

APPENDIX E-14
Spiking Contractor SOPs and QA Manual

ESS Standard Operating Procedures

Job Steps, Key Risks, and Measures to Control Risks

Equipment:	Metering pumps, scales, steam-heated vaporizer, connecting lines, drum dollies, spiking chemicals in drums, and tools
Job Scope:	Environmental performance test spiking: Meter a combination of Spiking Material to simulate maximum total loading and maximum feed rate to demonstrate performance.
Chemicals associated with SOP:	
Key Risks:	<input type="checkbox"/> Fire & Explosion <input type="checkbox"/> Elevated Work <input type="checkbox"/> Confined Space <input type="checkbox"/> Secondary Impacts <input type="checkbox"/> Chemical Exposure <input type="checkbox"/> Entanglement - Crushing <input type="checkbox"/> Transportation Impacts <input type="checkbox"/> Stored Energy <input type="checkbox"/> MSD <input type="checkbox"/> Regulatory Impacts <input type="checkbox"/> & Product Impacts

SYSTEM CONDITIONS FOR LINE BREAKS: (X) Not Applicable () Isolated and Cleared () Isolated but not Cleared () Not Isolated Not Cleared	Notes: ESS = Engineered Spiking Solutions Safety measures for flammables include: explosion-proof and grounded equip, fire extinguishers w/i 50', flame arresters, and nomex/fire-resistant clothing. Spiking activities are conducted inside of secondary containment. Use absorption pads under fittings, clean leaks & spills immediately. Carefully segregate potentially haz waste from normal debris and manage drainings, flushings, debris as directed by client environmental.
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Responsibility	Sequence of Basic Job Steps	Potential Risks	Preventative Measures
Setup & Checkout Spiking Equip (ESS)	1. Construct spiking operation secondary containment	Slip/Trips/Falls/Equip/ Personnel Impacts	General safe work practices; PPE coveralls, hardhat, steel -toes, safety glasses, and gloves; good housekeeping practices; barricade spiking system operational area.
	2. Setup/checkout pumps, vaporizer, scales, spiking material drums, drum dollies, and associated connections	Material spills from leaks; Fire/Explosion (FE)	GFCI extension cords; fire extinguisher ; activated carbon system for fume control; spiking system pressure relief valve.
	3. Align valves for recycle operation; start spiking pumps; check for proper pump operation and system leaks; make repairs and adjustments as needed; shut off pumps when initial checkout is complete; close system valves		
	Note: When using dispersion pressure feed system, the system pressure relief valve (PRV) must be tested prior to use. Set the PRV to lift at 10 psig and connect the pressure control/relief header (not connected to drum) to the pressure source. Gradually increase the regulator setting > 10 psig to confirm PRV lifts. Once confirmed, close the pressure source valve, set the regulator to normal operating level (7-8 psig), install the header on the dispersion feed drum, and open the pressure source valve.	Material spills and leaks, or personnel injury caused by an over pressurized drum.	Conduct field test as described once as part of the initial equipment setup (retesting is not required).
	Note: When using plant steam to operate vaporizer (e.g., for vaporizing organic chemicals), connect the steam supply line and perform two functional tests prior to introducing liquid organics, verify that: (1) the steam trap functions as intended, and (2) the vaporizer temperature increases as expected.	Personnel exposure if in service equipment required maintenance.	Conduct field test as described once as part of the initial equipment setup (retesting is not required).
Prepare Waste Feed Line Tie-in (CLIENT)	1. ESS provides control room operator w spiking connection fitting & SOP as part of safety permitting.	Slip/Trips/Falls/Equip/ Personnel Impacts	General safe practices; Coverall, hardhat, steel-toes, safety glasses, and gloves; good housekeeping
	2. Client's operator dons appropriate PPE (based on waste feed hazards, at min: (a) coveralls, (b) hard hat, (c) impermeable gloves, and (d) splash goggles) and verifies connection fitting threads/operating condition.	Exposure (E) to hazardous waste.	Wear specified PPE when purging line; use oil pad or kitty litter in purge container to absorb liquid; transfer contents of purge container to hazardous waste collection drum.
	3. Client's operator removes injection point plug and/or valve lock, notifies control room that injection valve is about to be opened, opens the valve, purges connection point line to waste container, and close valve.		
	4. Client's operator attaches connection fitting to injection point.		
Spiking Line Connection (ESS)	1. Connect hose to spiking side of connection fitting.	Material spills from leaks	Refer to "Spiking Equipment Setup (ESS)" above.
	2. Open valve on spiking side of connection fitting; check for leaks; make repairs and adjustments, as needed.		
	3. Close valve on spiking side of connection fitting.		
Vaporizer Startup (ESS)	1. Open valves in steam supply line.	Material spills from leaks	Refer to "Spiking Equipment Setup (ESS)" above.
	2. Open valves on spiking side of connection fitting and inspect/correct spiking operation, as needed.		
	3. Close valves on spiking side of connection fitting.		
Open Waste Feed Line Tie-in Valve (CLIENT)	1. ESS asks control room to open valves on process side of connection fitting.	Material spills from leaks	Refer to "Spiking Equipment Setup (ESS)" above.
	2. Client's operator opens valves on process side of connection fitting.		
Spiking Full System Checkout (ESS)	1. Align valves for recycle operation, start spiking pumps, and inspect/correct spiking operation, as needed.	Material spills from leaks	Refer to "Spiking Equipment Setup (ESS)" above.
	2. Notify control room that spiking is about to begin, open valves on spiking side of connection fitting & begin spiking, and inspect/correct spiking operation, as needed.		

