



**SOFTWARE DESIGN SPECIFICATION  
FOR THE  
EXAMPLE VALIDATION SPREADSHEET  
SERVING**

**OFNI SYSTEMS  
RALEIGH, NORTH CAROLINA**

*Ofni Systems*

DOCUMENT NUMBER: SDS-001  
DATE ISSUED: 11/12/08  
REVISION: 0

PREPARED BY  
DANIEL WATERMAN  
VALIDATION MANAGER  
OFNI SYSTEMS

---

<b>Ofni Systems: Example Validation Spreadsheet Software Design Specification</b>		Doc. #: SDS-001 Rev. #: 0
Department: Validation	Author: Daniel Waterman	Page 2 of 16

Thank you for downloading this sample validation document.

Ofni Systems can validate all of your software, databases, spreadsheets and computer systems, and develop the appropriate documentation for all phases of the software life cycle. We can provide any level of service required, from executing test scripts generated from your existing specifications to writing the entire validation package. Ofni Systems will perform risk assessments to focus the validation effort on the most appropriate sections of your system.

These sample validation documents were produced with the [FastVal Validation Document generator](#) software, which allows us to complete validation projects in [70% less time](#) than traditional validation methods, with more time spent testing your software and less time preparing documentation. Our goal in all software validation projects is to improve the quality and value of your computer system.

Ofni Systems validation specialists have experience working within the compliance requirements of established regulated companies. Our specialists are experts in industry validation standards and will produce validation documents which will meet or exceed your exacting standards.

Ofni Systems is a leader in providing regulatory compliance solutions for pharmaceutical, biotech and medical device companies. They are the creators of [ExcelSafe for Excel spreadsheet security](#) and the [Part 11 Toolkit for compliant databases](#). They also are the creators of the [FastVal validation software for generating and executing validation documents](#), and have been providing [professional validation services](#) using FastVal since 2006. Their products for Part 11 compliant databases and spreadsheets are used by pharmaceutical, biotech and medical device companies across the globe, while it's products for computer validation, auditing and FDA submissions ensure that their clients meet every requirement for electronic records and electronic signatures.

How can we help you? Contact Ofni Systems at by [email](#) or by phone (919) 844-2494.

# Ofni Systems

## Tools for Compliance

### **FastVal™**

Produce validation documents, manage validation projects and execute testing protocols electronically in 70% less time.

### **ExcelSafe™**

Makes existing MS Excel spreadsheets compliant with all the technical requirements of 21 CFR Part 11.

### **Part 11 Toolkit™**

Transform MS Access programs into powerful, secure systems that meet all requirements of Part 11.

### **Part 11 Advisor™**

Assess all of your computer systems for compliance, perform gap analysis and create corrective action plans.

## Consulting and Services

### **Part 11 Assessments**

Determine the compliance status of your computer systems.

### **Computer Validation**

Validate new or updated software, database and computer systems.

### **Custom Programs**

Develop a compliant computer system specific to your requirements.

### **Data Migration**

Convert existing legacy data to an Access or SQL Server database.

### **Compliance Training**

Learn to build a fully Part 11 compliant electronic record system.

<b>Ofni Systems: Example Validation Spreadsheet Software Design Specification</b>		Doc. #: SDS-001 Rev. #: 0
Department: Validation	Author: Daniel Waterman	Page 3 of 16

**SIGNATURES**

Author: _____ Signature: _____ Date: _____
Document Control: _____ Signature: _____ Date: _____
Information Technology: _____ Signature: _____ Date: _____
Validation: _____ Signature: _____ Date: _____
Quality Assurance: _____ Signature: _____ Date: _____

**REVISION HISTORY**

Rev #	Description	Date Approved
0	Initial Issue.	

