ENGINEERED MEDICAL SYSTEMS, LLC

VALIDATION MASTER PLAN

for

Equipment and Processes Used By Engineered Medical Systems in the Manufacture of Product for Our Customers

VMP Approvals

Typed Name	Title	Approval Signature	Approval Date
Ben Smith	President / CEO	(Signature on File)	25 Sept 16
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Scope

The purpose of this Validation Master Plan (hereinafter known as the "Plan" or "VMP") is to provide guidelines and protocol for the validation of applicable processes, equipment, and software used in the production and verification of products manufactured by Engineered Medical Systems, LLC.

Introduction

Engineered Medical Systems, LLC (EMS), is a manufacturer of surgical products for the medical community and has its main operations in a 40,000 sq' facility located at 3325 Appling Road, Bartlett, TN. EMS holds lease to a second, 10,000 sq' facility at 7585 A.E. Beaty, Bartlett, TN 38133. EMS is registered through BSI, Inc., to ISO 13485 (Certificate # FM 589713) and the FDA (Registration # 10042524). Our policy is to provide the best product to our customers, on time, and at a fair price. Accordingly, EMS has identified certain equipment and processes which need to be validated to support that policy. These are listed on a Validation Log referenced within this Plan (updated dynamically and available upon request) and documentation is available to show steps taken to accomplish validations for applicable processes and pieces of equipment.

EMS has implemented a seven-step process for conducting validation exercises. These steps include

Step 1: Define equipment and processes to which these guidelines apply,

Step 2: Define validation objectives and hypotheses,

Step 3: Prepare and document the validation plan and test runs by specific process and / or equipment,

Step 4: Execute necessary test runs and record results,

Step 5: Analyze and report results,

Step 6: Develop and document conclusions, and

Step 7: Monitor and revalidated processes, when required.

Definitions

- Attribute: A characteristic or feature created as part of an output.
- Control: The application of measurements and analytical hypotheses to predict results.
- Critical Item: A feature or product resulting from a process upon which the successful application of a subsequent product, action, or mechanical interface depends.
- Environment: The theatre of operation in which a process occurs. This includes not only environmentally controlled areas (HVAC, lighting, etc.), but electronic (continuity of power, storage media, equipment capabilities, etc.) and human factors (skill level, training, and manpower).
- IQ: Also known as EIQ, (Equipment) Installation Qualification is the documentation created to provide evidence that the equipment or process being validated has been properly installed and made operational.
- Non-Conforming: Resultant process or product output that does not conform to what was specified.
- Non-Critical Item: A feature or product resulting from a process, but which is not critical to a subsequent product, action, or mechanical interface.
- Output: The outcome of a process, to include tangible (a part or feature that can be accepted by visual or mechanical means) and intangible (e.g., electronic output) results. Also defined as "product".
- OQ: Also known as EOQ, (Equipment) Operational Qualification is the documentation created to provide evidence that the equipment or process being validated can accurately perform its function.
- Process: Any human, electronic, or mechanical activity that produces output to be used by a customer or downstream process. As used, herein, process may also include the equipment used in an activity.

Example: The process of milling will include CNC and / or manual milling centers, as well as any software code required to run the equipment.

- Product: See "Output".
- PQ: Also known as POQ, Process (Operational) Qualification is documentation that the equipment or process being validated can repeatedly perform its function on a specific part or feature.
- Risk: A numerical value assigned to the severity of the potential to adversely affect output or repeatability based 1) on the probability of occurrence and 2) on the severity of the impact of that occurrence to a product or process.
- Software: An electronic program or series of programs created in a logical format to initiate, control, analyze, and / or record the results of an activity.
- SV: Software Validation (Qualification) is the documentation created to provide evidence that the software used to control the equipment or process being validated can accurately perform its function.

  NOTE: As regards SV of EMS software, only machine software used to produce or verify product will be validated. "Canned", off-the-shelf (OTS) software is considered validated by right of its commercial applications and acceptances and will not be validated by EMS. Examples include, but may not be limited to, Microsoft Products (Excel, Word, PowerPoint, Access); machine program and server administration software, gage tracking and records software (e.g., ToolBoss, GAGETrak, CIMNET, Mozy), and payroll and accounting software (e.g., QuickBooks). This is EMS' policy because extensive research, funding, and testing has been performed by the OEM and because EMS does not foresee using these OTS softwares in any capacity that might place EMS' nor our customers' applications at risk.
- Validation: The structured process of determining whether the creation of an output will be complete, correct, and repeatable and the final product will predictably comply with specified requirements.