Responsibility	Sequence of Basic Job Steps	Potential Risks	Preventative Measures
	3. Once rate and operability are confirmed, align system valves back to recycle mode, close valve on spiking side of connection fitting and notify control room that spiking system checkout is complete.		
	4. Shutoff all equipment, close all valves, secure all equipment/materials/tools/electrical & electronic connections.		
Spiking System Startup and Normal Operation (ESS)	1. Align valves for recycle operation, start spiking pumps, and inspect/correct spiking operation, as needed. 2. Notify control room that spiking is about to begin, open valves on spiking side of connection fitting & begin spiking, and inspect/correct spiking operation, as needed. 3. Adjust systems to achieve and maintain target rates, collect & record all spiking rate data, maintain close vigil on rates and systems for leaks &/or malfunctions, continue for duration of testing or as directed by test manager.	Material spills from leaks	Refer to "Spiking Equipment Setup (ESS)" above.
Spiking System Normal Shutdown (ESS)	1. At end of testing and/or as directed by test manager, align system valves back to recycle mode. 2. Close valves on spiking side of connection fitting. 4. Notify unit control room that spiking system is off. 4. Shutoff all equipment, close all valves, secure all equipment/materials/tools/electrical & electronic connections.	Material spills from leaks	Refer to "Spiking Equipment Setup (ESS)" above.
Spiking System Rapid Shutdown and Restart (ESS)	1. In event of AWFCO or as directed by test manager, place spiking system operation in stand-by by aligning valves for recycle operation. 2. Close valves on spiking side of connection fitting and continue spiking system operate in recycle mode until directed by test manager to restart spiking or to shutdown. Restart or shutdown spiking operations in normal manner.	Material spills from leaks	Refer to "Spiking Equipment Setup (ESS)" above.
Spiking System Drum Change Out (ESS, assumes tandem scale system not in use)	1. Prepare new spiking material drum by attaching drum fittings and staging near scale base. 2. Stop spiking pump, close drum feed valve, place drip pan/pad under connection, disconnect suction hose from empty drum, remove empty drum from scale, position full drum horizontally on scale (for flooded suction), connect suction hose to full drum, open drum feed valve, restart pump, and swap out drum fittings w original plugs in empty drum. 3. Inspect/correct spiking operation, as needed.	Material spills from leaks; Fire/Explosion (FE)	Refer to "Spiking Equipment Setup (ESS)" above.
Clear Lines/Equipment of Spiking Materials (ESS)	1. Stop spiking pump, position drum vertically, disconnect suction hose from pump skid, and drain suction hose into feed drum. Close drum feed valve, disconnect suction hose from drum, and remove drum from scale base. Depressurize all tubing/equipment, drain liquid(s) and dispersion (as 2. Reconnect suction hose to pump skid, place drum end of suction hose in a 5 gallon container of clean cutter fluid, adjust pump to max rate, pump fluid through pump skid/lines and into process until fluid is gone, and drain any fluid from lines into appropriate container. 3. When purge is complete, shutoff all equipment, close all valves, notify control room that spiking has been completed and spiking system is off.	Material spills from leaks; Fire/Explosion (FE)	Refer to "Spiking Equipment Setup (ESS)" above.
Recover Spiking Equipment (ESS)	1. Clean spiking equipment/tools, disconnect all hoses, electrical/electronic cables, and load/pack all equipment/tools/supplies for secure transport. 2. De-construct spiking operation secondary containment. 3. Inspect all empty, partial, and full spiking material drums for proper identifying labeling. Clean residuals from empty/partial feed drums. 4. Place cleaning residuals, membrane, rags, drip pads, gloves, PPE, etc. into appropriate containers, as directed by client environmental and secure container lids. 5. Thoroughly police area for any contamination, debris, tools, materials, and trash. Do not stop until the entire area is clean & tidy .	Material spills from leaks; Fire/Explosion (FE)	Refer to "Spiking Equipment Setup (ESS)" above.
Recover from Spiking Operation (CLIENT)	1. Close valve on CLIENT side of waste line connection. 2. Disconnect spiking connection fitting & return to ESS. 3. Re-install connection point plug and/or valve lock. 4. Inspect area for any spiking material residues; cleanup/remove as necessary. 5. Inspect area of spiking operation; for any spiking material residues and equipment; direct ESS to cleanup/remove as necessary. 6. Label all empty and unused spiking material drums, and hazardous waste collection drum as directed by CLIENT Environmental. 7. Remove all empty and unused spiking materials drums, and hazardous waste collection drum for disposal as directed by CLIENT Environmental.	Exposure (E) to hazardous waste; Material spills from leaks; Fire/Explosion (FE)	Refer to "Spiking Equipment Setup (ESS)" and "Prepare Waste Feed Line Tie-in (CLIENT)" above.

Refer to the attached diagrams for additional detail on the spiking system setup and operation.

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[Rev 4, 10/14/2010]



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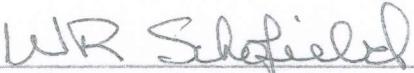
ATTACHMENTS

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REVIEW, RECORD OF CHANGES, & MANUAL APPROVAL

1.0 Documentation of Annual Quality Manual Review:

By way of my signature hereto, I am documenting that the Annual Review of the **ESS Quality Manual** was completed, in accordance with **ESS DIRC SOP #1: QUALITY DOCUMENTS & RECORDS CONTROL PROCEDURE**:



 Signature, W R (Bill) Schofield, PhD, PE
 ISO 9001 Management Representative (MR)

12/22/2011

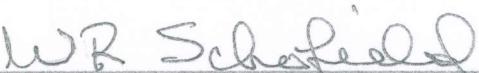
 Date

2.0 Record of Changes:

Rev #	Rev Date	Approved By:	Summary Description of Change:
#0	4/19/2004	WRS	Initial Issue
#1	6/30/2005	WRS	Revisions Based on: 1. The 2005 Comprehensive Review of the Quality Manual, & 2. ESS' Experience During the 1 st Year of Operation Under the QMS
#2	7/3/2006	WRS	Revisions Based on: 1. The 2006 Comprehensive Review of the Quality Manual, & 2. ESS' Experience During the 2nd Year of Operation Under the QMS
#3	6/16/2009	WRS	Revisions Based on: 1. The 2007 Comprehensive Review of the Quality Manual, & 2. ESS' Experience During the 3rd Year of Operation Under the QMS
#4	12/2/2011	WRS	REVISION BASED ON: 1. THE 2011 COMPREHENSIVE REVIEW & 2. ESS' EXPERIENCE 2009-2011 UNDER THE QMS.

3.0 Documentation that the Quality Manual, as Revised, Has Been Approved

By way of my signature hereto, I am documenting that the (Rev 4) **ESS Quality Manual** including all attachments, procedures, work instructions, & templates have been reviewed and approved, as revised.