<b>Ofni Systems: Example Validation Spreadsheet Software Design Specification</b>		Doc. #: SDS-001 Rev. #: 0
Department: Validation	Author: Daniel Waterman	Page 4 of 16

**TABLE OF CONTENTS**

1. INTRODUCTION ..... 5

1.1. Objectives ..... 5

1.2. Scope ..... 5

1.3. Assumptions ..... 5

1.4. Exclusions ..... 5

2. ACRONYMS AND REFERENCES ..... 5

2.1. Acronyms and Definitions ..... 5

2.2. References ..... 6

3. SPREADSHEET DESCRIPTION ..... 6

3.1. Spreadsheet Software ..... 6

3.2. Software Architecture ..... 6

3.3. Design Principles ..... 7

4. SYSTEM INTERFACES ..... 7

4.1. Introduction ..... 7

4.2. Calculation ..... 7

5. REGULATORY REQUIREMENTS ..... 8

5.1. Controls for Closed Systems (21 CFR 11 B Sec. 11.10) ..... 8

5.2. Electronic Signature Manifestations (21 CFR 11 B Sec. 11.50, 11.70) ..... 10

5.3. User Password Controls ..... 12

5.4. Additional System Controls ..... 13

5.5. User-Level Security ..... 13

6. ADDITIONAL REQUIREMENTS ..... 15

6.1. Procedural Regulatory Requirements ..... 15

6.2. Ofni Systems Requirements ..... 16

<b>Ofni Systems: Example Validation Spreadsheet Software Design Specification</b>		Doc. #: SDS-001 Rev. #: 0
Department: Validation	Author: Daniel Waterman	Page 5 of 16

## 1. Introduction

### 1.1. Objectives

This is the Software Design Specification for the Example Validation Spreadsheet (SDS), for use by Validation at Ofni Systems (Raleigh, NC). The Example Validation spreadsheet has been identified a Category 5 cGxP system (customized MS Excel spreadsheet).

The Software Design Specification for the Example Validation Spreadsheet describes the system elements, functions and configuration necessary to properly operate the system within functional requirements outlined in the Functional Requirements Specification for the Example Validation Spreadsheet (FRS). The technical requirements will be used to develop the criteria for technical testing and acceptance for the system.

### 1.2. Scope

This specification applies to the Example Validation spreadsheet and details how the Example Validation spreadsheet will technologically meet requirements outlined in the Functional Requirements Specification for the Example Validation Spreadsheet (SDS). This document also addresses how the Example Validation spreadsheet meets all applicable regulatory and Ofni Systems requirements.

### 1.3. Assumptions

The validation will be performed on a properly functioning Ofni Systems workstation, with MS Excel and ExcelSafe properly installed.

### 1.4. Exclusions

This validation applies to the Example Validation spreadsheet, and not to MS Excel, ExcelSafe, the workstation or computer environment.

## 2. Acronyms and References

### 2.1. Acronyms and Definitions

CFR - Code of Federal (US) Regulations

cGxP - Abbreviation which includes current Good Manufacturing, Clinical and Laboratory Practices

Closed System - An environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

FRS - Functional Requirements Specification

GUI - Graphical User Interface

IOQ - Installation/Operational Qualification

LAN - Local Area Network

Open System - An environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.

SDS - Software Design Specification

SOP - Standard Operating Procedure

Spreadsheet - Generic term for application containing rows and columns of cells, with functions to manipulate data within those cells.

Workbook - A group of one or more worksheets contained within a spreadsheet file. The workbook may also include code modules.

Worksheet - One of possibly multiple data sheets within a workbook.

<b>Ofni Systems: Example Validation Spreadsheet Software Design Specification</b>		Doc. #: SDS-001 Rev. #: 0
Department: Validation	Author: Daniel Waterman	Page 6 of 16

## 2.2. References

21 CFR Part 11, Part 210, Part 211

GAMP 5 Guide for Validation of Automated Systems

FRS-001, Functional Requirements Specification for the Example Validation Spreadsheet

Validation Package for ExcelSafe, V2.0

## 3. Spreadsheet Description

### 3.1. Spreadsheet Software

The Example Validation spreadsheet is an MS Excel spreadsheet, with file name Example Validation.xlt.

