

Department Audited:	Auditors:
Escort:	Audit Dates:

QSR/ISO/EN Section	Title/STS SOP	Look For	Observations
820.5 820.20	Quality System QSD-402 QAM-1	<ol style="list-style-type: none"> <li>1) Evidence that the quality policy is understood by all personnel.</li> <li>2) Is organizational chart accurate?</li> <li>3) Management Review</li> <li>4) Quality System procedures</li> </ol>	
820.160	Contract Review QSD-403	<ol style="list-style-type: none"> <li>1) Are there records that Contract Review is being performed?</li> </ol>	
820.30	Design Controls QSD-404	<ol style="list-style-type: none"> <li>1) Check design history file for: <ol style="list-style-type: none"> <li>a) Design input.</li> <li>b) Design output makes reference to acceptance requirements.</li> <li>c) Design outputs essential for the proper identification are identified.</li> <li>d) Approval of design output.</li> </ol> </li> <li>2) Design review is completed according to schedule.</li> <li>3) Design verification is documented including: <ul style="list-style-type: none"> <li>- Methods</li> <li>- Personnel</li> </ul> </li> <li>4) Design validation performed under defined operating conditions.</li> <li>5) Personnel and date of validation are documented.</li> <li>6) Is design correctly translated into production specifications?</li> </ol>	

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820.40	Document Control QSD-405	<ol style="list-style-type: none"> <li>1) Current revisions of SOP's and data sheets are used.</li> <li>2) SOP's are up-to-date.</li> <li>3) Technicians are familiar with the SOPs that affect quality.</li> </ol>	
820.50	Purchasing Controls QSD-406 PUR Series REG-16	<ol style="list-style-type: none"> <li>1) Raw materials are purchased from an approved vendor list.</li> <li>2) Quality requirements are on purchasing documents.</li> </ol>	
	Control of Customer Supplied Product	<ol style="list-style-type: none"> <li>1) Procedures that show control of verification, storage, and maintenance of customer supplied product (CSP).</li> <li>2) Evidence that CSP which is damaged or is otherwise unsuitable for use is recorded and reported to the customer.</li> </ol>	
820.60 820.65	Identification Traceability QSD-408	<ol style="list-style-type: none"> <li>1) All product (raw and test materials) are properly labeled or quarantined.</li> <li>2) Look to see if test numbers, personnel, dates, Z #'s, are recorded on data sheets.</li> </ol>	
820.70	Production and Process Controls QSD-404 QSD-409 QSD-411	<ol style="list-style-type: none"> <li>1) Are all instructions are formal?</li> <li>2) Revision #'s of controlled documents, labels, and signs.</li> <li>3) Are there procedures for all work affecting quality?</li> <li>4) Processes are performed to their written procedures.</li> <li>5) Housekeeping is scheduled, performed and documented.</li> <li>6) Correction factors are available</li> <li>7) Check maintenance schedules</li> <li>8) Validation of software processes.</li> </ol>	

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820.170	Installation/ QSD-409	<ol style="list-style-type: none"> <li>1) If necessary, are there procedures for installation.</li> <li>2) Inspection of installation.</li> <li>3) Installed by qualified personnel.</li> </ol>	
820.75	Process Validation QSD-409	<ol style="list-style-type: none"> <li>1) Are methods of processing and testing validated?</li> <li>2) Are there procedures defining validations?</li> <li>3) Are training records for people performing validations up-to-date?</li> <li>4) Does raw data from validation activities document: <ul style="list-style-type: none"> <li>- date</li> <li>- personnel</li> <li>- major equipment</li> <li>- control method</li> </ul> </li> <li>5) If changes have been made to the equipment and process, has a determination been made on revalidations?</li> </ol>	
820.80 820.86	Receiving, In-Process and Finished Device Acceptance QSD-410	<ol style="list-style-type: none"> <li>1) Are receiving logs up-to-date?</li> <li>2) Raw materials reflect acceptance status.</li> </ol>	
820.72	Inspection, Measuring, and Test Equipment QSD-411	<ol style="list-style-type: none"> <li>1) Is the status of all M &amp; TE identified?</li> <li>2) Are M &amp; TE stored to prevent invalidation of calibration?</li> <li>3) All measurements and specifications have tolerances where necessary.</li> <li>4) Is equipment being using within its limitations.</li> </ol>	

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820.120	Device Labeling QSD-412 LRP-15	1) Are all labels controlled? 2) Look for information labels. 3) Are all labels controlled properly? - locked up - identified in a procedure - control #'s 4) Is everything that should have labels, labeled? 5) Is FIFO practiced? 6) Are off-test products returned to the log-in area?	
820.90	Non-Conforming Product (NCP) QSD-413	1) Is rejected product properly labeled, and or quarantined? 2) Has NCP been properly evaluated?	
820.100	Corrective and Preventive Action QSD-414 REG-14	1) Check log sheets to ensure out of specification (OOS) temperatures have a CAR. 2) Check CAR log to see if the department has any CAR's that are not resolved. 3) Check corrective actions for effectiveness.	

