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Prepared By: Date:	Reviewed By: Date:	Approved By: Date:
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1. PURPOSE AND OBJECTIVE

The purpose of this Standard Operating Procedure is to define the requirements for the creation, testing, approval, management, revision (change), distribution control and retirement 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.

1.1. To ensure that all personnel at **{Company}** understand the risk associated to the use of Spreadsheet.
1.2. MS Excel is not Part 11 Compliant due to the inability to meet the requirements of 21 CFR Part 11.10(e) Audit Trails;
1.3. It is understood that the software can create a quality and regulatory risk situation.
1.4. To ensure that all personnel at **{Company}** understand that individual Spreadsheets are considered to be software applications and should follow the procedures and requirements for any new software systems.
1.5. The objective of this procedure is to ensure that all personnel at **{Company}** understands the processes for requesting, creation, testing, approval, management, revision (change), distribution control and retirement.
1.6. The objective of this procedure is to outline the process and procedure for development, testing, and qualifying of Spreadsheets.

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2. 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 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 Spreadsheets.
e) Set forth a process to formally protect the software integrity of spreadsheets.
f) To set forth a process to formally protect and control access to spreadsheets.
g) Ensure that Employees understand the software's capabilities and understand that the Developer's capabilities cannot be used without IT Authority.

3. RESPONSIBILITIES

- Users (Developers) are responsible to ensure that they follow the procedures pertaining to Spreadsheet develop and all applicable procedures pertaining to Electronic Systems.
- Users (Developers) must have the education, training, background and experience to develop and test 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 Workbook is properly protected and that 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 Spreadsheets as required.
- It is the responsibility of the IT Manager and Quality Assurance to ensure that 'As-Like software or systems do not exist.

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4. DEFINITIONS

- 'As-Like' – Software which performs the same function as another software or spreadsheet. A redundant system.
- Developer or Requester – 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.
- Double-key verification – Two (2) separate operators both key the same indexing values while data entry software compares the information.
- 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.
- 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.
- Functional Specification or 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.
- Native Data – Data imported from a raw source or directly from a logical source from equipment or processes.
- Truncated – Shortened in duration or extent.
- 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.

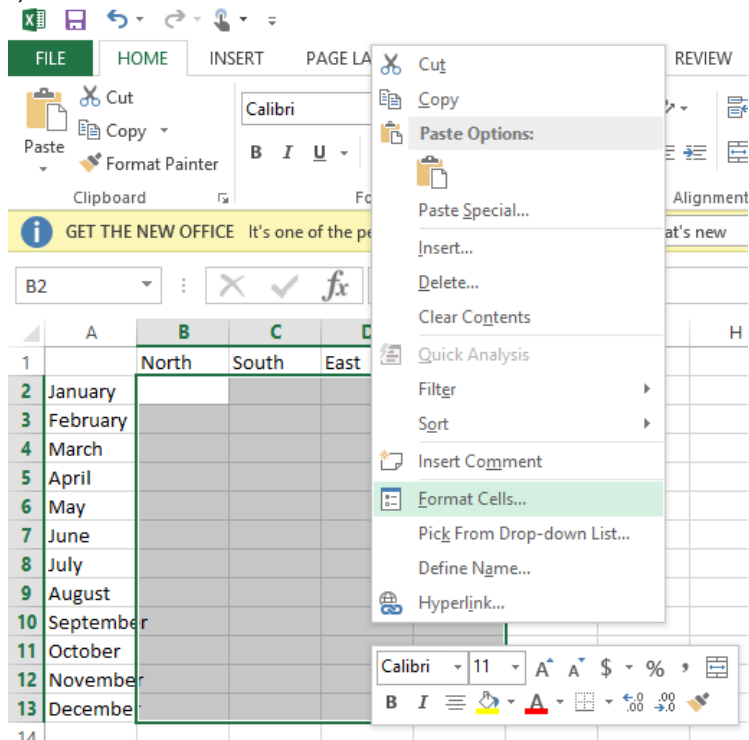| {Add Logo Here} | **STANDARD OPERATING PROCEDURE** | SOP No: QA-010 |
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5. PROCEDURE

5.1. The request process:

  5.1.1. All Microsoft (MS) Spreadsheets (here forth referred to as 'spreadsheet'(s) or 'application') will be considered Software Applications.