 Signature, W R (Bill) Schofield, PhD, PE
 ISO 9001 Management Representative (MR)

12/22/2011

 Date

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REFERENCES:

1. INTERNATIONAL STANDARDS ORGANIZATION (ISO) DOCUMENTS:
 - A. AMERICAN NATIONAL STANDARD, Quality Management Systems- Fundamentals & Vocabulary, **ANSI, ISO, & ASQ, Q9000-2000**
 - B. INTERNATIONAL STANDARD **ISO 9001:2000, Quality Management Systems- Requirements**, Third Edition, 12/15/2000.
 - C. INTERNATIONAL STANDARD **ISO 19011, Guidelines for Quality &/or Environmental Management Systems Auditing**, First Edition, 10/01/2002
 - D. **ISO 9000** Introduction and Support Package: **Guidance on the Process Approach** to Quality Management Systems, 5/17/2001
 - E. **ISO 9000** Introduction and Support Package: **Guidance on the Terminology** Used in **ISO 9001:2000** and **ISO 9004:2000**
 - F. **ISO 9000 Introduction and Support Package: Guidance on the Documentation Requirements of ISO 9001:2000**
 - G. **ISO 9000** Introduction and Support Package: **Guidance on ISO 9001:2000 Clause 1.2 'Application**
 - H. **ISO 9001:2000** Interpretation of fourteen (14) **ISO 9001:2000 Clauses**
2. Schofield, Bill, et. al., The Effect of Measurement Uncertainty on Spiking Material Composition and Spiking Rate Uncertainties, 2004 **IT3** Conference Proceedings
3. Schofield, Bill, et. al., The Effect of Measurement Uncertainty on Field Spiking Rate and Overall Specie Spiking Rate Uncertainties, 2004 **IT3** Conference Proceedings
4. Schofield, Bill, et. al., An Extended Analysis of Measurement Uncertainty in the Spiking Function, 2006 **IT3** Conference Proceedings
5. Schofield, Bill, et. al., Model QA/QC Program for the Spiking Function, 2007 **IT3** Conference Proceedings

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1.0. INTRODUCTION

1.1 Purpose

The purpose of the Quality Management System (QMS) is to implement the requirements of **ISO 9001:2000** (Reference 1 B) as applicable to **ESS**' Spiking Products and Services including **ESS**' associated Products & Services Realization Process (or Products & Services Delivery System).

Further, this Manual defines the goals, objectives, methods, checklists, &/or procedures through which **ESS** meets these requirements.

1.2 Discussion

ESS established this **QMS**:

- To effect continuous improvements to all aspects of **ESS**' operations that affects **ESS**' ability to meet customer requirements, &/or has a bearing on customer satisfaction, and
- In order to enhance customer satisfaction through the effective application of the **ISO 9001:2000** system¹.

Definition of Terms: As used herein, the terms:

- "**Product**" is defined to include: (a) spiking material(s), &/or (b) spiking services, which **ESS** provides on behalf of a customer.
- "**Customer**" is defined to include **ESS** customer &/or perspective **ESS** customer.
- "**Quality Year**" is defined to begin on July 1 of that year and to end on June 30 of the following year.
- "**Review and Approval**" of certain limited access Quality Documents (e.g., **POs** for mission-critical Materials, Proposals, Spiking Reports, Project-Specific Work Instructions [Project Plans], etc.) will be defined as having occurred when project-specific versions of these standard templates have been issued by the **ESS** Project Manager.
- A "**Mission-Critical**" Material is defined as a material that contains one or more **POHCs** &/or heavy metal spiking species, which is "direct shipped" to the test facility or is used by **ESS** s to prepare custom spiking. Normally materials which contain only ash, Cl-, &/or S= producing species are not considered to be "mission-critical."

1.3 Reference to the **ISO 9001:2000 Standard**

Reference is made throughout this Quality Manual & Attachments to specific sections of the **ISO 9001:2000 Standard**. When not identified within the text, the referenced clause number is enclosed in parentheses, such as: (4.1).

All references to other documents are specifically identified within the accompanying text.

1.4 Quality Manual Organization

The Quality Manual is organized as follows:

Section 2.0	A Map & Description of the Product Realization Process,
Section 3.0	ISO 9001:2000 Requirements,
Section 4.0	ISO 9001:2000 Management Responsibilities,
Section 5.0	ISO 9001:2000 Resource Management,
Section 6.0	ISO 9001:2000 Product Realization, and,
Section 7.0	ISO 9001:2000 Measurement, Analysis, and Improvement.

Major aspects of **ESS**' **QMS** are defined &/or described within the attachments to this manual, as follows:

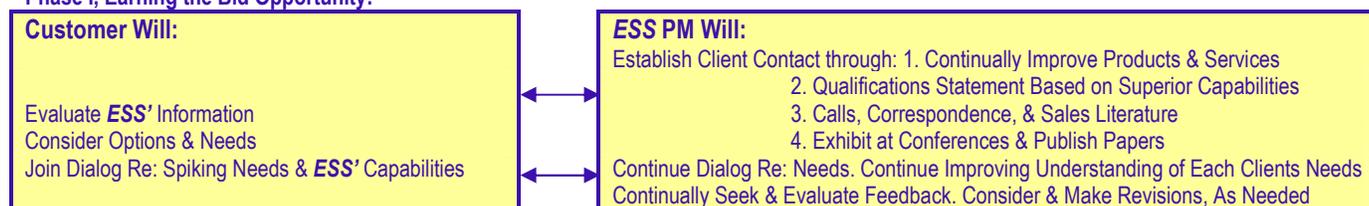
Attachment 0	ESS Quality Infrastructure
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Attachment II	Product Realization Process, Phase II, Proposal Preparation
Attachment III	Product Realization Process, Phase III, Pre-Test Preparation
Attachment IV	Product Realization Process, Phase IV, Field-Spiking Services
Attachment V	Product Realization Process, Phase V, Report Preparation

Footnotes: 1. Including processes, which ensure continual improvement and conformity to the customers requirements/needs and to applicable statutory and regulatory requirements.

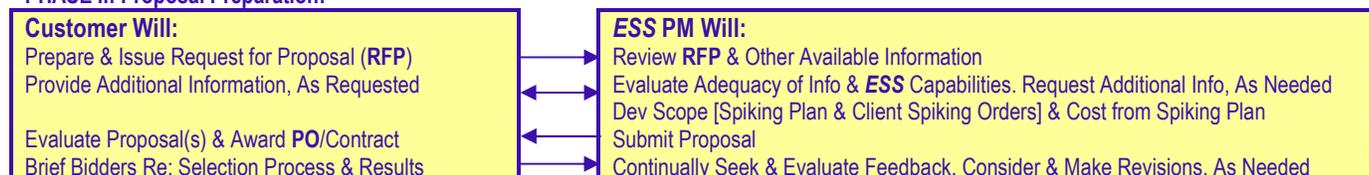
2.0 ESS' PRODUCT REALIZATION PROCESS:

2.1 A Map of ESS' Five Phase Product Realization Process¹.

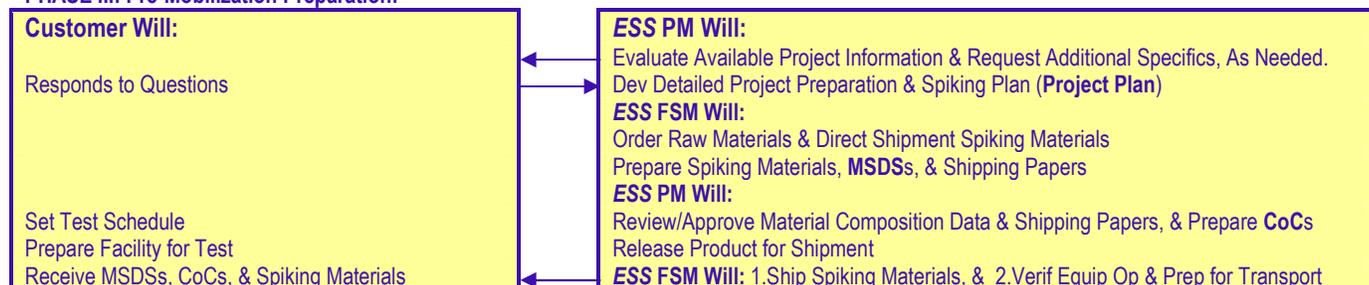
Phase I, Earning the Bid Opportunity:



PHASE II: Proposal Preparation:



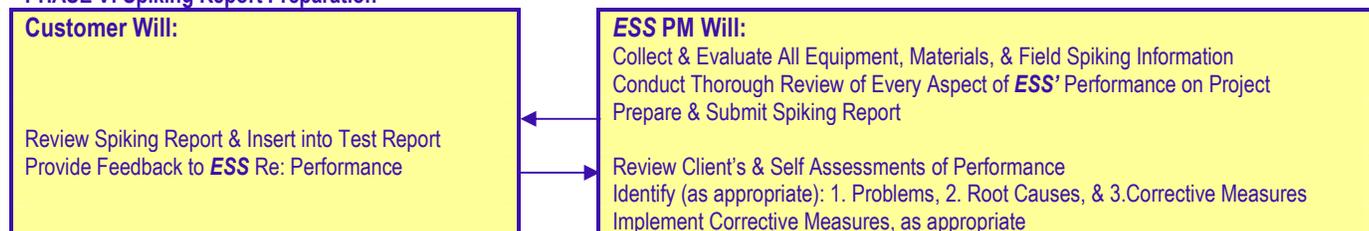
PHASE III: Pre-Mobilization Preparation:



PHASE IV: Spiking Plan Execution



PHASE V: Spiking Report Preparation



¹ This map & following description of the process is based on a complete execution of all steps in each phase. Many of the process steps are abbreviated &/or omitted in actual practice. For example, the client may choose to omit a formal, written **RFP** and simply describe verbally the services needed. Similar circumstances can occur with most of the other steps described.

The Methods, Systems, Procedures, Checklists, & Work Sheets used to implement **ESS'** Product Realization Process, Phases I through V are described in Attachments I through V, respectively. These Attachments compliment the description of **ESS'** Product Realization Process (alternatively described as: "**ESS'** Products & Services Delivery System"), which is further described in Attachment 0, Section 0.1.8.

ESS' 2005, 2006, and 2010 Quality Objectives are provided in Attachment 0, Section 0.1.6 and **ESS'** 2006 Quality Performance in relation to the 2006 Quality Objective is provided in Attachment 0.1.7.

2.2 ESS Product Realization Process [Described as a Five (5) Phase Process]

Φ FUNCTION:	LEAD:	INPUTS:	OUTPUTS:	MEASURE OF EFFECTIVENESS:
1 Business Development	PM	List of Prospective Clients, Test Information from Marketplace &/or Regulations, Knowledge of Facilities, & Regulatory Requirements.	Feedback from Client, Needs Information from Client, & Proposal Opportunity (RFP).	Feedback from Clients, Degree of Info Exchanged, & # of RFP Opportunities.
2 Proposal Preparation	PM	RFP & Client Information, Prior Knowledge of Facility & Reg Requirements	Proposal w Spiking Plan & Orders	Stated & Un-Stated Client Feedback.
3 Pre-Mobilization Planning & Prep Prepare Project Plan Prepare Spiking Mat'ls, & Verify Operability of Assigned Eq	PM FSM FSM	RFP & Client Info, & Knowledge of Facility & Reg Requirements.	Project Plan Spiking Mat'ls W CoCs & MSDSs Verification of Equip Op, Validation of Dispersion Pumpability	Post-Test Client Feedback, & Detailed, Self-Assessment.
4 Spiking Plan Execution	FSM	Project Plan.	Spiking Rate Data, Data Quality, & Operational Availability.	Post-Test Client Feedback, & Detailed, Self-Assessment.
5 Detailed Self Assessment, & Report Preparation	PM	Absolute ² & Relative ² Spiking Rate Results, & Mat'ls & Measurement Data Quality.	Lessons Learned Re: Assessment, & Spiking Report.	Results of Assessment, & Post-Test Client Feedback.
1. See Attachment 0, Section 0.1.6 for details Re: Quality Objectives, Quality Measurement Method, & Quality Results to date based on these methods. 2. Absolute Spiking Rate Results are expressed in units of Lbs S/Hr, & Relative Spiking Rate Results are expressed as a percent of the corresponding Target Spiking Rate. S is the Spiking Specie of interest.				

3.0 QUALITY MANAGEMENT SYSTEM (4.0)

3.1 General Requirements (4.1)

ESS has established, documented, implemented, and maintained a **QMS** and continually improves its effectiveness in accordance with the requirements of International Standard **ISO 9001:2000** [3rd] Edition.

ESS is responsible for:

- 3.1.1 Identifying the processes needed for the quality management system and their application throughout **ESS** (See Quality Manual, Section 2.0),
- 3.1.2 Determining the sequence and interaction of these processes (See Quality Manual, Section 2.0),
- 3.1.3 Determining criteria and methods needed to ensure that both the operation and control of these processes are effective (See Quality Manual, Section 2.0, & Attachment 0, Section 0.1.6),
- 3.1.4 Ensuring the availability of resources and information necessary to support the operation and monitoring of these processes (See Quality Manual, Sections 2.0, 4.0, & 5.0),
- 3.1.5 Monitoring, measuring, and analyzing processes (See Quality Manual, Section 2.0, & Attachment 0, Sections 0.1.6 & 7), &
- 3.1.6 Implementing actions necessary to achieve planned results and continual improvement of these processes (See Quality Manual, Section 2.0, and Attachments 0 - V).

ESS does not outsource any aspect of its Product Realization Process.