  Note: 21 CFR 820.75(a) states, "Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures." EMS interprets this, literally, and may apply it to processes such as welding and certain assembly results, unless otherwise mandated by a customer.
- Verification: Initial and continuing confirmation, by examination of evidence, that a piece of equipment or a process continually fulfills specified requirements. Methods include, but may not be limited to, measurement, torque tests, pressure testing, and comparative feature profile or outcome testing.

Step One: Define Equipment and Processes for Validation

EMS uses one or more of three input methods to determine which equipment and processes need to be validated. 1) Process outputs that could affect the final outcome of a part that cannot be fully verified by objective means must be validated. 2) Equipment and processes used in the manufacture of product before formal manufacturing begins will be validated. 3) Customer-specified equipment or processes which may not be addressed in 1 or 2 may be included in Validation determinations.

Step Two: Validation Aims, Objectives, and Hypotheses

The Goal of validation is to ensure the applicable process is capable of producing and sustaining the desired output on a consistent and repeatable basis. To accomplish this, a Validation Project Leader is identified for each process validation effort. The leader may not be the subject matter expert on the process, but will have full access to all data and personnel required to accomplish this task. It is the responsibility of the Validation Project Leader – independently or collaboratively for each identified project – to…

- Identify validation requirements;
- Identify required resources and their availability and capability;
- Initiate, write, and route for review and approval all required validation documentation;

- Coordinate the execution of required protocols;
- Submit validations for final review and filing (including customer interface and approval); and
- Respond to the need for revalidation while following the above steps in accomplishment.

Responsibilities

Validation Team: The Validation Team, one of whom is designated as the Project Leader, consists of the Director of Product Support, QA Management, and / or at least one other member of production or Engineering Management and / or staff. These individuals may differ by name and title as each type of activity is engaged, but the positions will be represented on every validation referred to by this Plan.

Plant Safety / Maintenance / Engineering: These individuals are assigned when and as necessary and are available during the validation process.

Computer Operations (IT) Support: EMS employs on-site IT support. However, EMS utilizes OEM and OEM-specified software in its applicable processes, so IT support requirements are generally minimal.

Quality Assurance: In addition to QA Management's participation as part of the Validation Team, QA Inspectors may also be used to facilitate output verification.

Records Storage: Validation documentation and results are stored in accordance with QMS 4230, EMS' Control of Documents and Records procedure.

Training: Unless a particular validation or operation within the validation of a process or piece of equipment requires specialized training, EMS relies on the existing skills and training of the employees used in the validation process. That is to say, if the validation requires an employee to run a part on a CNC machine, an employee will be used who has already demonstrated his / her ability to perform that operation and training records are available as confirmation of those skills.

System Owner: System Owner is EMS, under the authority of the CEO and Engineering Director.

Step Three: Prepare and Document the Validation Plan and Test Runs

EMS will use the IQ / OQ / PQ / SV process validation elements, where and as applicable, to document that subject processes are installed and functioning correctly, in accordance with pre-determined OEM, Customer, and / or EMS specifications. Certain processes may not require all four elements of validation, due to applicability, feasibility, and / or minimized criticality to quality, process effect, and / or safety.

A Validation Protocol (consisting of IQ, OQ, SV [as applicable], and PQ [if applicable] documents) will detail the validation process and requirements; each of which must be approved by the Validation Team prior to beginning validation activities for each applicable new or revised process. This Plan will describe the validation stages, in detail, including but not limited to a pre-determined sampling or test plan and acceptance criteria, if and where appropriate. Each Plan will be individually identified so as to specifically identify the product (PQ, if applicable) and process to be validated.

Final reports will be written – unless content of validation documents warrants otherwise – and routed for review and approval after validation activities have been completed. Appropriate raw data supporting validation activities shall be attached to or annotated within the reports. Successful completion of validation is indicated through completed, reviewed, and signed validation reports. Where required, completed protocols may require customer acceptance, as well, which is documented in the Validation Log; however, no validation effort will be specifically identified to a customer.

