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Prepared By:	Reviewed By:	Approved By:	
Date:	Date:	Date:	
DEPARTMENT: Quality Assurance			

1.0 PURPOSE AND OBJECTIVE

The purpose of this Standard Operating Procedure is to define the requirements for the creation, approval, management and revision and distribution control of Spreadsheets utilized in support of quality and business critical operations.

It is fully understood that Excel Spreadsheets are incapable of meeting the requirements of 21 CFR Part 11.10(e), and thus are incapable of complying with the Federal Regulations.

This procedure will ensure that procedural controls are in place to evaluate use, qualify and control to ensure data integrity is maintained.

The objective of the procedure is to ensure that the process exists, for ensuring that all spreadsheets used in support of the Quality initiatives are in compliance and that all data created, generated, calculated, and distributed for analysis has undergone appropriate qualification and quality review.

- a) To ensure that all personnel at **{Company}** understand the risk associated to the use of MS Excel spreadsheet.
- b) MS Excel is not Part 11 Compliant; however, it is understood that the software can create a quality and regulatory risk situation.
- c) To ensure that all personnel at **{Company}** understand that individual MS Excel spreadsheets are considered to be software applications and should follow the procedures and requirements for new software systems.
- d) The objective of this procedure is to ensure that all personnel at **{Company}** understands the process for requesting,
- e) The objective of this procedure is to outline the process and procedure for development, testing, and qualifying of MS Excel spreadsheets.

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2.0 SCOPE

- a) Set a process for initiating a formal request for a new software application and outline the process for filling out the IT software request form in accordance with formal procedure.
- b) All employees of **{Company}** who possess access to MS Excel software can create an Excel spreadsheet.
- c) This procedure applies to all spreadsheets created and used for quality and regulatory activity.
- d) Set forth a process to formally test and qualify MS Excel spreadsheets.
- e) Set forth a process to formally protect the software integrity of MS Excel spreadsheets.
- f) To set forth a process to formally protect and control access to MS Excel spreadsheets.

3.0 RESPONSIBILITIES

- Users (Developers) are responsible to ensure that they follow the procedures pertaining to MS Excel spreadsheet develop and all applicable procedures pertaining to Electronic Systems.
- Users (Developers) must have the education, training, background and experience to develop and test MS Excel Spreadsheets.
- Users must understand the applicability of 21 CFR Part 11 and all predicate rules.
- Users must have training in filling out of the Software Evaluation form.
- Quality Assurance Managers are responsible for ensuring that all request forms are properly filled out and assessed for compliance.
- Quality Assurance Manager is responsible for ensuring that the formulations and integrity of the software has been pre-tested and qualified.
- IT Manager is responsible for ensuring that the formulations, integrity and protection of the Work Sheets have been performed and qualified.
- IT Manager is responsible for ensuring that the Workbook is properly protected and that the spreadsheet files have been moved to the appropriate folders on the server.
- The IT Manager is responsible for deleting the original developer's copy of the Workbook from the local machines.
- It is the responsibility of the IT Manager to inventory all MS Excel spreadsheets as required.

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4.0 DEFINITIONS

- Developer – The person(s) who creates the spreadsheet or database. This person, must have the education, experience and training to develop the applications in accordance with the approved defined user requirement.
- Dynamic data – Data that can be modified, altered, deleted, changed or added. This data is generally user entry data and not formulas or titles (labels) of rows and columns.
- Functional requirement – The description of the functionality of the software to meet the needs of the user requirements. Mostly consists of a user interaction interface description.
- User requirement – The description of the purpose of the application to perform a function or process. Describing what the objective of the proposed application in laymen’s terms.
- Work Sheets – A worksheet or sheet is a single page in a file created with electronic spreadsheet program such as Excel. A worksheet is used to store, manipulate, and display data. Each worksheet is composed of a very large number cells - which are the basic storage unit for data in a file or workbook. The cells are arranged in a grid pattern using rows and columns.
- Workbook – A workbook is the MS Excel file in which you enter and store related data. Each workbook can contain many worksheets. (It’s a lot like a book. One book contains an entire story. Each page of the book contains part of the story.) Often one workbook has a single theme, such as Vendors and Suppliers. Each worksheet would then have a part of the theme, such as the Vendors broken down by Services or Products.