3.2 Documentation Requirements (4.2)

3.2.1 General (4.2.1)

The quality management system documentation includes:

- a) Written **quality policy** and **quality objectives** (See Attachment 0, Section 0.1),
- b) A written **Quality Manual** (e.g., this Manual & Attachments),
- c) Written **Procedures** required by the Standard (These Procedures are identified within the pertinent sections of the Manual and the complete procedures including requisite report forms are provided in Attachment 0, Section 0.2),
- d) Documents needed by **ESS** to ensure effective planning, operation and control of its processes (**Project Plans**), &
- e) **Quality Records** required by the Standard (See Attachment 0, Section 0.2.1 for a Master List of **ESS**' Quality Records).

3.2.2 Quality Manual (4.2.2)

ESS has established and maintains this Quality Manual, which includes:

- a) The **Scope of the QMS** (See Attachment 0, Section 0.1.5), including details of and justification for any **Exclusions** (**ESS claims four Exclusions from ISO 9001:2000 Requirements: 1. ¶ 7.3 Design & Development, 2. ¶ 7.5.2 (d) Process Validation where output cannot be verified, 3. ¶ 6.5.4 Customer Property, & 4. ¶ 7.6 (a) Basis of Calibration when no National Standards exist.**) See the identified sections for justifications for the respective exclusions),
- b) Written procedures established for the quality management system (See Attachment 0, Section 0.2), and
- c) A description of the interaction between the processes of the QMS (See Quality Manual, Section 2.0).

3.2.3 Control of Documents (4.2.3)

ESS controls those documents required by the **QMS** through a written procedure (**ESS D/RC SOP #1: Quality Documents & Records Control Procedure**). The written procedure was established to define the controls needed to:

- a) Approve documents for adequacy in meeting the **ISO 9001:2000** requirements prior to issue,
- b) Review previously approved documents and revise/re-approve them, as necessary,
- c) Ensure that changes to and the current revision status of each document are identified,
- d) Ensure that the effective versions of applicable documents are available at points of use,
- e) Ensure that documents remain legible and readily identifiable,
- f) Ensure that documents of external origin are identified and their distribution controlled, and
- g) Prevent the unintended use of obsolete documents, [and to apply suitable identification to them if they are retained for any purpose].

3.2.4 Control of Quality Records (4.2.4)

Records are a special type of document, which are required to provide evidence of: (1) conformity to client and **ISO 9001:2000** requirements, and (2) the effective operation of the QMS. Controls on quality records have been established through a written procedure (**ESS D/RC SOP #1: Quality Documents & Records Control Procedure**) and in accordance with **ISO 9001:2000** requirements. This procedure is designed to ensure that such records are:

- a) Properly identified,
- b) Safely stored, & protected,
- c) Remain legible,
- d) Are readily retrievable,
- e) Held for the appropriate retention time, and
- f) Managed as intended at the end of the designated retention period.

4.0 MANAGEMENT RESPONSIBILITY (5.0)

4.1 Management Commitment (5.1)

ESS management provides evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- 4.1.1 Communicating the importance of meeting customer as well as statutory and regulatory requirements,
- 4.1.2 Establishing the quality policy (See Attachment 0, Section 0.1.4),
- 4.1.3 Ensuring that quality objectives are established (See Attachment 0, Section 0.1.7),
- 4.1.4 Conducting Management Reviews (See Attachment 0, Section 0.3.4), and
- 4.1.5 Ensuring the availability of resources.

4.2 Customer Focus (5.2)

Top management ensures that customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction (See Quality Manual, Section 2.0, and Attachments I, II, & III).

4.3 Quality Policy (5.3)

ESS management has documented its policy for quality, which states:

“ESS Will:

1. Provide Spiking Products, Services, and Results, which Consistently Exceed Customer Expectations and Industry Standards for Accuracy, Completeness, and Documentation Thoroughness.
2. Provide Absolutely Reliable Equipment, Systems, & Personnel.
3. Further, **ESS** is committed to compliance with all **ISO 9001:2000** Requirements and to Continually Seek & Implement Means to Improve the Effectiveness of Our **QMS**.”

ESS believes that this Quality Policy:

- 4.3.1 Is appropriate for the purpose of the organization,
- 4.3.2 Includes a commitment to comply with the applicable requirements and continually improve the effectiveness of the QMS,
- 4.3.3 Provides a framework for establishing and reviewing Quality Objectives,
- 4.3.4 Is communicated and understood within the organization, and
- 4.3.5 Is reviewed for continuing suitability.

4.4 Planning (5.4)

4.4.1. Quality Objectives (5.4.1)

ESS management has established 2005, 2006, and 2010 Quality Objectives (See Attachment 0, Section 0.1.6), which include those needed to meet client product requirements. These Quality Objectives:

- a) Are applicable to relevant functions and levels within **ESS**,
- b) Were developed based on client feedback and self assessment of **ESS**' performance in comparison to client's needs and specifications,
- c) Are measurable and consistent with the quality policy, and
- d) Are documented in the Management Review Report.

4.4.2 Quality Management System Planning (5.4.2)

ESS management ensures that:

- a) The planning of the **QMS** is carried out in order to meet client requirements, as well as the Quality Objectives,
- b) The integrity of the **QMS** is maintained when changes to the **QMS** are planned and implemented,

4.5 Responsibility, Authority, and Communication (5.5)

4.5.1 Top Management Responsibilities (5.5.1)

ESS management ensures that the responsibilities, authorities and their interrelation are defined and communicated within **ESS** and are detailed in the organizational structure (See Quality Manual, Section 2.0, and Attachments 0 - V).

4.5.2 Management Representative (5.5.2)

ESS management has appointed a member of management (W R [Bill] Schofield, PhD, PE, & **ESS**' Project Manager) who, irrespective of other responsibilities, has responsibility and authority that includes:

- a) Ensuring that processes needed for the quality management system are established, implemented, and maintained,
- b) Reporting to top management on the performance of the quality management system and any need for improvement, and
- c) Ensuring the promotion of quality awareness and customer requirements throughout **ESS**.

4.5.3 Internal Communication (5.5.3)

ESS management ensures that appropriate communication processes are established within **ESS** and that communication takes place regarding the effectiveness of the quality management system.

4.6 Management Review (5.6)

4.6.1 General (5.6.1)

ESS management formally reviews **ESS' QMS** annually to ensure its continuing suitability, adequacy, and effectiveness (See Attachment 0, Section 0.3.4). This review includes assessing opportunities for improvement and the need for changes to the **QMS**, including the quality policy and quality objectives. Records from management reviews are maintained. Reviews of the quality of **ESS'** products and services are conducted and revisions to the **QMS**, **ESS** Procedures & Project-Specific Project Plans, Training, etc are implemented, as appropriate, on an ongoing basis.