  5.1.2. All **{Company}** personnel who use spreadsheets must request the ability to create the spreadsheet with the Quality Assurance Manager.

  5.1.3. The 'Requester' or Developer will fill out the Software Request Form (xxx).

  5.1.4. The request should discuss the *User Requirement* and *Functional Specification* of the application in accordance with Industry Standards.

  5.1.5. The form will be presented to the Quality Manager, who will consider the risk applicability.

  5.1.6. The form will be reviewed by the IT Department for suitability and technical validity and to ensure that no 'as-like' software exists. IT will forward the form back to the Quality Assurance Department for final approval.

  5.1.7. 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.

  5.1.8. If the request is not approved, a statement of denial will be noted within the request form discussing the reasoning for the denial.

5.2. The development process:

  5.2.1. Users must understand the use of the application within the organization and the basic concepts of the application software develop process and protection concepts.

  5.2.2. Only the Company approved Microsoft Excel software will be used to create spreadsheets.

  5.2.3. There are two (2) types of spreadsheets for use;

    5.2.3.1. Imported data Acquisitions – Spreadsheets that are created by the importing of data from other systems;

    5.2.3.2. Static Non-Imported – Spreadsheets created by no imported data;

  5.2.4. For Static Systems – Users will open MS Excel and create a new spreadsheet on their local drive.

    5.2.4.1. Local drives should have a folder on the desktop titled 'Unapproved Files'. If folder does not exist, see IT Manager.

    5.2.4.2. The user shall use the basic naming convections for the spreadsheet files. {**SoftwareName** (i.e. Vendors Names, Equipment List, Employees, etc.) **–** (Hyphen) Revision or VersionNr**.** (Only numbers, i.e. 1, 2, 3, 4, Do not use decimals or commas)} (example: **Vendors-1.xls**)
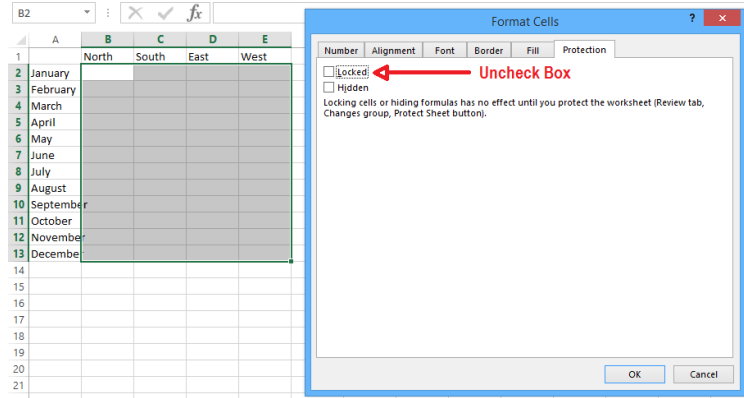
5.2.4.3.   Versions and Revision numbers will be used as required at the end of the identification numbering system.

5.2.4.4.   User shall save the spreadsheet file into the folder 'Spreadsheet'.

5.2.5. Basic development concepts shall apply:

5.2.5.1.   All new spreadsheets and templates must be pre-approved for use by the Quality Assurance Department.

5.2.5.2.   Three (3) types of protection will be discussed:

5.2.5.2.1.   Cell Locking

5.2.5.2.2.   Work Sheets

5.2.5.2.3.   Work Books

5.2.5.3.   Once the spreadsheet has been developed you will protect the Work Sheet:

5.2.5.3.1.   Cell Locking – 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'.

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

5.2.5.3.3.   Only uncheck the dynamic data cells only and not the fields with formulas attached.

5.2.5.3.4.   Save the file.

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

5.2.5.5.   Complete Section (x) of the Software Evaluation form and submit to the Quality Assurance Manager along with a copy of the raw spreadsheet.

5.3. The Testing and Qualification process (to be performed by the IT Department).

5.3.1. The Testing and Qualification process does not constitute full system validation requirements based upon the complexity or applicability of the software.

5.3.2. If the Microsoft Visual Basic Development Code capabilities are employed or used, to create a 'Stand-alone' type of software, then additional Validation Requirements would need to be developed in accordance with the Validation Master Plan (VMP). See additional Software Validation procedures as required.

5.3.3. The Quality Assurance Manager will verify all formula functionality and submit the form and raw spreadsheet to the IT Manager.