3.1.1. All documentation required to operate and maintain the system is present.

3.1.2. All required ExcelSafe files are loaded.

### 3.2. Software Architecture

#### 3.2.1. Operating System

The Example Validation spreadsheet and ExcelSafe operate on any standard PC workstation which meets the minimum hardware specifications of the required operating system and has the required software application installed.

3.2.1.1. The operating system required for use is MS Windows 2000, MS Windows XP or MS Vista.

#### 3.2.2. Networking and System/Equipment Interactions

The Example Validation spreadsheet will be operated over the LAN, through the ExcelSafe program. The application supports use by multiple users from a shared location that is compatible with standard Microsoft Windows networking. Through the LAN, ExcelSafe and the Example Validation spreadsheet can use both a users local and network printers. This functionality will be demonstrated through successful installation and operation testing for the system. The following software must be installed:

3.2.2.1. All required ExcelSafe files are loaded.

3.2.2.2. Microsoft Access, Version 2000 or higher is installed.

3.2.2.3. Microsoft DAO, Version 3.51 or higher is installed.

3.2.2.4. The Example Validation spreadsheet is properly loaded in ExcelSafe.

#### 3.2.3. Hardware Description

The Example Validation spreadsheet and ExcelSafe will reside on the Ofni Systems LAN and allow remote access via the Ofni Systems network. An Ofni Systems standard PC workstation or Laptop PC, including remote access, is used to access the program.

3.2.3.1. The Example Validation spreadsheet can use local or networked printers.

#### 3.2.4. Security Configuration

The Example Validation spreadsheet is configured so it is not possible to access the spreadsheet without using ExcelSafe.

3.2.4.1. The spreadsheet will not open from outside ExcelSafe.

3.2.4.2. The spreadsheet opens correctly from inside ExcelSafe.

---

<b>Ofni Systems: Example Validation Spreadsheet Software Design Specification</b>		Doc. #: SDS-001 Rev. #: 0
Department: Validation	Author: Daniel Waterman	Page 7 of 16

### 3.3. Design Principles

All data entry cells are designated with a yellow background.

All calculation cells are designated with a green background.

All cells not designated as data entry cells are locked.

## 4. System Interfaces

### 4.1. Introduction

The Introduction worksheet provides a general introduction to the Example Validation worksheet. It also provides links to the validation documents. This is a non-regulated section of the workbook and has no requirements.

### 4.2. Calculation

The Calculation worksheet accepts data for Sample ID, Mass and Volume, and performs calculations on the data. The worksheet also includes the Plotting Mass vs. Volume chart, described below. The Calculation worksheet:

#### 4.2.1. Input Ranges

4.2.1.1. Allows users to enter appropriate values for Sample, Mass and Volume.

Range A6:A36 (Sample ID)

Range B6:B36 (Mass)

Range C6:C36 (Volume)

#### 4.2.2. Formulas and Functions

4.2.2.1. Calculates Maximum(Volume), Minimum(Volume) and Average(Volume).

Cell G6 (Max(Volume)) = Max(C6:C36)

Cell G8 (Min(Volume)) = Min(C6:C36)

Cell G10 (Average(Volume)) = Average(C6:C36)

4.2.2.2. Calculates Volume<sup>2</sup>

Range D6:D36 (Volume<sup>2</sup>) = C6:C36<sup>2</sup>

4.2.2.3. Allows users to secure and unsecure data by adding or removing electronic signatures.

ExcelSafe allows users to secure and unsecure data by adding or removing electronic signatures.

4.2.2.4. Records changes in user data to the ExcelSafe audit trail.

ExcelSafe records changes in user data to the ExcelSafe audit trail.

#### 4.2.3. Outputs (Data and charts)

4.2.3.1. Plotting Mass vs. Volume

The Plotting Mass vs. Volume spreadsheet meets the following requirements:

4.2.3.1.1. Chart Type

Plotting Mass vs. Volume is an XY (Scatter) chart.