Installation Qualification (IQ). IQ shall be utilized to demonstrate that the installation or re-installation of a process has been completed within OEM requirements. Installation includes relevant documentation, preventive maintenance, calibration, spare parts requirements, process setup, process function, and software function (if and as applicable).

Equipment that has been previously installed and validated does not require IQ when validating or re-validating a new device or process utilized on the equipment. However, moving and re-installing previously validated equipment requires IQ where such relocation could jeopardize previously validated results.

IQ shall be the first of the **IQ** / OQ / PQ / SV documentation to be completed.

Software Validation (SV). Where process software can affect the creation or verification of a feature or product, SV shall be utilized to demonstrate that the software can produce repeatable and reproducible outputs that meet specified / programmed requirements.

SV shall be the second of the IQ / OQ / PQ / **SV** documentation to be completed.

Operational Qualification (OQ). OQ shall be utilized to demonstrate that a process performs as intended when utilized in the production of product. It will demonstrate that the process is capable of producing verifiable output over the entire range of intended process variables. This includes applying a worst-case approach in testing and qualifying output capability and repeatability.

Determining OQ Sample Size. Unless otherwise specified, EMS will use a standard range of production materials and configurations to demonstrate worst case conditions. Guidelines stress the importance of equipment qualification simulating actual production conditions. Three consecutive lots is recommended for this purpose; however, EMS believes that PQ runs and continued product verification during production runs will add validity to OQ validation findings; thus, reducing sample sizes. Unless customer specified, no specific number of samples is required for OQ validations, only enough that they simulate the production process, to a high degree of EMS confidence, that the process is capable of producing desired results.

OQ shall be the third of the IQ / **OQ** / PQ / SV documentation to be completed.

Process Qualification (PQ). Using statistically quantified sample sizes, PQ shall be utilized to demonstrate that processes produce repeatable and reproducible outputs meeting the requirements of a specific feature or product. EMS will use a target approach to demonstrate capabilities. Inspection levels are pre-determined by a customer or the Validation Team. PQ validation may assume two delimiters: Specific and General.

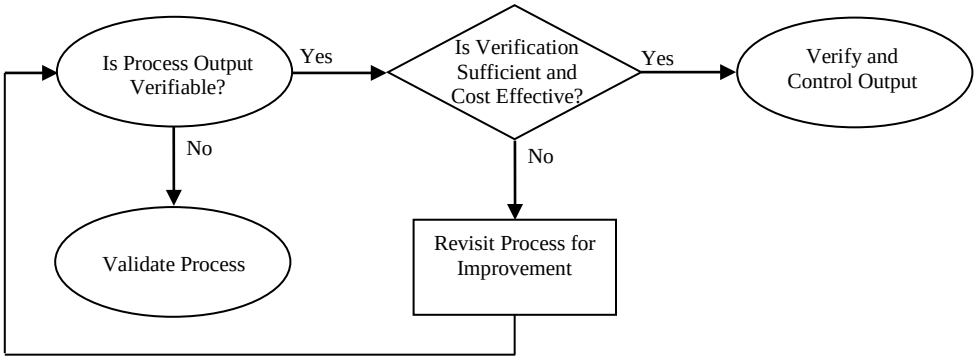
Specific: When a customer is qualifying the manufacture of a specific product or range of products at a specific process (e.g., CNC Mill #xyz), successful PQ validation will apply only to that product and the equipment on which the PQ was run. Example: Part number X123 needs to be qualified on a CNC process; however, because of variables even within 'identical' equipment, validation of X123 manufacture must be specific to only particular equipment. Therefore, if EMS plans to run X123 on one or more 'identical' piece of equipment, a PQ validation will first be run on each piece of equipment. Once approved, no other 'identical' equipment may be used to run X123. That said, every part manufactured on these types of equipment will require its own, individual PQ validation performed before its production can begin.

General: When the output of a process can be predictably applied over a range of products, successful PQ validation of a process is not applied to any single product, but across the range of qualified products. Example: PQ validation of a wire EDM process can be applied to any number of products, so long as the parameters defined in the PQ are maintained; e.g., material types, equipment settings, etc. That said, a PQ validation run can be performed once and, within the stated PQ parameters, numerous parts can be run without running specific PQ validations by product. However, if a customer requests a PQ run on a specific process, it must be performed as described under "Specific", above.

The number of sample or production runs required is determined by the customer or Validation Team with the following considerations.