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5.0 PROCEDURE

- a) The request process:
- 5.a.1 All MS Excel spreadsheets (here forth referred to as 'spreadsheet'(s) or 'application') will be considered Software Applications.
 - 5.a.2 All **{Company}** personnel who use spreadsheets must request the ability to create the spreadsheet with the Quality Assurance Manager.
 - 5.a.3 The request should discuss the user requirement and functional specification requirement specification of the application in accordance with Industry Standards.
 - 5.a.4 The form will be presented to the Quality Manager, who will consider the risk applicability.
 - 5.a.5 If the application request is approved by the Quality Assurance department, the software request form will be returned to the requestor who will then develop the application.
 - 5.a.6 If the request is not approved, a statement of denial will be noted within the request form discussing the reasoning for the denial.
- b) The development process:
- 5.b.1 Users must understand the use of the application within the organization and the basic concepts of the application software develop process and protection concepts.
 - 5.b.2 Users will open MS Excel and create a new spreadsheet on their local drive.
 - 5.b.2.1 Local drives should have a folder on the desktop titled 'Unapproved Files'. If folder does not exist, see IT Manager.
 - 5.b.2.2 The user shall use basic naming convections for the spreadsheet files. **{SoftwareName}** (i.e. Vendors Names, Equipment List, Employees, etc.) – (Hyphen) VersionNr. (Only numbers, i.e. 1, 2, 3, 4, Do not use decimals or commas)} (example: **Vendors-1.xls**)
 - 5.b.2.3 User shall save the spreadsheet file into the folder 'Spreadsheet'.
 - 5.b.3 Basic development concepts shall apply:
 - 5.b.3.1 All new spreadsheets and templates be pre-approved for use.
 - 5.b.3.2 Two (2) types of protection will be discussed:

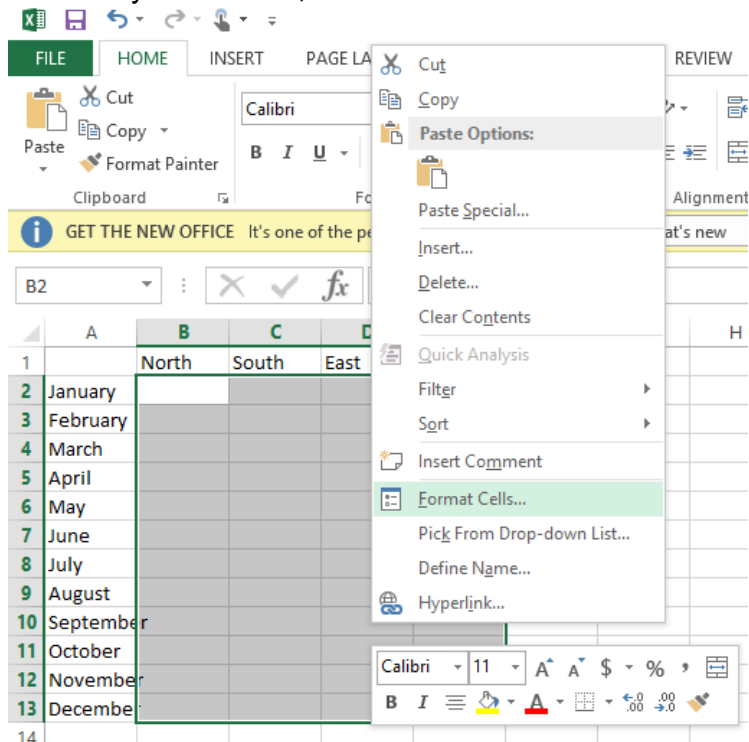
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5.b.3.2.1 Work Sheets

