is detected, both operators should re-test following the agreed upon procedure that follows the SOP. If both operator's results are now within the same category (1a-1c above) the results stand. If both operator's results are not in the same category, then the manufacturer is given the benefit of the doubt and the less restrictive defect rate will apply.