- Operator / Shift. Where applicable, at least two different operators should be used; preferably, spanning two or more different shifts.
- Material Variation. Processes which may be affected by material variation should use a different lot or type of raw material for each PQ run to ensure the variation does not adversely affect the process.

The following flow chart may be referenced to determine if verification can be substituted for validation.



PQ shall be the last of the IQ / OQ / **PQ** / SV documentation to be completed.

General. IQ, OQ, and (if applicable) SV are to be performed for each applicable process; however, they are only performed once per process until revalidation is necessary, so long as verification is achieved. IQ, OQ, and (where applicable) SV of a process may be applied to many different outputs (e.g., parts). PQ is to be performed, where specified, on each product prior to formal production of that product, as defined above.

Step Four: Execute Test Runs and Record Results

1. Determine which process / software is to be validated.
2. Define the purpose of the process / software.
3. Assess the overall risk the process / software poses within the production string.
4. Determine what level of validation will be required for each process / software type (IQ, OQ, SV, PQ). Where applicable, this will include running the equipment to its operational maximum and minimum.
5. Determine what course of action will be followed for each process / software type.
6. Determine what resources will be required (e.g., manpower, facility, utilities, test equipment, materials, and tests) for each process / software type.
7. Create validation documents that outline the aforementioned approach steps for each process / software type. Define and apply IQ, OQ, PQ, and SV, where appropriate, to each validation.
8. Instruct Validation Team on processes to be performed, expected outcome, and course(s) of action after validation is completed. If team is new to a process, record training as part of validation documents.

   Note: Members of the validation team will most often be selected from experienced EMS employees. Training only applies to new processes or employees used during validations.
9. Perform validation.
10. Record results of validation.
11. If validation is successful, forward documents to the Director of Product Support for recording, filing, and, if appropriate, requesting customer acknowledgments and / or acceptance.
12. If validation is not successful, determine root cause, initiate corrective action, and re-run validation under the same parameters as initially stated, unless amended as part of the CAPA. Record all results.
13. A Validation Log is created to keep track of the validation status of each process or piece of equipment and its validation status. The log will be updated as new processes and equipment come on line or as currently validated systems are revalidated.
14. Equipment or Process Rationalization. If there is more than one machine type that performs an identical process using identical hardware and / or software, each machine may have its own validation document and the machine data particular to that unit applied to its documentation *or* a rationalization alternative may be implemented. Where approved by EMS and / or its customer, the validation process for one

machine (or process) may be applied (rationalized) one or more identical machines or processes, provided 1) the equipment / processes are identical in construction, components, operations, and software and 2) the equipment / processes are used in and for the same function and environment as the equipment / process initially validated. If implemented, a rationalization statement to that affect shall be included in the affected documentation package for the rationalized equipment / process.

Step Five: Analyze Results

General Process Validation Information

- Purpose of the Process
- Background / Scope
- Objectives
- Prerequisites
- Applicable Documents
- Equipment Description (if applicable to the process)
- Equipment Identification (Vendor, type, model #, serial #).
- Equipment Installation Status. (If equipment is existing, list as preexisting.)
- Identification of Verification / Inspection Equipment Used on Installation, if known (e.g., gages, micrometers, test software, etc.), including calibration status. Note: Prior to implementation of the EMS validation program, some equipment was installed by an OEM or EMS employee with whom we no longer have contact. In those cases, installation equipment cannot be determined. EMS understands that process first articles and in-process inspections are an allowable alternative for verifying the accuracy of the affected process.
- Material(s) Needed (if and as applicable)
- Operational Software (if and as applicable) and Revision Level
- Objectives of the Validation, including Accept / Reject Parameters.
- Determination of the Level of Ability to Fully Validate the Process
- Personnel Performing Validation.
- Documentation of Results of Validation.
- Documentation of Disposition of any Materials Used.
- Documentation of Participant Sign-off.

Cleaning Process Validation

At this writing, EMS does not sterilize product nor enclose product in its final packaging; however, EMS has developed the following procedures to describe Citric and Nitric passivation, Electropolishing, and Chemical Cleaning processes – QMS 7501, 7502, 7503, and 7506 – and made provision for inclusion in QMS 7510. The final product cleaning process has been validated. Product cleaning is performed at four stages at EMS.

