

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

1.0 Scope

This manual applies to Liberty Dental Lab, Inc. which is located at 2210 Guilderland Avenue, Schenectady, NY, 12306.

Liberty Dental Lab, Inc. realizes that the quality of its products directly impacts the safety and satisfaction of its customers. It further understands that good design, management, and continuous improvement create quality products. To that end, a system of policies and procedures are in place and described in this Quality Manual for the manufacture of custom made dental devices.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

2.0 Normative references

Use the following paragraphs if complying with DAMAS:

This manual describes the methods used to ensure and control the level of quality in our products. The sections in this manual are based on the requirements of the Dental Appliance Manufacturers Audit Scheme (DAMAS) Specifications, US Food and Drug Administration (FDA) Quality System/Good Manufacturing Practices (QS/GMP) as well as best practices from known quality systems such as ISO and Six Sigma.

This Quality Manual is an oversight document that is supported by Standard Operating Procedures (SOP's) and other work instructions and all will be generated, revised, or deleted as necessary for compliance and continuous improvement of our products.

Use the following paragraphs if not complying with DAMAS:

This manual describes the methods used to ensure and control the level of quality in our products. The sections in this manual are based on the requirements of the US Food and Drug Administration (FDA) Quality System/Good Manufacturing Practices (QS/GMP) as well as best practices from known quality systems such as DAMAS, ISO and Six Sigma.

This Quality Manual is an oversight document that is supported by Standard Operating Procedures (SOP's) and other work instructions and all will be generated, revised, or deleted as necessary for compliance and continuous improvement of our products.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

3.0 Terms and definitions

A Glossary of Terms is attached to this Quality Manual as Appendix A and may be used within the context of this Quality Manual. Also the terms and definitions contained in the DAMAS specifications and the Definitions in Sec. 820.3 of FDA's Title 21, Subchapter H, Part 820 are incorporated into this Quality Manual by reference.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.0 Management system requirements

4.1 Management responsibility

4.1.1 Conformity Policy/Quality Policy

Liberty Dental Lab, Inc. provides custom-made dental devices to customers and recognizes that the quality of our products have a direct impact on customer satisfaction. It is with this in mind that we set forth this Quality System mission of continuous improvement of our products, processes, and relationships. Liberty Dental Lab, Inc. is committed to conformance with the U.S. Code of Federal Regulations and more specifically the US Food and Drug Administration (FDA) Quality System/Good Manufacturing Practices (QS/GMP) and DAMAS specifications.

Our quality policy is stated below in our mission statement:

We believe that our first responsibility is to the doctors, assistants, patients, and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to reduce our cost in order to maintain reasonable prices.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.1.2 Management Representative

Liberty Dental Lab, Inc. has appointed Gary M. Spadaro as the Management Representative.

The principal function of the Management Representative is to ensure that Liberty Dental Lab, Inc. conforms, implements, and maintains a quality system that meets the requirements of all codes, specifications, and requirements detailed above and under Section 4.2.2 below.

Furthermore, the Management Representative is to ensure that **effective** training is provided to all affected personnel in the procedures specific to their job function. Secondly, they will develop methods and procedures to ensure the quality in process and finished products. The Management Representative will also be required to manage specific committees, where appropriate, to ensure that management is informed of the quality of products.

Other responsibilities of the Management Representative include:

- Charge management with individual responsibility for the performance of their departments/areas.
- Ensure the prompt investigation, correction and communication of all non-conformances
- Provide initial and continuing training of employees in issues of quality, individual responsibilities and actions to be taken to mitigate potential errors and non-conformances.
- Implement programs for self-monitoring and undertake periodic quality assessments.
- Identify alternate vendors and have them qualified to limit risk to the business.
- Ensure that contractors and subcontractors follow procedures, loss prevention and security standards consistent with Liberty Dental Lab's policies.
- Develop annual quality objectives focused on prevention and risk reduction.

In addition to administering the quality system, the Management Representative will coordinate with other managers to develop and enforce quality related procedures and continuous improvement programs. It is of utmost importance that the Management Representative provides sufficient advice and guidance to the aforementioned personnel, as well as ensuring top management is aware of regulatory trends that may affect future procedures, processes and construction.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.2 Management System

4.2.1 General

Products manufactured by Liberty Dental Lab, Inc. are custom-made devices and are designed according to the dental client's prescription; therefore, each device is unique. Liberty Dental Lab, Inc. has established, and documented this quality system in order to ensure also that all dental appliances are manufactured in compliance with applicable codes, specifications, and regulations including the U.S. Code of Federal Regulations and the FDA Quality System/Good Manufacturing Practices.