4.6.2 Review Input (5.6.2)

The input to the management review includes information on:

- a) Results of audits,
- b) Customer feedback,
- c) Process performance and product conformity,
- d) Status of preventive and corrective actions,
- e) Follow-up actions from previous management reviews,
- f) Planned changes that could affect the **QMS**, and
- g) Recommendations for improvement.

4.6.3 Review Output (5.6.3)

The output from the management review includes any decisions and actions related to:

- a) Improvement of the effectiveness of the **QMS** and its processes,
- b) Improvement of product related to customer requirements, and
- c) Resource needs.

5.0 RESOURCE MANAGEMENT (6.0)

5.1 Provision of Resources (6.1)

ESS determines and provides the resources needed to:

- 5.1.1 Implement and maintain the **QMS** and continually improve its effectiveness, and
- 5.1.2 Enhance customer satisfaction by meeting customer requirements.

5.2 Human Resources (6.2)

5.2.1 General (6.2.1)

Personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills, and experience.

5.2.2 Training (6.2.2)

ESS:

- a) Determines the training needs for personnel performing work affecting product quality,
- b) Provides training to satisfy these needs,
- c) Evaluates the effectiveness of the training,
- d) Ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- e) Maintains appropriate records of education, training, skills, and experience (See Attachment 0, Section 0.3.1)

5.2.3 Infrastructure (6.3)

ESS determines, provides, and maintains the infrastructure needed to achieve conformity to product requirements.

Infrastructure includes:

- a) Buildings, workspaces, and associated utilities,
- b) Process equipment, both hardware and software, and
- c) Supporting services such as transport, or communication.

5.2.4 Work Environment (6.4)

ESS determines and manages the work environment needed to achieve conformity to product requirements.

6.0 PRODUCT REALIZATION (7.0)

6.1 Planning of Product Realization (7.1)

ESS plans and develops the processes needed for product realization and ensures that planning of product realization is consistent with the requirements of the other processes of the **QMS**. In planning product realization, **ESS** (See Quality Manual, Section 2.0, and Attachments 0 – V) determines the following, as appropriate:

- 6.1.1 Quality objectives and requirements for the product,
- 6.1.2 The need to establish processes & documents, and provide resources specific to the product,
- 6.1.3 Required inspection and test activities specific to the product and the criteria for product acceptance, and
- 6.1.4 Records needed to provide evidence that the production processes and resulting product fulfill requirements.

The output of this planning includes (See Attachments II, III, & IV):

- 6.1.5 Proposals, which include **ESS** prepared Spiking Plans, & Customer Spiking Orders to **ESS** [both for customer review & approval],
- 6.1.6 Spiking Materials, and
- 6.1.7 Spiking Reports.

6.2 Client Related Processes (7.2)

6.2.1 Determination of Requirements Related to the Product (7.2.1)

With the use of a written evaluation & acceptance checklist (2.1.1 Evaluation Check List Re: The Adequacy of: A. Available Information to Define, & B. **ESS**' Capability to Meet Client's Spiking Requirements), and through the review of available **RFP**, **PO**, Agreement, &/or other information provided by the customer as well as **ESS**' recognized expertise in the applicable **HWC** regulatory requirements, Agency policies & guidance, and best work practices within the field, **ESS** determines:

- a) Requirements specified by the customer, including the requirements for delivery,
- b) Requirements not stated by the customer but necessary for specified use or known and intended use,
- c) Statutory and regulatory requirements related to the product, and
- d) Additional requirements determined by **ESS**.

6.2.2 Review of **RFP** Requirements Related to the Product (7.2.2)

Prior to **ESS**' commitment to supply a product to the customer (e.g. submission of proposal), and with the use of a written evaluation & acceptance checklist (e.g., 2.1.1 Evaluation Check List Re: The Adequacy of: A. Available Information to Define, & B. **ESS**' Capability to Meet Client's Spiking Requirements), **ESS** reviews the product requirements via a **ESS**' capabilities to provide the product and ensures that:

- a) Product requirements are adequately defined,
- b) Contract, **RFP**, &/or **PO** requirements differing from those previously expressed, and/or normal test or regulatory requirements are resolved, and
- c) **ESS** has the ability to meet the defined requirements.

Records of the results of the contract, **RFP**, &/or **PO** review and actions arising from the review are maintained.

- a) Where the customer provides no or an insufficient documented statement of requirements, the customer requirements are determined &/or partially specified by **ESS** and confirmed by the client prior to committing to supply the product.
- b) Where product requirements are changed, **ESS** ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

6.2.3 Customer Communication (7.2.3)

ESS determines and implements effective arrangements for communicating with customers (See Quality Manual, Section 2.0, and Attachments 0 – V) in relation to:

- a) Product information,
- b) Inquiries, contracts or order handling, including amendments, and
- c) Customer feedback, including customer complaints.

6.3 Design and Development (7.3, **EXCLUSION #1**)

ESS does not provide design & development services to or on behalf of customers.

ESS does provide spiking materials [& associated spiking services], which fall into five general categories, all of which are based on well established production methods and more than 10 years of successful experience:

- Dispersions of very-fine particles of metal oxides dispersed [using **ESS**' proprietary dispersing system] in a mineral oil matrix,
- Un-saturated aqueous solutions of soluble metal salts,
- Neat [e.g., un-mixed, or un-diluted] organic liquids (MCB, Perc, o-DCB, Benzene, Toluene, TCB, etc.), and

- Unsaturated solutions of an organic solid (almost always Naphthalene) in an organic solvent (almost always Toluene),
- Large numbers of individually filled, weighed, labeled, and tracked containers [packets] each containing specified quantities of solid &/or liquid spiking materials.

Effectively, **ESS** repeated provides the same five products with variations in project specific details. Thus, **ESS** does not apply design and development services to spiking products.

While **ESS** has expended and currently continues to expend funds and effort to expand and perfect the operating range and reliability our equipment fleet, our approach has always been to adopt tried and true equipment, designs, configurations, & approaches [which have been perfected by others over decades of successful experience] rather than attempt true design efforts. Thus, **ESS** does not apply design and development services on our equipment fleet.

ESS does not provide/apply design and development services:

- To or on behalf of customers,
- To **ESS** spiking products, or
- To **ESS**' equipment fleet.