- In-process. At varying stages of production, some product may require a general cleaning to facilitate downstream manufacture, inspection, or outsource processing (e.g., chrome coating).
- EDM. After EDM processes, product may be routed through the nitric passivation or electropolish treatment; then cleaned, rinsed, and forwarded to a downstream process.
- Heat Treatment. After heat treat, parts are processed through electropolish or nitric acid to remove residual burnishing; then cleaned, rinsed, and forwarded to a downstream process.
- Metal Finishing. After some buffing or blasting processes, the product may need to be cleaned before forwarding to a downstream process.

- Final. All product is cleaned prior to shipment.

Cleanroom Process Validation

To support our customers' medical product fabrication, assembly, and testing operations that require strict adherence to the cleanliness of its manufacturing environment, EMS has constructed a nationally certified, Class 8 cleanroom. Our cleanroom operates in accordance with the ISO 14698 standard and was brought on line under the guidance of a microbiologist with over 20 years of experience in the industry. HEPA-filtered air is used to maintain environmental levels in both the cleanroom and gowning areas. Finished product is hermetically packaged. Output of the cleanroom is not sterile. Regularly scheduled cleaning and testing protocols are performed, per QMS 7508 and QMS 7509, and test samples analyzed by a third-party lab to ensure the cleanroom continues to meet or exceed Class 8 standards.

Software Validation

- Software Description
- Purpose of the Software
- Determination of the Level of Ability to Fully Validate the Software
- Operating System Description (if applicable to the process)
- Software Identification (Vendor, title, and revision level)
- Determination of How Software Was Loaded and Tested, if Known
- Personnel Performing Software Validation
- Objectives of the Validation, Including Accept / Reject Parameters
- Documentation of Results of Validation
- Documentation of Participant Sign-Off

Facilities Validation

- Electrical
  - Electrical validation involves ensuring adequate power is provided to the equipment / process being validated.
  - Because electrical requirements and parameters are recorded in the IQ for each validated process, a specific electrical validation IQ / OQ for EMS' facilities is not created, at this time.
- Pneumatic
  - EMS has primary and reserve air compressors capable of supplying all present and perceived future pneumatic requirements. Should the primary unit fail, the reserve unit(s) initiate(s) to continue a steady air supply. These units are on a regular preventive maintenance program. Should failure of or concern for any unit occur, an OEM provider is contacted immediately to initiate repair.
  - Air is also used to blow-dry product which has been washed via the in-process or final cleaning process. At this writing, the quality of that air has not come under question, but filtered air may be provided, where required.

    Pneumatic validation also involves ensuring adequate air is provided to the equipment / process being validated and is recorded in each applicable process' IQ. IQ / OQ validations are also created for these compressors.
- Water
  - Clean, Publicly Owned Treatment Works (POTW) – "tap" – water is provided for use during product in-process and final cleaning. At this writing, EMS does not sterilize any in-process components or product destined for our customer. EMS instrumentation monitors the particulate parts per million of standard rinse water so as not to exceed 200 ppm. This same water source is

used throughout the clean and rinse processes; therefore, the ppm count at the test source is presumed to be the same at other uses.

- EMS uses deionized (DI) water for certain operations. These processes are specified. At this writing, few products are cleaned using DI water.
- EMS uses reagent-grade water on parts being cycled through cleanroom-supported cleaning processes. This water is purchased and certificates of conformance supplied with each purchase.
- Facility water use validation involves ensuring adequate water supply is provided for the process being validated; therefore, although a cleaning validation has been performed using POTW water, a specific POTW water validation is not created, at this time.

Material Validation

General policies are in place in QMS' Purchasing procedure, QMS 7400, to provide for material validation; however, if and as the need arises, EMS will develop a supplemental and specific plan to ensure material suppliers are validated. At this writing and only if that plan should be implemented, that plan will include random sampling by heat lot of no less than three separate lots per identified vendor. This will be accomplished by submitting samples from each lot to a third party laboratory for material analysis and comparing the results with the supplier's certification documents. Note: The amount of time required to complete this validation will directly correlate with the time it takes to receive three different lots.

Metal Finishing Validation

Metal Finishing encompasses removal of rough surfaces from the product by buffing, polishing, grit blasting, and / or tumbling. As this is primarily a process directly impacted and affected by the skill of the employee performing these manual tasks, any validation efforts will focus on the proper set-up, media selection, and operational steps and subsequent verifications required to perform the tasks and assess the results, as defined in applicable EMS procedures. Only IQ / OQ validation is performed, at this time.