4.2.3.1.2. Title and Axis Label

<b>Ofni Systems: Example Validation Spreadsheet Software Design Specification</b>		Doc. #: SDS-001 Rev. #: 0
Department: Validation	Author: Daniel Waterman	Page 8 of 16

Title: Plotting Mass vs. Volume

X Axis: Mass (g)

Y Axis: Volume (mL)

#### 4.2.3.1.3. Data Ranges

	X Values	Y Values
Volume	B6:B36	C6:C36
Volume <sup>2</sup>	B6:B36	D6:D36

4.2.3.2. Is properly formatted for printing.

Printing is performed by the MS Excel print functionality.

## 5. Regulatory Requirements

### 5.1. Controls for Closed Systems (21 CFR 11 B Sec. 11.10)

There are five technical requirements for systems in order to be compliant with 21 CFR Part 11 guidelines for closed systems. The Example Validation spreadsheet will meet or exceed all five of these requirements. The Example Validation spreadsheet uses ExcelSafe to meet regulatory requirements.

#### 5.1.1. Accurate Record Generation and Review

ExcelSafe and the Example Validation spreadsheet have the ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review and copying by regulatory agencies.

The functionality meets the following requirement of 21 CFR 11:

11.10.b The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform review and copying of the electronic records.

The Example Validation spreadsheet will meet the following requirements:

5.1.1.1. Users are able select search queries.

Users specify search queries in the Search Source field.

5.1.1.2. Users are able to customize the criteria used to view data from the search.

Users are able to customize search criteria in the Search Criteria field.

5.1.1.3. Users are able to view resulting data on a standard report created by the developer for the search being used.

Users specify a report in the Select a Report field. The report is displayed by clicking Preview Report on the Search Information and Generate Reports screen.

5.1.1.4. Users are able to export data to MS Excel.

Users can export data to MS Excel by clicking Excel on the Search Information and Generate Reports screen.

#### 5.1.2. Program Time-Outs

ExcelSafe provides the Example Validation spreadsheet with will automatically time-out after 10 minutes of non-activity. This functionality is provided by ExcelSafe.



<b>Ofni Systems: Example Validation Spreadsheet Software Design Specification</b>		Doc. #: SDS-001 Rev. #: 0
Department: Validation	Author: Daniel Waterman	Page 9 of 16

The functionality meets the following requirements of 21 CFR 11:

11.10.d Limiting system access to authorized individuals.

11.300.d Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.

The Example Validation spreadsheet meets the following Program Timeouts requirements:

5.1.2.1. The program provides users with the ability to secure the program without exiting.

Clicking Lock Program under the Tools menu puts the ExcelSafe and the spreadsheet into Locked mode.

5.1.2.2. If the current user cannot re-enter the session, the only other option is to close the program.

The user cannot exit Locked mode without entering the correct password. This functionality is provided by ExcelSafe.

5.1.2.3. Only the current user may have the ability to unsecure the program to continue the current session.

Only the current users password will exit the program from Locked mode. This functionality is provided by ExcelSafe.

5.1.3. Audit Trails

ExcelSafe provides the Example Validation spreadsheet with an audit trail, recording changes to all spreadsheet data. The audit trail is provided by ExcelSafe.

The functionality meets the following requirements of 21 CFR 11:

11.10.e Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.

11.10.k.2 Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.

The audit trail is tested generally on each worksheet and further tested in a test case dedicated to the audit trail.

The Example Validation spreadsheet audit trail meets the following requirements:

5.1.3.1. Computer Generated

The spreadsheet audit trail records are automatically generated from ExcelSafe.

5.1.3.2. Secure

The spreadsheet audit trail records are secure (read-only access), stored within the compiled ExcelSafe data core.

5.1.3.3. Date/Time Stamp

<b>Ofni Systems: Example Validation Spreadsheet Software Design Specification</b>		Doc. #: SDS-001 Rev. #: 0
Department: Validation	Author: Daniel Waterman	Page 10 of 16

The spreadsheet audit trail records have an accurate Date/Time stamp, provided by ExcelSafe.