The expected performances of Liberty Dental Lab's custom-made devices are established by the dental client and Liberty Dental Lab, Inc. has implemented this quality system to ensure that the finished device meets the dental client's design. Liberty Dental Lab's warranty to the dental client establishes our expected performance of each custom-made dental device. The method of assessment of conformity with the dental client's design are documented by the feedback from the dental client and are documented in Liberty Dental Lab's non-conformity process described in Section 4.14 of this quality system.

Liberty Dental Lab, Inc. manages this process by implementing quality systems that are not limited to a quality department but are systemic controls that require the participation of all employees. It is understood that a good quality system requires resources to be effective and this policy describes the commitment to provide those resources. Therefore, the quality system is managed primarily by the Management Representative. The Management Representative is responsible for ensuring that the quality systems in place are carried out and that personnel are properly trained for its implementation. Budgeting for necessary training, test equipment, hiring of qualified persons, and other resources are the responsibility of the Management Representative.

The Management Representative is supported by members of the Quality Management Team who have been appointed to ensure that the Quality System is integrated into the daily production of dental appliances.

The quality system ensures that the customer supplier relationship is recognized from an internal and external perspective and material suppliers are included in this process. Where appropriate the proper controls are in place to prevent defects or non-conformities. Defects identified by the customer will be reviewed and an investigation for the root cause will be performed in order to prevent future occurrences.

Due to the nature of the business, Liberty Dental Lab, Inc. is an FDA regulated company and endeavors to remain compliant with those regulations. In addition we may use the *best practices* available to manage our quality system. Thus, systems such as Six Sigma, ISO, DAMAS or other systems will be considered and utilized where advantageous.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

Liberty Dental Lab, Inc. has established and maintains an organizational structure to ensure that dental appliances are designed and produced in accordance with this quality management system. The organization structure is depicted on Appendix 2.

It is generally understood that product quality is everybody's responsibility. However, specific responsibilities are provided in greater detail in the following sections.

Lab Owner, President and Chief Executive Officer, Vice Presidents are ultimately responsible for providing the resources necessary for the product quality for all employees through the quality program. Resources are funding for training, hiring of appropriate personnel and tools/equipment for proper execution of tasks. Executive Management is referred to in some parts of the Quality System. Executive Management is comprised of one or more of the individuals described in this paragraph.

They are also responsible for ensuring that an up-to-date quality program is established and maintained, and that responsible individuals are accountable for quality goals and objectives at Liberty Dental Lab, Inc.

Department Heads/Directors/Managers are responsible for all employees within their respective departments and for providing the means for executing tasks correctly and within specifications.

Supervisors/managers are responsible for all individuals within their jurisdiction. For the purposes of this manual, a supervisor or manager is the person that has direct oversight with the activities of the group or room. This may be a project manager, director, etc. No other person has a greater impact than the supervisor. All supervisors/managers will:

- a) Ensure communication and enforcement of procedures applicable to their area(s).
- b) Orient and train employees in their area on applicable safety rules, work practices, procedures and any anticipated product non-conformances.
- c) Ensure appropriate housekeeping practices are followed.
- d) Investigate all non-conformances and complete appropriate reports.
- e) Provide appropriate quality training and document accordingly (where applicable).
- f) Cooperate with, conduct, and document necessary quality inspections.

Employees are responsible for following all procedures and notifying their supervisors of any non-conformance or risk of non-conformance. In each job performance, quality should be a part of job duties. Failure to perform work consistent with procedures or reporting an error/deviation from procedures is comparable to not fulfilling any other job duty (i.e., safety, prompt arrival, etc.). All employees are responsible for the following:

- a) Adhering to general rules and policies.
- b) Participating in the expected training.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

- c) Reporting any non-conformance or trend toward non-conformance to their supervisor.
- d) Cooperating with the investigation of any quality or product non-conformance or continuous improvement effort.
- e) Proper use of any required personal protection equipment (i.e., respirator, safety glasses, gloves, etc.).
- f) Maintaining a positive attitude toward quality of work and understanding the impact of failing to adhere to procedures.

