JOHN ZORICH'S RECOMMENDATIONS REGARDING HOW TO INCORPORATE HIS STATISTICAL SPREADSHEETS INTO A COMPANY'S QUALITY SYSTEM

The goal of the following 2 recommendations is for the company to...

- be able to find the Validation Report for a given spreadsheet when needed (e.g., during an audit by the FDA)
- ensure that an undamaged copy of the Master Copy of the spreadsheet is always available
- ensure that company technicians are always using the most recent version of the spreadsheet.

RECOMMENDATIONS:

1. Use the Quality System's "Document Control" process to formally approve the spreadsheet:
    a. as part of that process, put relevant information (e.g., DCO #, if the company uses such an identification process) into the corresponding blank cells on the spreadsheet's "Doc#etc" worksheet, and then lock that worksheet with a password known only by Document Control personnel
    b. attach or associate the spreadsheet's validation report to the approval records, so that the report can be quickly found by anyone who knows how to use the Document Control system
    c. maintain a Master Copy of the spreadsheet as a controlled document in the Document Control system; ensure that that copy cannot be altered (except by Document Control personnel) when it is in the official Document Control folder.

2. Train technicians who use the spreadsheet to <u>not</u> keep a <u>blank</u> copy of it for their own future use; rather, when they need a copy, they should always download a copy of the Master Copy (since, from time to time, the Master Copy may replaced by newer revisions that incorporate bug-fixes and/or additional features).