#### 5.1.3.4. Journal Function

The spreadsheet audit trail records the Date/Time of operator entries and actions that create, modify and delete electronic records. This functionality is provided by ExcelSafe.

#### 5.1.3.5. Unalterable

Changes to the spreadsheet audit trail does not obscure previously recorded information.

#### 5.1.3.6. Retention

Audit-trail records are maintained for at least as long as the retention of the underlying records. The audit trail is imbedded within the record and cannot be separated. Record retention is controlled by Ofni Systems SOP.

#### 5.1.3.7. Accessibility

Audit trail records are available for FDA review and copying. The audit trail is accessible by clicking Audit Trail, with the appropriate spreadsheet open.

#### 5.1.4. Operational System Checks

The Example Validation spreadsheet uses operational system checks to enforce permitted sequencing of steps and events, as appropriate.

The functionality meets the following requirements of 21 CFR 11:

11.10.f Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.

Operational System Checks for the Example Validation spreadsheet will be tested on the appropriate worksheet.

#### 5.1.5. Device Checks

The Example Validation spreadsheet uses of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.

The functionality meets the following requirements of 21 CFR 11:

11.10.h Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.

Data input for spreadsheets is typically performed through the keyboard and is tested implicitly throughout the validation.

#### 5.2. Electronic Signature Manifestations (21 CFR 11 B Sec. 11.50, 11.70)

ExcelSafe has the ability to secure data in the Example Validation spreadsheet through electronic signatures. Data secured with an electronic signature cannot be edited or deleted unless the electronic signature is removed. Application of an electronic signature requires use of the users ID and password. This functionality will be provided by ExcelSafe, supplemented by the Example Validation System Administration SOP.

##### 5.2.1. Electronic Signature and Meaning

Electronic signatures within the Example Validation spreadsheet include the printed name of the signer, the date/time the signature was added and the meaning of the electronic signature. This functionality is provided by ExcelSafe.

The functionality meets the following requirements of 21 CFR 11:

<b>Ofni Systems: Example Validation Spreadsheet Software Design Specification</b>		Doc. #: SDS-001 Rev. #: 0
Department: Validation	Author: Daniel Waterman	Page 11 of 16

11.50.a Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:

11.50.a.1 The printed name of the signer;

11.50.a.2 The date and time when the signature was executed; and

11.50.a.3 The meaning (such as review, approval, responsibility, or authorship) associated with the signature.

The electronic signatures will meet the following requirements:

5.2.1.1. Application of an electronic signature requires use of the User ID and password.

The user selects an appropriate cell in the spreadsheet. The user enters their password in the appropriate field. (The User ID was entered previously when the User opened ExcelSafe.) Without entering the correct password associated with the User ID, ExcelSafe will not apply the electronic signature.

5.2.1.2. Data secured with an electronic signature cannot be edited or deleted unless the electronic signature is removed.

Once the electronic signature is applied to a worksheet, data cannot be edited or altered on the worksheet. This functionality is provided by ExcelSafe.

5.2.1.3. Multiple electronic signatures can be applied to a single workbook page.

This functionality is provided by ExcelSafe.

5.2.1.4. Include the printed name of the user applying the electronic signature. ExcelSafe includes the user name in the electronic signature.

5.2.1.5. Include the Date/Time when the electronic signature was applied. ExcelSafe includes the Date/Time in the electronic signature.

5.2.1.6. Include the Meaning of the electronic signature.

ExcelSafe includes the meaning of the electronic signature in the electronic signature.

5.2.1.7. Electronic signature is human-readable.

The electronic signature created by ExcelSafe is text and is human-readable.

5.2.2. Electronic Signature Compliance

Electronic Signatures within the Example Validation spreadsheet meets all requirements for 21 CFR 11 identified in this document, including audit trails and password controls. The ExcelSafe audit trail tracks the application and removal of electronic signatures. ExcelSafe also enforces all password controls.

The functionality meets the following requirements of 21 CFR 11:

11.50.b The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).