All employees are expected to follow the policies and procedures of the company.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.2.2 Legal and system documentation

A copy of the latest DAMAS Management System Specification is retained by the Management Representative. Also, a copy of the U.S. Code of Federal Regulations, Title 21, Chapter I, Subchapter H, Part 820 - FDA Quality System/Good Manufacturing Practices, is retained by the Management Representative.

The system also considers the Occupational Safety and Health Act, more specifically Infection Control and Exposure Control as defined in Federal Regulations 29 CFR 1910.1200 and Hazard Communication as defined in 29 CFR 1910.1030. The Management Representative retains copies of both of these OSHA standards.

In addition, the Management Representative retains a copy of any applicable state regulations affecting this quality system.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.2.3 Registration

4.2.3 Registration with the competent authority

Liberty Dental Lab, Inc. is registered as an initial distributor/importer with the FDA and has been issued registration number 300488691

Liberty Dental Lab, Inc. is registered as a participating dental laboratory with the National Association of Dental Laboratories (NADL). Liberty Dental Lab, Inc. shall allow third party assessment bodies to access the documentation that verifies these registrations.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.3 Documented review of the licensed dental client’s requirements; Receiving Acceptance Activities; Design Input/Design Changes

4.3.1 Documented Review/ Receiving Acceptance Activities

Liberty Dental Lab, Inc. has established and maintains procedures for acceptance of incoming work. Prior to manufacture of any dental appliance, Liberty Dental Lab, Inc. confirms that all information that has been received from a dental client is adequate to provide sufficient information to determine if Liberty Dental Lab, Inc. can manufacture the dental appliance to the dental client’s requirements. Prior to distribution into production, Liberty Dental Lab, Inc. reviews the documentation, which is typically a prescription, from the dental client. When adequate information is not received by Liberty Dental Lab, Inc., then a process is in place for acquiring adequate information to amend the original prescription for design changes. All prescriptions and amendments are retained for the period of time indicated on the Records Retention Schedule.

Work directed to a subcontractor will be accompanied by appropriate documentation so the subcontractor has adequate information for the manufacture of the dental appliance.

Prescriptions that become damaged or unusable during the manufacturing process shall be replaced using the process described in the Standard Operating Procedures.

4.3.2 Design Input/Design Changes

Liberty Dental Lab, Inc. relies on the dental client to determine the design input for each dental appliance manufactured. Records of dental clients’ design input preferences are maintained in written records and referred to in the manufacture of dental appliances for those dental clients providing such design input. The prescription received from the dental client and any amendments made after initial receipt of the prescription are considered as design input and design changes.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.4 Patient Contact Materials

4.4.1 Materials

It is recognized that the product is the sum total of all parts and labor combined. A major component of continuous improvement is prevention of a defective/non-conforming product. Thus, one of the best controls is to ensure that the materials that make up our product meet the quality expectations of Liberty Dental Lab, Inc. To that end, suppliers will be informed of the required specifications of the materials they provide and they will be qualified to provide them.

Material specifications are considered controlled documents and will be managed as listed above.

4.4.2 Subcontractor/supplier approval

Subcontractors and suppliers that supply materials and/or provide services to Liberty Dental Lab, Inc. will be qualified to perform them prior to hire via the selection process that is a part of this quality system. Subcontractors and suppliers will agree to notify Liberty Dental Lab, Inc. of changes in the product or service so that Liberty Dental Lab, Inc. may determine whether the changes may affect the quality of a finished dental appliance.

Subcontractors, both domestic and foreign, will meet all FDA requirements including the completion of an FDA inspection of the foreign facility for the purpose of determining compliance.

A list of approved subcontractors and suppliers and the selection process are included as a part of this quality system.

Liberty Dental Lab, Inc. has established a system for evaluation of the performance of our suppliers and subcontractors. Records are maintained to document any of their non-conformances. This information is recorded on a Supplier Complaint Form. These records are reviewed by the Management Review Committee.

All subcontractors and vendors are required to provide Liberty Dental Lab, Inc. with a Statement of Assurance.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.4.3 Purchasing

Purchasing controls for all patient contact materials are documented and retained in accordance with the Records Retention Schedule that is attached as Appendix 3 and made a part of this quality system.

4.4.4 Verification of purchased materials

Liberty Dental Lab, Inc. has established and maintains procedures for acceptance of incoming materials. Upon receipt of patient contact materials for processing, each item received from a supplier and/or subcontractor is verified to be conforming to the original purchase order requirements. Any patient contact material containing a lot or batch number by the manufacturer of the product or material will be recorded.