5.b.3.2.2 Work Books

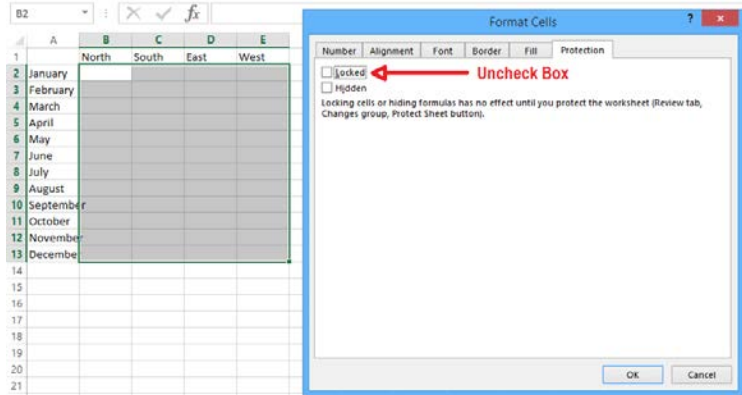
5.b.3.3 Once the spreadsheet has been developed you will protect the Work Sheet:

5.b.3.3.1 Unlock only the data fields that will be considered 'dynamic' data by highlighting only the data fields, left click your mouse, and select 'Format Cells'.



5.b.3.3.2 When the 'Format Cells' dialog box appears, select the 'Protection' tab and uncheck 'Locked'.

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5.b.3.3.3 Only uncheck the dynamic data cells only and not the fields with formulas attached.

5.b.3.3.4 Save the file.

5.b.3.4 For cells that have formulas, verify the functionality of formula by use of 'Test Data'. Ensure that the formulas return true and accurate values.

5.b.3.5 Complete Section 3 of the Software Evaluation form and submit to the Quality Assurance Manager along with a copy of the raw spreadsheet.

c) The Testing and Qualification process (to be performed by the IT Department):

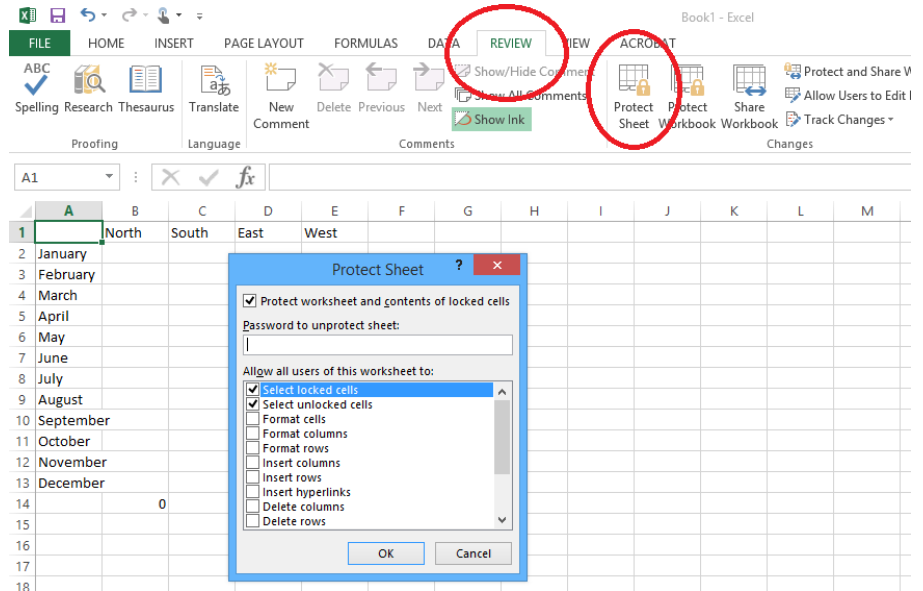
5.c.1 The Quality Assurance Manager will verify the formula functionality and submit the form and raw spreadsheet to the IT Manager.