5.2.3. Signature/Record Linking

Electronic Signatures within the Example Validation spreadsheet are linked to the respective electronic records in such a manner that the record and the electronic

<b>Ofni Systems: Example Validation Spreadsheet Software Design Specification</b>		Doc. #: SDS-001 Rev. #: 0
Department: Validation	Author: Daniel Waterman	Page 12 of 16

signature cannot be separated, copied, transferred or otherwise falsified. Electronic signatures are imbedded into the appropriate cell of the worksheet. There is also a corresponding record placed in the audit trail for the spreadsheet.

The functionality meets the following requirements of 21 CFR 11:

11.70 Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.

### 5.3. User Password Controls

ExcelSafe allows users to update their passwords. ExcelSafe also provides the ability for administrators to control user access and security group membership, define password complexity and time limits, add new users and reset the passwords of existing users. The functionality should also meet the following requirements of 21 CFR 11:

11.10.d Limiting system access to authorized individuals.

11.10.g Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.

11.300.a Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.

11.300.b Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).

11.300.d Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.

User Password Controls are controlled by ExcelSafe and testing the password controls is beyond the scope of this validation.

Passwords will meet the following technical requirements:

#### 5.3.1. Limited Access and Unauthorized Access

ExcelSafe limits system access to the Example Validation spreadsheet to authorized individuals. User passwords prevent unauthorized access to the system. The Example Validation spreadsheet cannot be accessed without an active UserID and password to ExcelSafe. Example Validation permits the detection of and report in an immediate and urgent manner any attempt at unauthorized access to the system and may notify the security unit, and/or organizational management. This functionality is controlled by the ExcelSafe security protocols.

#### 5.3.2. Authority Checks

ExcelSafe provides the Example Validation spreadsheet uses authority checks to ensure that only authorized individuals can use the system, electronically sign a record or remove an electronic signature.

#### 5.3.3. Password Uniqueness

ExcelSafe maintains the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.

<b>Ofni Systems: Example Validation Spreadsheet Software Design Specification</b>		Doc. #: SDS-001 Rev. #: 0
Department: Validation	Author: Daniel Waterman	Page 13 of 16

#### 5.3.4. Password Periodic Review

ExcelSafe ensures that identification code and password issuance's are periodically checked, recalled, or revised (e.g., to cover such events as password aging). User passwords expire after a certain period of time, in according with Ofni Systems rules or a system administrator.

#### 5.3.5. Password Expiration

User passwords will expire after a certain period of time, in according with Ofni Systems rules or a system administration SOP.

### 5.4. Additional System Controls

#### 5.4.1. Event Logging

ExcelSafe records significant Example Validation spreadsheet events, including system log-ins, log-outs, system errors and failed log-in attempts. This functionality is provided by ExcelSafe.

#### 5.4.2. System Access

Access to the ExcelSafe and the Example Validation spreadsheet must be controlled by User Access to the LAN controlled by System Identification and Password, i.e. the folder in the LAN must be set up to allow users to read/write the data files from the folder as well as set up to deny access to personnel not on the user list. This functionality is controlled by the LAN and proceduralized by Ofni Systems SOP.

#### 5.4.3. Input Checks

Where appropriate, entries may be programmatically checked before being accepted by the Example Validation Spreadsheet. This includes the use of combination boxes to restrict allowed values into text boxes, programmatic checks of numerical values (For example, no negative values accepted for number of donors). Testing input checks is done on the appropriate spreadsheet interface.

### 5.5. User-Level Security

The Example Validation spreadsheet is protected by ExcelSafe, which uses four levels of user security:

#### 5.5.1. GenUsers

Members of the GenUsers group:

##### 5.5.1.1. Can open the spreadsheet.

ExcelSafe does not restrict users from opening spreadsheets.

##### 5.5.1.2. Cannot add spreadsheet data.

ExcelSafe only allows GenUsers to open spreadsheets in Read-Only mode.

##### 5.5.1.3. Cannot edit spreadsheet data.

ExcelSafe only allows GenUsers to open spreadsheets in Read-Only mode.