Thus, **the requirements of ISO 9001:2000, ¶ 7.3 are excluded from ESS' QMS.**

6.4 Purchasing (7.4)

6.4.1 Purchasing Process (7.4.1)

ESS utilizes industrial or technical grade chemicals as neat spiking materials and as raw materials or ingredients used by **ESS** to prepared solutions, mixtures, dispersions, &/or packets. Since **ESS** can correct for purity in a spiking material by increasing the spiking rate to account for the level of impurity, the use of high purity spiking material is not needed, only a spiking material with a known purity level.

ESS purchases mission-critical raw materials [e.g., materials containing a Spiking Specie with a certified purity] from large, national, supply houses with which we have years of successful experience. These firms purchase our materials from large [typically ISO Certified] chemical manufacturers and sell the same and similar products to chemical manufacturers and formulators.

Because of the nature of the materials **ESS** purchases, the types of companies that manufacture them, and the types of companies that purchase from our suppliers, there is in essence only **one supplier selection and evaluation criterion**, e.g., **doing what they say they will do, i.e., meeting delivery dates, providing accurate descriptions of products, and supplying required documentation.**

ESS ensures that purchased, mission-critical raw materials conform to **ESS**' Quality Assurance Specifications, which are included as "boiler plate" within the **PO** as conditions of purchase (See Manual Section 6.4.2, which follows). **ESS** periodically re-evaluates a supplier, typically following the occurrence of a problem.

6.4.2 Purchasing Information (7.4.2)

ESS ensures through the review and preparation of the **PO** that adequate descriptions of "mission-critical" [specie-specific] raw materials are provided by our suppliers. Such **POs** typically include the following information:

a) Definition of Purchase:

1. The common &/or chemical name of the material,
2. The number, size, & weight of shipping containers, and
3. The total quantity ordered and unit price (**FOB ESS**' shop/lab for raw materials, or the test site for "direct ship" spiking materials).

b) Shipping Instructions:

1. The shipping address [client company for "direct ship" spiking materials, &/or **ESS** for raw materials] & contact name, phone #, &
2. The "deliver no later than" date, if applicable

c) **QA/QC** Requirements:

1. The entire order of each material order must be provided from a single production lot or batch (Lot #),
2. The concentration of the material purchased must appear on the Certificate of Analysis (**CoA**) typically expressed as a weight %,
3. The same [matching] Lot # must appear on the: (a) all shipping containers, (b) the **CoA**, & (c) Shipping Manifest, and
4. **ESS** will not consider this order complete for Accounts Payable (**A/P**) purposes until these three conditions (6.4.2.c: 1, 2, & 3) are completed.

These [or materially similar] words are set into **ESS' QuickBooks (QBs) "Materials PO" template**. This template is used by the **PM** to prepare all **POs** for (a) "mission-critical," "direct ship" spiking materials, or (b) raw materials used to prepare "mission-critical" spiking materials. These conditions have successfully provided the information needed. Thus, by using the template, **ESS** has ensured the adequacy of specified purchase requirements prior to their communication to the supplier. **ESS' PM** signifies his review & approval of the product specifications by signing the **PO**.

6.4.3 Receiving Inspection (7.4.3)

ESS has established and implements the inspection activities necessary for ensuring that purchased product meets specified purchase requirements, e.g., the **PM** provides a copy of the **PO** to the **ESS FSM** when produced attached to a copy of **ESS Form III.B.2 (III.B.2 Material Receipt/Inspection/Acceptance, and Invoice Review/Approval Checklist)**. The **FSM** uses this form to document both processes. In the event that a given requirement cannot be satisfied, the acceptance process includes a provision for waiving that requirement if both the **FSM & PM** agree that the spiking requirements can be met in other ways.

6.5 Production and Service Provision (7.5)

6.5.1 Control of Production (7.5.1)

ESS plans and carries out production and service provisions under controlled conditions using a project-specific Project Plan (that contains all the Instructions, Checklists, Worksheets, Operating, Maintenance, & Data Logs, and Documentation Forms required to successfully meet all customer requirements). With the **Project Plan**, controlled conditions include:

- a) The availability of information that describes the composition/characteristics of the product,
- b) The use of project-specific instructions, checklists, worksheets, operating, maintenance, & data logs, and documentation forms,
- c) The selection & testing of suitable equipment on a project-specific basis,
- d) The availability and use of inspection and test equipment,
- e) The implementation of inspection and testing, and
- f) The implementation of an independent review of product quality information and a formal product release process, as well as delivery, and post delivery activities.

6.5.2 Validation of Processes for Production and Service Provision (7.5.2, **EXCLUSION #2**)

All the products & services, which **ESS** uses to meet customer requirements, have properties that can be measured. Thus, **the requirements of ISO 9001:2000, ¶ 7.5.2 are excluded from ESS' QMS.**

6.5.3 Identification and Traceability (7.5.3, Applicable to Spiking Specie Related Raw Materials)

Where appropriate [e.g., "mission-critical" spiking materials], **ESS** tracks the critical components of a [spiking material] product from the supplier's facility, though **ESS'** facility, to the client's test site using a "chain of custody" tracking system based on the following components:

- a) Supplier provided container identification, **CoA**, & Shipping Manifest from the Supplier's facility to **ESS' Shop**, all with matching Lot #.
- b) Tracking raw materials throughout **ESS'** product realization process with a:
 1. A raw material inventory control system,
 2. A job specific Materials Prep Work Instructions,
 3. Form III.B.2, and
 4. A formal product release process.
- c) Tracking from **ESS'** shop to the Test Site using **ESS'** Shipping Manifest.

ESS demonstrates product status with respect to inspection and test requirements using appropriate sheets from the **Project Plan**. Where traceability is a requirement, **ESS** controls and records the unique identification [Lot #] through the system described above.

6.5.4 Customer Property (7.5.4, **EXCLUSION #3**)

ESS does not hold or use customer property. Thus, **the requirements of ISO 9001:2000, ¶ 7.5.4 are excluded from ESS' QMS.**

6.5.5 Preservation of Product (7.5.5)

ESS preserves the conformity of products and their essential parts during internal processing and delivery to the intended destination through the raw material inventory, product labeling, and product release process described above. This preservation includes identification, handling, packaging, storage, and protection.

6.6 Control of Monitoring and Measuring Devices (7.6)

ESS has determined the inspection and testing to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to customer requirements. **ESS** uses weigh scales as our primary measuring systems with respect to: (a) materials preparation and composition demonstration (See References 2 & 4), and (b) spiking rate measurement (See References 3 & 4).