An inventory rotation system will be utilized for storage and use of products and materials. Where the quality of the material affects the finished product, it will not be used until deemed acceptable. Material failing to meet the required specifications will be placed in quarantine. Thus the purchasing department will label and segregate the nonconforming or unacceptable product that is held in Quarantine until proper disposition is handled.

This dental laboratory uses an inventory control system that is designed to rotate materials to follow the first in first out rule and to ensure that dated materials determined not useable are removed from inventory and not used in the manufacturing process.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.5 Defined Manufacturing Processes/Process Controls

4.5.1 Defined Manufacturing Processes/Process Controls

Liberty Dental Lab, Inc. has defined its dental appliance manufacturing processes. A flow chart is attached as Appendix 4. Standard Operating Procedures (SOP's) detail each type of dental appliance being manufactured along with descriptions of the process in each area or department of the manufacturing process. The SOP's and/or work instructions detail any design controls required.

In order to decrease variation within the processes, all operations that affect quality will have a policy, procedure, and/or work instruction that provides adequate information to perform the task in a consistent manner and according to a quality plan.

Quality control and design review are performed throughout the manufacturing process. Personnel are trained to perform at competent levels in all areas of the manufacturing process. Instructions for use or guidance for all patient contact materials and manufacturing equipment are available to personnel for reference purposes.

4.5.2 Design Controls

The requirements of FDA's Section 820.30 are established and maintained as a part of work instructions where applicable. Design inputs are described above in Section 4.3.2. Design outputs are not applicable in the usual manufacture of a custom-made dental device; therefore, they are not a detailed part of this quality system. As applicable, the device, its packaging and labeling, and the device master record make up the total design output.

4.5.3 Design Verification

The review of the final product described in Section 4.9 of this Quality Manual verifies that the dental appliance was manufactured according to the dental client's specifications. The acceptance by the dental client evidences and verifies that the dental appliance met his specifications.

4.5.4 Identification

Liberty Dental Lab, Inc. has established and maintains procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mix-ups.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.5.5 Traceability

Patient contact materials that are used in the manufacture of dental appliances that are identified by control numbers, such as lot or batch, are documented in the Device History Record. These records are retained according to the Records Retention Schedule attached as Appendix 3.

4.5.6 Automated Processes

At this time no dental appliances or components of dental appliances manufactured by Liberty Dental Lab, Inc. are manufactured using CAD-CAM software and technology. These systems provide product validation reports that are reviewed as a part of this quality system. If CAD-CAM systems are installed at a future date, Liberty Dental Lab, Inc. will receive assurances from the manufacturer of the CAD-CAM equipment that it meets all FDA requirements.

4.5.7 Change Control

Change control is a system used to ensure that all systems work in concert together in a positive constructive manner. That is, one change to a system, product, process, label, does not create a problem or error in another system or department. To keep this process centralized, the Management Representative will be responsible for managing change control in cooperation with other departments.

4.5.8 Device Master Records

A Device Master Record (DMR) has been prepared for each type of dental appliance manufactured by Liberty Dental Lab, Inc. These DMR's are included in the Standard Operating Procedures.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.6 Training

The most important part of any quality program is the people. Employees, contractors, and consultants must be qualified to perform their job. It is the responsibility of the Management Representative to ensure that all persons hired are technically able to perform their jobs. This should be determined by resume, curriculum vitae, job application, certifications, physical demonstration of skill, etc.

Liberty Dental Lab, Inc. maintains procedures to identify training needs for all personnel. Training is provided to ensure that all personnel are competent to carry out the dental appliance manufacturing and management system tasks. Responsibilities of employees are further defined in 4.2.1 of this quality system.

The summary of the qualifications and training is retained in the personnel file as a record of this effort.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.7 Maintenance, calibration and validation of equipment; Optical Impression Systems for CAD/CAM

4.7.1 Maintenance

All equipment must be reviewed and approved for use to ensure it will perform as designed and will conform to specified standards. Where applicable, equipment will be monitored to ensure it performs within specified limits. The Equipment Maintenance and Repair Record is a part of the Standard Operating Procedures. This Record is reviewed at the Management Review Meeting.

Because Liberty Dental Lab, Inc. manufactures custom made dental devices, its personnel are competent to recognize when the equipment is not functioning correctly. Where applicable, Liberty Dental Lab, Inc. visibly posts any inherent limitations or allowable tolerances on or near equipment requiring periodic adjustments and/or this information is readily available to personnel performing the adjustments to the equipment.