##### 5.5.1.4. Cannot delete spreadsheet data.

ExcelSafe only allows GenUsers to open spreadsheets in Read-Only mode.

##### 5.5.1.5. Cannot sign pages within the spreadsheet.

The sign spreadsheet control is inactive for GenUsers.

##### 5.5.1.6. Cannot remove electronic signatures from the spreadsheet.

<b>Ofni Systems: Example Validation Spreadsheet Software Design Specification</b>		Doc. #: SDS-001 Rev. #: 0
Department: Validation	Author: Daniel Waterman	Page 14 of 16

The button to remove electronic signatures does not allow a GenUser to remove an electronic signature.

#### 5.5.2. DataEntry

Members of the DataEntry group:

5.5.2.1. Can open the spreadsheet.

ExcelSafe does not restrict users from opening spreadsheets.

5.5.2.2. Can add spreadsheet data.

Members of DataEntry open spreadsheets in editable mode.

5.5.2.3. Can edit spreadsheet data.

Members of DataEntry open spreadsheets in editable mode.

5.5.2.4. Can delete spreadsheet data.

Members of DataEntry open spreadsheets in editable mode.

5.5.2.5. Cannot sign pages within spreadsheets.

The sign spreadsheet control is inactive for members of DataEntry.

5.5.2.6. Cannot remove electronic signatures from the spreadsheet.

The button to remove electronic signatures does not allow members of DataEntry to remove an electronic signature.

#### 5.5.3. Managers

Members of the Managers group:

5.5.3.1. Can open the spreadsheet.

ExcelSafe does not restrict users from opening spreadsheets.

5.5.3.2. Can add spreadsheet data.

Managers open spreadsheets in editable mode.

5.5.3.3. Can edit spreadsheets.

Managers open spreadsheets in editable mode.

5.5.3.4. Can delete spreadsheet data.

Managers open spreadsheets in editable mode.

5.5.3.5. Can sign pages within spreadsheets.

The sign spreadsheet control is active for Managers.

5.5.3.6. Cannot remove electronic signatures from the spreadsheet.

The button to remove electronic signatures does not allow Managers to remove an electronic signature.

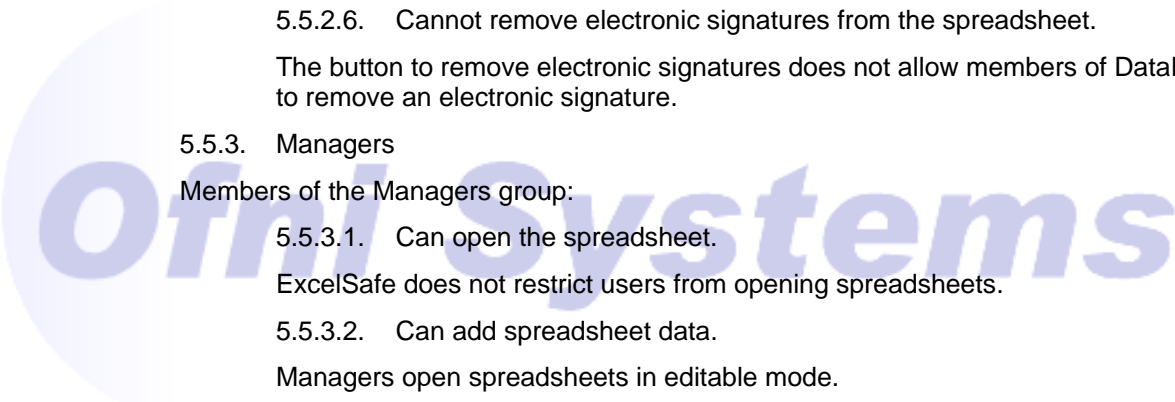
#### 5.5.4. Administrators

Members of the Administrators group:

5.5.4.1. Can open the spreadsheet.

ExcelSafe does not restrict users from opening spreadsheets.