Measurement Validation / Gage R&R

Gage R&R is performed by or under the direction of QA management. Gages on which validation is performed are identified by QA Management, engineering staff, and / or our customers. All gages validated are logged and maintained on EMS' calibration software, per QMS 7600 (EMS' Control of Monitoring and Measurement Procedure). Gage R&R follows accepted industry protocol and results are documented and filed. Gage families may be validated as such, unless otherwise required; that is, gages are separated into groups by family, then validation is performed on a sampling of gages within each family. Family types include, but may not be limited to, micrometers, calipers, height gages, depth gages, optical comparators, vision systems, and CMM equipment. Standard commercial-grade or off-the-shelf straight or tape rulers are not included in calibration or gage validation. Gages supplied by or manufactured for our customers may also be required to undergo Gage R&R, as determined by customer and / or EMS requirements. Validation considerations, in addition to those listed above, include the following.

- What type of feature will be measured by this instrument?
- What type of gage or device is best suited to perform the measurement and is that gage or device available at EMS?
- Is the inspecting employee trained in the use of the gage or device and the proper technique for measuring the feature?
- Are there special handling or environmental conditions to be considered for the gage or in the measurement process?
- Has the validating gage or device been calibrated and traceable to a national or international standard?

- Is the gage or device listed and maintained in the EMS calibration software and is its calibration status current?
- Reference QMS 7600 procedure for elaboration on gage tracking and registration.

Risk Assessment

A certain level of risk is associated in the performance or use of any of the aforementioned processes, materials, and operations (known, collectively, as a "process"). A rating, known as a risk factor, is assigned by EMS to each appropriate process based on the impact a negative event may have on the ability of EMS to meet customer requirements; where "customer" refers to the next using process; i.e., "customer" may be the end user or the next process in the manufacturing flow. Assessment considers 1) the probability of an adverse event occurring, 2) the likelihood of detection of the event, and 3) controls put in place to detect an event and / or control the event before or after detection. QMS 7100 Risk Management procedure defines EMS' risk assessment protocol, determination, classification process, and application.

Activities supporting or exhibiting a high risk are addressed by management and / or manufacturing leadership as soon as they become known. The recipients of this information shall take one or more of the following actions, based on an assessment of the risk and its impact.

- If risk assessment indicates an adverse effect of an event potential, immediately cease the activity in question, as appropriate, and begin documented analyses of the issue.
- If applicable, notify the customer(s) of any impact the risk may have on product and / or delivery.
- If applicable, shift the activity to another approved machine, process, or employee.
- Respond to the results of the analyses, to include equipment repair or replacement, material replacement and quarantine, replacement personnel, initiation of an NC tag or CAPA (ref QMS 8300 and 8520), and / or revalidation of the process.
- Document the event and report results to affected personnel, including any affected customer(s).

Spare Parts for Manufacturing and Inspection Equipment

EMS has a number of redundant systems; therefore, EMS does not keep a standard spare parts inventory for its equipment. Our relationship with the OEM or OEM-approved supplier is such that rapid response is received any time repair or repair parts are required.

Step Six: Develop and Document Conclusions

After each process validation, results are analyzed and conclusions developed and documented, and may be reviewed by EMS Management at any time and by customers upon request. Conclusions may be input into a special report or may be included within the validation documents.

Step Seven: Monitor and Revalidate Processes, When Required

Revalidation

It is EMS' policy to perform and document first articles, in-process inspections, and final inspections on all manufactured features. Not only does this afford us the opportunity to continuously monitor (verify) the quality of our product, it means we are continuously monitoring the accuracy and repeatability of the manufacturing and inspection equipment and processes. For this reason, equipment revalidation is not placed on a specific, recurring schedule.