4.7.2 Calibration

Typically the appearance and form of the manufactured device is a more reliable indicator that the process has been successfully carried out than through inspection, measurement, or testing of the equipment. All equipment used for inspection, measurement, or testing will be used for the designed purpose and placed on a maintenance schedule and, if required, a calibration schedule. Where possible the calibrations will be traceable to a known reference standard such as National Institute of Standards and Technology. Equipment will be labeled in some form to ensure that operators do not use equipment that is not approved for use and may jeopardize the integrity of the product. Examples of labeling include but are not limited to: "Out of Service – Do Not Use" or "Calibrated" or "Approved for Use."

4.7.3 Validation

Equipment that is critical to the quality of the manufacture/processing of the product requires validation to ensure that it operates within the expected parameters. That equipment will have the necessary protocols designed and executed and documentation will be maintained per document control policies.

4.7.4 Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD-CAM)

Liberty Dental Lab, Inc. has not installed CAD-CAM systems as a fabrication tool and a component in the manufacture of some dental appliances.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

If at a future date CAD-CAM systems are installed, Liberty Dental Lab, Inc. has secured the assurances from the manufacturer of the equipment that its device meets the recommendations of FDA's guidance or in some other way provides equivalent assurances of safety and effectiveness. Liberty Dental Lab, Inc. has not made any alterations to this equipment or its software that would require additional approvals by FDA.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.8 Cleanliness

To ensure cleanliness of all processing areas, Liberty Dental Lab, Inc. has controls in place for the prevention of contamination of materials and equipment. Cleaning of all areas that are critical to the quality of the final product is performed on a regular basis, i.e. daily, weekly and monthly. Documentation of cleaning is evidenced on cleaning schedules attached to the Standard Operating Procedures.

Further controls of contamination consist of a regular cleaning schedule of equipment and facilities. Liberty Dental Lab, Inc. has established and maintains decontamination procedures in accordance with the Occupational Safety and Health Administration's Bloodborne Pathogen Standard.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.9 Documented review of the final product

Throughout this document there has been reference to inspections and acceptance criteria. The acceptance criteria will be determined based on the quality attributes of the desired process output, the finished product, and the satisfaction of the customer. Quality checks are performed and documented throughout the manufacturing process and are records of the acceptance status. The final inspection checklist included in the Standard Operating Procedures is used at a minimum to check the final quality of the product.

Final inspection of dental appliances manufactured by subcontractors is performed using the same criteria as for dental appliances manufactured by Liberty Dental Lab, Inc. The final inspection is documented as set forth above. All employees who perform quality control or final inspection are properly trained.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.10 Defined handling, packaging, distribution, and servicing

All devices manufactured by Liberty Dental Lab, Inc. are custom-made dental devices. Specific procedures for handling, storage, packaging, preservation, distribution, and delivery of finished dental appliances are detailed in the Standard Operating Procedures.

Liberty Dental Lab, Inc. does not provide any type of servicing that would require procedures to be established and maintained.

Any specific handling, storage, or installation information will be provided in the packaging to the customer.

If any products are potentially affected by the environmental conditions such as relative humidity, they will be manufactured or processed in controlled areas with documentation of the methods and operating conditions.

All packaging will be designed to protect the product from damage during shipment to the dental client or subcontractor.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.11 Control of records

Liberty Dental Lab, Inc. manages documents that are product related based on a hierarchy of Policy, Procedure, Work Instructions, and Specifications. These documents are defined in detail below:

- Policy – is a document that is broad in scope and typically will not have specific actions described. It is used to provide vision and direction without instruction. For example: “All employees are expected to follow procedures...”
- Procedure – is a document that provides general work flow for a specific area.
- Work Instructions – is a document that provides specific step by step directions for the manufacture of custom-made dental devices.
- Specifications – are documents that provide the performance requirements for product, equipment, and/or materials that are critical to the manufacturing process.

The documents are managed via a document controls system that tracks origination, approval, numbering, effective date, reviews, and change control. The Document Control system is detailed in the Standard Operating Procedures. The Management Representative will be responsible for Change Control as stated in Section 4.5.7.

The Management Representative is responsible for assigning the document numbers and the originator is responsible for coordinating or providing training to affected personnel.

Other important documents include the Device Master Record, Device History Record, non-conformances, change control, validation protocols, calibrations, and adverse events/complaints. These files will be maintained a minimum of 5 years or the life expectancy or label claim of the product associated with it, whichever is longest. All records that are a part of the quality system will be made available for review and copying to employees of FDA who are designated to perform inspections.