5.c.2 The application should undergo formal qualification review to determine whether the functional requirement can and/or has fulfilled the user requirements, and to determine if there exist any limitations and/or risks of the use of the application once the application has been developed

5.c.3 The IT Manager will develop test data and verify the functionality of the formulas and the overall spreadsheet functionality.

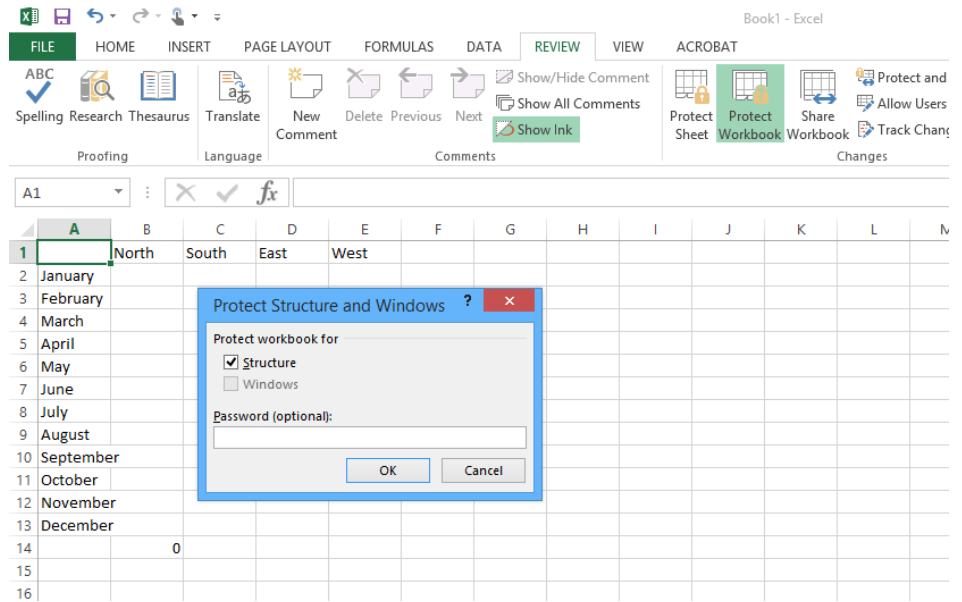
5.c.4 If the software functions as designed, the IT Manager will do a formal sheet protection operation by going to the tab 'Review' and select the 'Protect Sheet' button

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- 5.c.5 Keep the default top two boxes checked, 'Select locked cells' and 'Select unlocked cells'
- 5.c.6 Enter the Password and re-enter the Password as required.
- 5.c.7 The Work Sheet is protected. Users will not have the ability to change any field which is protected. Only dynamic data fields could be changed.
- 5.c.8 Protect and move the file to the server:
- 5.c.9 Protecting the Workbook prevents anyone from deleting, renaming or inserting new Work Sheets.
- 5.c.10 Protecting the Work Book is performed by going to the 'Review' tab and select 'Protect Workbook'

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- 5.c.11 Only the 'Structure' check box should be checked.
 - 5.c.12 Enter Password and re-enter as required.
 - 5.c.13 Move the file into the 'Approved Spreadsheets' folder on the shared server.
 - 5.c.14 Ensure that the Developer's local copy is erased, and the trash emptied to avoid accidental use.
- d) IT Manager should formally complete the Software Evaluation form and file the form with Document Management.

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6.0 ATTACHMENTS

NONE

7.0 REFERENCES

- MS Excel Training
- 21 CFR Part 11 Electronic Records; Electronic Signature
- 21 CFR Part 11 Electronic Records; Electronic Signature; Scope and Application

8.0 REVISION HISTORY

Rev.	Reason for Revision	Change Control No# (if applicable)	Effective Date
1.0	New Procedure	NONE	