If a piece of validated equipment is to be moved and the move is a simple relocation from one placement to another in the same environment of the same facility, and if no action is observed or incurred that could potentially alter that process' accuracy, formal revalidation may not be performed. However, EMS will advise the customer *prior* to the move and, together, they will determine the need for revalidation. In addition, if measurement of the output meets input requirements after movement and reinstallation of the equipment, existing IQ, OQ, PQ, and SV are considered verified. If output does not meet input

requirements, documentation to that affect is begun and appropriate revalidation must be performed prior to resuming production. (See Note, below)

If the equipment receives an upgrade in or replacement of hardware or moves to a location providing a different environment that could affect its operation or performance (e.g., HVAC, electrical, pneumatic, or different facility), IQ, OQ, PQ, and / or SV revalidation must be performed, as appropriate. If the equipment receives an upgrade in software that could affect its operation or performance, SV must be revalidated. If any revalidation could affect Process Qualification of any product, PQ shall be revalidated for each affected product. When revalidation is required, the protocol used in "Validation Approach", above, shall be used.

Note: When a piece of validated equipment is relocated, the customer(s) shall be advised *before* relocation; at which point, discussions and decisions between EMS and the customer(s) will take place as to the disposition of future customer product which has undergone PQ on that equipment. If need be, but OEM validation time and expense may not be initially warranted, EMS will develop a program specific to that equipment's process capabilities to produce statistically valid samples requiring critical or tight tolerances. These samples will be measured and their measurements recorded. Should the customer agree with this approach and the measurements be within the required tolerances, the equipment may be considered revalidated. If accuracy is not achieved, the equipment is not used until OEM-qualified technicians can service the equipment; at which point, appropriate revalidation occurs.

Change Control

Any change that may affect the validation of a process, software, equipment, or product included in this Plan shall be reviewed by EMS manufacturing personnel and a determination made prior to implementation as to whether or not revalidation, as defined herein, is required. In all cases where change affects a customer's product, the affected customer shall be notified for approval *prior* to change implementation. In all cases, the Director of Product Support shall be notified *prior* to or immediately following change implementation – depending on circumstances – in order to monitor validation documentation and notification compliance.

Record Storage

Validation protocol hardcopies are filed for historical record. Electronic copies and this VMP are filed in designated file location(s) and electronically backed up, daily.

Process Validation Log

A list of processes and equipment validations is created as a separate document from this Plan and is available upon request. It may be updated independently of this Plan as processes are updated, added, revalidated, or removed. Contact the Directors of Product Support or Engineering for a copy of the Validation Log.

References (Available upon requested.)

Validation Log	Equipment and Process List
Gage R&R Log	Gage Repeatability and Reliability List
POQ Log	List of POQs that have been performed
QMS 4230	Document and Records Control Procedure
QMS 7100	Risk Management Procedure
QMS 7400	Purchasing Procedure
QMS 7501	Citric Passivation Procedure
QMS 7502	Nitric Passivation Procedure
QMS 7503	Electropolish Procedure
QMS 7504	Metal Finishing
QMS 7505	Heat Treat Procedure

QMS 7506	Chemical Cleaning Procedure
QMS 7508	Cleanroom Use and Operations Procedure
QMS 7509	Cleaning Cleaning Procedure
QMS 7510	Production and Servicing Procedure
QMS 7600	Control of Monitoring and Measurement Equipment Procedure
QMS 8300	Control of Non-Conforming Product Procedure
QMS 8520	Corrective and Preventive Action Procedure

CHANGE CONTROL

(Approvals provided on first sheet.)

DATE	CHANGES
9/23/09	Initial Release
1/27/10	Revised format. Added Schedule of Processes.
4/19/10	Moved Schedule of Processes to / as an addendum to the Plan. Revised target completion dates on Schedule of Processes. Added "Change Control" page. Updated IT Support status. Some verbiage amended, but not to the point that it impacts the intent of the content edited.
11/15/10	Addressed any modified, added, open, and / or unclear entries. Added text to elaborate on areas where knowledge has been acquired since last revision. Changed revision format to date ilo –xx, per customer request.
4/12/11	Updated process validation status
7/26/12	Updated and some verbiage edited throughout the document to provide a more concise information platform and document structure.
10/28/14	Added "Note", at end of document. Added Tumbler and updated verbiage in Addendum. Removed COO as active signer. Updated some verbiage to provide clarification and / or elaboration.
7/30/15	Added references to cleanroom operations. Revised and updated some text and formatting.
1/4/16	Added A.E. Beaty facility.
9/25/16	Added "Note" to SV bullet, under "Definitions" section. Added "Note" to Validation bullet, under "Definitions" section. Added "Note" to Step 4, Pp 8. Removed "Addendum".