Records deemed to be confidential by Liberty Dental Lab, Inc. are so marked to aid FDA in determining whether information may be disclosed under the public information regulation.

The Records Retention Schedule attached as Appendix 3 indicates the criteria for retention of control records. These records comprise the Quality System Record (QSR).

The Management Representative is responsible for compliance with records retention.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

All records stored in automatic data processing systems shall be backed-up.

The Device History Records (DHR) are established and maintained for each dental appliance manufactured by Liberty Dental Lab, Inc.. The records, that make-up the DHR for each dental appliance, are listed on Appendix 5.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.12 Statement

Statements of Conformity are provided by Liberty Dental Lab, Inc. to its dental clients. An example of the Statement of Conformity is attached as Appendix 6.

When the dental client or a subcontractor provides materials that Liberty Dental Lab, Inc. incorporates into the dental appliance, then the dental client and/or subcontractor will confirm to Liberty Dental Lab, Inc. that only FDA approved material or CE marked material are being provided. Such statements of assurance are retained by the Management Representative.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.13 Labeling and Packaging

Labeling is sufficient for the customer to determine the contents of the packaging and to prevent misapplication of the product. Contents of the packaging are included either on the invoice or the label containing identification of the manufacturer and/or distributor, country of origin of the manufacturer, and any specific information concerning the contents of the appliance.

All dental appliances manufactured by Liberty Dental Lab, Inc. indicate to the dental client that it is a “custom-made dental device”.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.14 Complaints/Non-conforming Product; CAPA

4.14.1 Complaints/Non-conforming Product

A system is in place to define what constitutes a complaint or non-conformity. All complaints and non-conformities are processed in a uniform and timely manner. Complaints can include turnaround time, delivery time, remakes, and similar issues. These complaints are documented and reviewed periodically. Liberty Dental Lab, Inc. reviews and evaluates all complaints to determine if an investigation is necessary.

Statistical techniques are used to evaluate rework and remake activities. This process is used to monitor remake rates and make corrections in the quality processes accordingly.

4.14.2 Corrective Action and Preventive Action (CAPA)

Procedures are in place to ensure that personnel can properly identify a non-conforming product/defect while processing and in the finished product prior to shipment to the customer. However, should a customer report a defect or non-conformity, the CAPA system will be used to remove existing defects and prevent recurrence.

The CAPA program consists of:

- Root Cause Analysis
- Determination of the scope of the problem
- Implementation of the corrective measures
- Communication of the method to identify the defects and necessary corrective actions to prevent a non-conforming finished product
- Follow-up of corrective measures to ensure efficacy

The purpose of CAPA is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence.

The Management Representative is responsible for the CAPA Program. A description of the CAPA program is attached as Appendix 7. CAPA is instituted for all complaints unless it is determined by management that no investigation is to be made. Any such decision is documented.

Procedures are also in place to evaluate the complaint to determine if it represents an event which is required to be reported to FDA.

Liberty Dental Lab, Inc.		
Quality Manual	Effective Date:	Doc No: QM1-000

4.15 Internal audits and management review

Quality audits shall be conducted periodically to assure that the Quality System is in compliance and to determine the effectiveness of this Quality System.

4.15.1 Internal Audits/Quality Audits

Quality audits shall be conducted at least twice a year to assure that the quality system is in legal compliance and also to determine the effectiveness of the quality system. Quality audits are performed by individuals who do not have direct responsibility for the matters being audited. Quality audits are documented and appropriate corrective actions are taken. Re-audits of deficient matters will be performed when necessary.

Quality Audits and re-audits, where taken, shall be reviewed by the appropriate management and at the Management Review Meeting. All dates and results will be documented.

4.15.2 Management review

The Management Representative will ensure that the quality system is reviewed at a minimum annually to determine that the quality system is suitable and effective and that the quality system satisfies the legal requirements of Section 4.2.2 hereof. Records of Management Review Meetings will be maintained by the Management Representative. The following is the Agenda for the Management Review Meeting:

Review the records for the following:

- Results of Quality Audits
- Supplier and Subcontractor Performance
- Customer Complaints and CAPA
- Staff training
- Effectiveness of the Quality system to meet quality objectives
- Continuous improvement actions taken over the past year
- Any changes made during the year and future changes to the Quality System due to new technology and/or processes.