5.5.4.2. Can add spreadsheet data.



<b>Ofni Systems: Example Validation Spreadsheet Software Design Specification</b>		Doc. #: SDS-001 Rev. #: 0
Department: Validation	Author: Daniel Waterman	Page 15 of 16

Administrators open spreadsheets in editable mode.

5.5.4.3. Can edit spreadsheets.

Administrators open spreadsheets in editable mode.

5.5.4.4. Can delete spreadsheet data.

Administrators open spreadsheets in editable mode.

5.5.4.5. Can sign pages within spreadsheets.

The sign spreadsheet control is active for Administrators.

5.5.4.6. Cannot remove electronic signatures from the spreadsheet.

The button to remove electronic signatures allows Administrators to remove an electronic signature.

## 6. Additional Requirements

### 6.1. Procedural Regulatory Requirements

There are four procedural requirements for systems in order to be compliant with 21 CFR Part 11 guidelines. Compliance with these requirements will be done through verification of the appropriate established Ofni Systems policies and procedures. The Example Validation spreadsheet will meet or exceed all four of these requirements.

#### 6.1.1. System Validation

The Example Validation spreadsheet will be validated.

The functionality meets the following requirement of 21 CFR 11:

11.10.a Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.

#### 6.1.2. System Documentation

Ofni Systems Standard Operating Procedures covering operation, maintenance, security, backup and recovery, and data archival and retrieval will be created before the system is considered validated. The system operational procedure will outline the responsibilities associated with the electronic signatures, including that each electronic signature must only be used by their genuine owners.

The functionality meets the following requirement of 21 CFR 11:

11.10.j The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.

11.10.k.1 Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.

#### 6.1.3. System Training

All personnel using the Example Validation spreadsheet will be adequately trained. This training will be documented per Ofni Systems procedure.

The functionality meets the following requirement of 21 CFR 11:

11.10.i Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.

#### 6.1.4. Archive and Backup/Recovery

<b>Ofni Systems: Example Validation Spreadsheet Software Design Specification</b>		Doc. #: SDS-001 Rev. #: 0
Department: Validation	Author: Daniel Waterman	Page 16 of 16

The archive of Example Validation spreadsheet will follow Ofni Systems Record Retention and Backup/Recovery policies.

The functionality meets the following requirement of 21 CFR 11:

11.10.c Protection of records to enable their accurate and ready retrieval throughout the records retention period.

#### 6.1.5. Software Version Control

Changes to the Example Validation spreadsheet can be recorded on a Software Version Control plan. All changes should be made and tested in a controlled version of Example Validation in a development environment. A testing protocol, appropriate to the changes being proposed should be written. Both the software version control and testing protocols need to be in accordance with Ofni Systems requirements for Qualification and Validation. Once the software version control plan and testing protocol are written, a change control can be opened. If changes to the Functional Requirements Specification or Software Design Specification are required, these revisions should be included in the change control. The testing protocol is then executed. If the testing is successful, Example Validation can be updated and the change control closed.

#### 6.2. Ofni Systems Requirements

##### 6.2.1. System Interactions

The Example Validation spreadsheet does not interact with any other validated computer systems beyond those described in this document.

##### 6.2.2. System Performance

There are no system performance requirements for the Example Validation spreadsheet.

##### 6.2.3. System Availability

The system is available during normal business hours 800-1700 EST. The Example Validation spreadsheet will be maintained by the Validation group, supported by IS, where appropriate. When changes to the spreadsheet required, they should be scheduled outside of business hours, if possible.

##### 6.2.4. Backup/Recovery

6.2.4.1. The Example Validation spreadsheet will be backed up daily on the LAN.

6.2.4.2. The Example Validation spreadsheet will be 100% recoverable within one business day.

6.2.4.3. A master copy of the MS Excel, ExcelSafe and the Example Validation spreadsheet must be securely maintained.

6.2.4.4. The method to load MS Excel, ExcelSafe and the Example Validation spreadsheet exists.

##### 6.2.5. Physical Environment

Example Validation uses standard Ofni Systems PC workstation located in a typical office environment.

---