5.3.4. The application should undergo formal qualification review to determine whether the functional requirement can and/or has fulfil 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.

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

5.3.6. The IT Manager will print out the Test Data and attach the Software Request form, and save the raw Test Data in a protected sub-folder under the specific Spreadsheet folder labeled with the Spreadsheet software name.

5.3.7. The IT Manager will verify the formulations using the Peer-to-Peer method, saving screen shots or printed verification of calculations against the spreadsheet formulas.

5.3.8. Another way to ensure validity of data is to perform a 'Double-key verification'.

5.3.9. No Developer Code should be used to create spreadsheets or to be used to support spreadsheet functionality without approval from the Quality Assurance Department and the IT Department. If custom code is developed, the methods, procs, and scripts must be tested individually, and maintained by the IT Department.

5.3.10. Custom developed methods, procs, and scripts must be managed by change control outside of the Spreadsheet revision or version numbering system.

5.4. 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
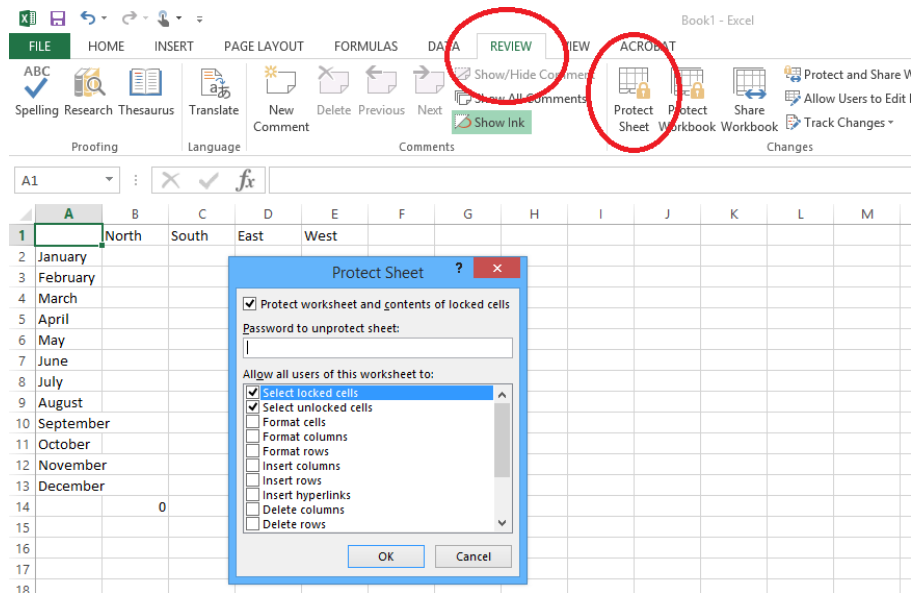
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5.4.1. Keep the default top two boxes checked, 'Select locked cells' and 'Select unlocked cells'

5.4.2. Enter the Password and re-enter the Password as required. The list of passwords should be protected in a secured file, accessible by the Quality Assurance Department.

5.4.3. The Work Sheet is protected. Users will <u>not</u> have the ability to change any field which is protected. Only dynamic data fields could be changed.

5.4.4. Protect and move the file to the server:

5.4.5. Protecting the Workbook prevents anyone from deleting, renaming or inserting new Work Sheets.

5.4.6. Protecting the Work Book is performed by going to the 'Review' tab and select 'Protect Workbook'
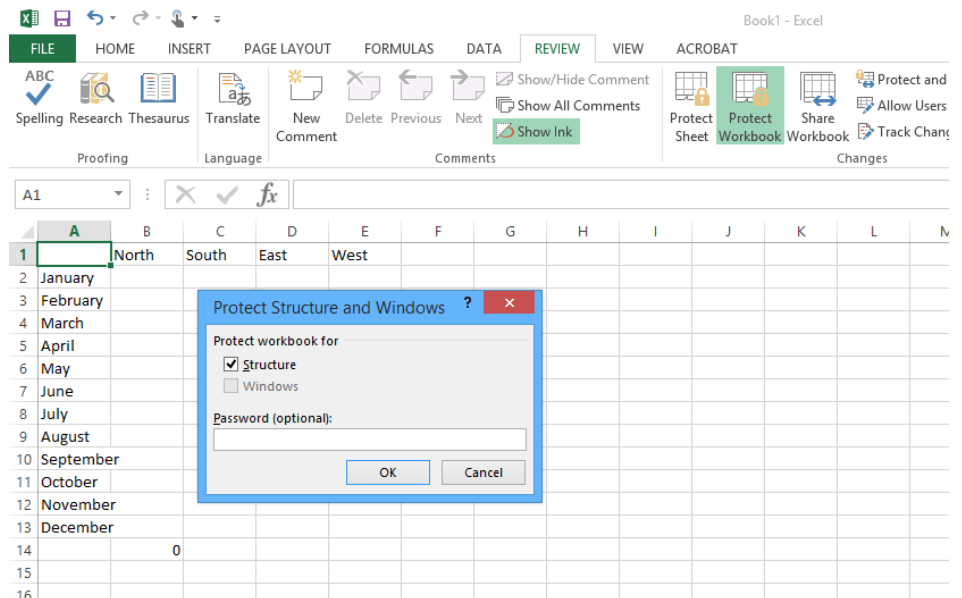
5.4.7. Only the 'Structure' check box should be checked.