ESS has established processes through weigh scale Calibration Verification (& if necessary Recalibration) with **NIST** Traceable Weight Standards prior to each use to ensure that accurate & reliable monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements, as follows:

- 6.6.1 Weigh scales are calibrated &/or their calibration verified prior to use with **Certified, NIST Traceable Weight Standards**.
- 6.6.2 Weigh Scales are adjusted, re-adjusted, or otherwise serviced, as necessary,
- 6.6.3 Certified Standards are uniquely identified to enable their accuracy status can be determined,
- 6.6.4 Certified Standards are safeguarded from adjustments or damage and deterioration during handling, maintenance, and storage that would invalidate their absolute accuracy,
- 6.6.5 Certified Standards are periodically Re-Certified, as needed, to ensure continuing accuracy, at a minimum re-certification schedule as follows:
 - a) Field Standards: Cast Iron, field standards¹ are re-certified no less often than once every 24 months, and
 - b) Laboratory Standards: **SS** laboratory standards² are re-certified no less often than once every 5 years.Standards outside of this re-certification frequency are removed from service and tagged³ to prevent their inadvertent use on project related work.

ESS assesses and records the validity of the previous measuring results when one or more standards are found to be outside of the tolerance range of the applicable certification. **ESS** ensures appropriate action is taken with respect to the weight standards(s) and any product, which could have reasonable been affected by the tolerance range exceedence. Records of the results of Certifications are maintained.

EXCLUSION #4: If calibration(s) are done in cases where nationally/internationally recognized standards do not exist, then [per **ISO ¶ 7.6 (a)**] the basis for such calibration(s) must be documented and maintained within the QMS records. Since all the products & services, which **ESS** uses to meet customer requirements have properties that can be measured and have nationally/internationally recognized standards available, **the requirements of ISO 9001:2000, ¶ 7.6 (a) are excluded from ESS' QMS.**

1. **ESS** has 25-50 Lb & 1-25 Lb, cast iron, Class F [e.g., "F" signifies a field standard classification] field standards.
2. **ESS** has two types of laboratory standards:
 - A. A matched Lb/Oz based set of 32 **SS** standards, ranging from 0.001 to 10.000 Lb, totaling ~51 Lbs, & contained within a hard-shell storage/carrying case, and
 - B. Two individual, **SS**, 200 g standards.
3. Tagged with red &/or yellow tape, which is the method **ESS** uses throughout our operation to indicate equipment that cannot be used for project t work in it present condition.

7.0 MEASUREMENT, ANALYSIS, AND IMPROVEMENT (8.0)

7.1 General (8.1)

ESS plans and implements the monitoring, measurement, analysis, and improvement processes needed to:

- 7.1.1 Demonstrate conformity of the product,
- 7.1.2 Ensure conformity of the **QMS**, and
- 7.1.3 Continually improve the effectiveness of the **QMS**.

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

7.2 Monitoring and Measurement (8.2)

7.2.1 Customer Satisfaction (8.2.1)

As one of the measurements of the performance of the **QMS**, **ESS** monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information are determined (Attachment 0, Section 0.1.6).

7.2.2 Internal Audit (8.2.2)

ESS conducts internal audits at planned intervals through a written procedure (**ESS ISO IA SOP #2: Internal Quality Audit Procedure**), to determine whether the **QMS**:

- a) Conforms to the planned arrangements,
- b) Adheres to client requirements,
- c) Conforms to the **QMS** requirements established by **ESS**, and
- d) Is effectively implemented and maintained.

The audit program takes into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, and methods have been defined. Selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors will not audit their own work.

The responsibilities and requirements for planning and conducting audits, reporting results and maintaining records are established in a documented procedure defined in Attachment 0.

The individual responsible for the area being audited ensures that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

7.2.3 Monitoring and Measurement of Processes (8.2.3)

ESS applies suitable methods for monitoring and, where applicable, measurement of the **QMS** processes (See Attachment 0.1.6 & 7). These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product.

7.2.4 Inspection and Testing of Product (8.2.4)

ESS inspects and tests the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process and the planned arrangements.

Evidence of conformity with the acceptance criteria is maintained. Quality records indicate the person(s) authorizing release of product.

Product release and service delivery does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

7.3 Control of Nonconforming Product (8.3)

ESS ensures that products, which do not conform to product requirements, are identified and controlled to prevent their unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming products are established in a written procedure (**ESS ISO NCP SOP #3: Management of Non-Conforming Products &/or Services (NCP) Report**).

ESS deals with nonconforming products by one or more of the following ways:

- 7.3.1 Taking action to eliminate the detected nonconformity,
- 7.3.2 Authorizing its use, release or acceptance under concession by a relevant authority &, where applicable, by the customer, &
- 7.3.3 Taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained.

When a nonconforming product is corrected, it will be subjected to re-verification to demonstrate conformity to the requirements.

When a nonconforming product is detected after delivery or use has started, **ESS** takes action appropriate to the effects, or potential effects, of the nonconformity.

7.4 Analysis of Data (8.4)

ESS determines, collects, and analyses appropriate data to demonstrate the suitability and effectiveness of the **QMS** and to evaluate where continual improvement of the **QMS** can be made. This includes data generated as a result of monitoring, measurement, and other relevant sources.

The analysis of data provides information relating to:

- 7.4.1 Customer satisfaction,
- 7.4.2 Conformance to product requirements,
- 7.4.3 Characteristics and trends of processes and products including opportunities for preventive action, and
- 7.4.4 Suppliers.

7.5 Improvement (8.5)

7.5.1 Continual Improvement (8.5.1)

ESS continually improves the effectiveness of the **QMS** through the use of the quality policy, quality objectives, audit results, analysis of data, corrective & preventive actions, and management review.

7.5.2 Corrective Action (8.5.2)

ESS takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A written procedure (**ESS ISO C/PA SOP #4: Corrective/Preventative Action Report**) has been established for:

- a) Reviewing nonconformities (including customer complaints),
- b) Determining the causes of nonconformities,
- c) Evaluating the need for action to ensure that nonconformities do not recur,
- d) Determining and implementing action needed,
- e) Records of the results of action taken, and
- f) Reviewing corrective action taken.

7.5.3 Preventive Action (8.5.3)

ESS determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems. A written procedure (**ESS ISO C/PA SOP #4: Corrective/Preventative Action Report**) has been established for:

- a) Determining potential nonconformities and their causes,
- b) Evaluating the need for action to prevent occurrence of nonconformities,
- c) Determining and implementing action needed,
- d) Records of results of action taken, and
- e) Evaluating the effectiveness of preventive action taken.