5.4.8. Enter Password and re-enter as required.

5.4.9. Move the file into the 'Approved Spreadsheets' folder on the shared server.

5.4.10.   If this is a Spreadsheet to be used as a Template, ensure to save the file as a 'Excel Template'.

5.4.11.   Ensure that the Developer's local copy is erased, and the trash emptied to avoid accidental use.

5.5. IT Manager should formally complete the Software Evaluation form and file the form with Document Management.

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5.6. Employees or Developers should not utilize any unapproved spreadsheets in their local Hard drives.

5.7. IT will 'Spider' or audit all Hard drives on a regular frequency to ensure that no 'unapproved' software is available.

5.8. For Imported Data Acquisition systems or Data Imported spreadsheets.

    5.8.1. Ensure that the Native data source comes from a validated source.

    5.8.2. Ensure that the Native data mapping process is validated prior to use.

    5.8.3. If import is derived from a Native source, then the 'Export' must be qualified.

    5.8.4. Print out the raw data or save to a qualified drive supporting the development process or software file.

    5.8.5. If the Native source is an Exported file to a .CSV, .TXT, or .XLS(*) file, print out the raw data or save to a qualified drive supporting the development process or software file.

    5.8.6. Import the data in accordance with the instructions within the Spreadsheet software.

    5.8.7. Ensure that the Native data meets the import criteria, i.e., Comma, Tab or other Separated values, and import.

        5.8.7.1. Verify the data import had functioned as designed.

        5.8.7.2. Print out the data import verification screen and attach to the Software Request form.

    5.8.8. If importing to a template, ensure that the template is approved for use.

    5.8.9. Reports derived from Spreadsheets;

        5.8.9.1. Pre-set all margins and page lay-outs as required.

        5.8.9.2. Ensure that all Reports created by the Spreadsheet has approved Headers and Footers for use. The Header and Footer information will consist of, but not limited to;

            5.8.9.2.1. Company Name

            5.8.9.2.2. Date of Create or Reporting

            5.8.9.2.3. Page Number

        5.8.9.3. Ensure that data fields do not extend beyond the pre-set margins.

        5.8.9.4. Ensure that no data is 'Truncated' or return an 'Error'.

        5.8.9.5. Ensure that all reports are properly inspected and approved by the Quality Assurance Department prior to use.

    5.8.10. All data reported, should undergo Peer-to-Peer review for quality.

    5.8.11. All data reported, based upon risk will be verified by a formal sampling plan utilizing a Statistical Analysis criteria for data integrity based upon risk and applicability assigned to the data.

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5.8.12.　　Double-key verification should be employed, when necessary, based upon risk and applicability.

5.8.13.　　Secondary Verification review process should be employed where required, based upon risk and applicability.

5.8.14.　　All reports created by the Spreadsheet software will be formally archived and come under Document Change Control as required.

5.9. Exclusions;

5.9.1. Any MS Excel file which is to be considered 'Exempt' from this procedure should not be saved to any physical or logical hard drive.

5.9.2. Any 'Reporting' or calculations printed, derived from 'Exempt' software should be verified by independent review processes, in accordance with a formal statistical analysis plan and Secondary Verification review process.

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6. ATTACHMENTS

- Software Request form (xxx)

7. REFERENCES

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

8. REVISION HISTORY

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