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820.130 820.140 820.150 820.160	Device Packaging, Handling, and Storage Distribution QSD-415	<ol style="list-style-type: none"> <li>1) Are sterile items stored to prevent contamination?</li> <li>2) Is media that is supposed to be stored in the dark, stored properly?</li> <li>3) Are accepted raw materials and test articles kept separate from product that has not been accepted?</li> <li>4) Look for documentation demonstrating customer's original requirements were met.</li> </ol>	
820.181	Device Master Record (DMR)	<ol style="list-style-type: none"> <li>1) Are device specifications included in the DMR?</li> <li>2) Are all SOP's for production in the DMR.</li> <li>3) Are inspections, labels, tags identified?</li> <li>4) Specifications for labeling.</li> </ol>	
820.184	DHR Device History Record QSD-416	<ol style="list-style-type: none"> <li>1) Can you find the dates of processing?</li> <li>2) How many were completed.</li> <li>3) How many were released.</li> <li>4) Acceptance and rejection records.</li> <li>5) Labeling identification.</li> </ol>	
820.180	Records QSD-416	<ol style="list-style-type: none"> <li>1) Are records stored properly?</li> <li>2) Is restricted access practiced?</li> <li>3) Check log books, notebooks, folders and data sheets for proper documentation practices (cross-outs, writeovers, white-out, etc.)</li> </ol>	

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820.22	Quality Audit QSD-417	1) Completion of corrective action from previous audit.	
820.25	Personnel QSD-418 SRP-11	1) Completeness of training records. 2) Anyone who needs a CV, has one.	
820.200	Statistical Techniques QSD-420	1) Are there any requirements for statistical techniques? 2) Statistical techniques can be found in: <ul style="list-style-type: none"> <li>■ customer specifications</li> <li>■ SOP's</li> <li>■ Reference Standards</li> <li>■ Acceptance Criteria (i.e. sampling plans)</li> </ul>	

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SOPs Audited	Comments

**Internal Auditor Notes and Comments**

Audited to:  
QSR = Quality System Regulation, Part 820, CFR21

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<i>Required Procedures</i>	<i>21 CFR Section</i>	<i>Check</i>
<b>Procedures for MDRs</b>	<b>803.17</b>	
<b>A documented quality program</b>	<b>820.20</b>	
<b>Documentation of Management review of quality system at defined intervals and at sufficient frequency</b>	<b>820.20</b>	
<b>Procedures for audits</b>	<b>820.22</b>	
<b>Records of audits</b>	<b>820.22</b>	
<b>Procedures for identifying training needs</b>	<b>820.25</b>	
<b>Documentation of any necessary personnel training programs</b>	<b>820.25</b>	
<b>Documents relating to design controls including the Design History File</b>	<b>820.30</b>	
<b>Procedures for specification control measures to assure that device, components , and packaging design results in approved specifications</b>	<b>820.40</b>	
<b>Document controls not previously mentioned</b>	<b>820.40</b>	
<b>Document of specification changes</b>	<b>820.40</b>	
<b>Procedure of approval of change of manufacturing process</b>	<b>820.40</b>	
<b>Record of percentage of defective components for each lot and the percentage of lots rejected</b>	<b>820.50</b>	
<b>Purchasing controls not previously mentioned</b>	<b>820.50</b>	
<b>Limitations or allowable tolerances on equipment</b>	<b>820.70</b>	
<b>Records of equipment inspections</b>	<b>820.70</b>	
<b>Procedures and specifications for manufacturing processes</b>	<b>820.70</b>	

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Records of maintenance activities	820.70	
Procedures for processing control	820.70	
Documentation of inspections of any required environmental control system	820.70	
Procedures for contamination control	820.70	
Procedures and schedules for maintenance, adjustment, and cleaning of equipment	820.70	
Procedures for use and removal of manufacturing material	820.70	
Record of removal of manufacturing material	820.70	
Procedure for approval of changes to software programs	820.70	
Procedures for acceptance of components	820.80	
Records of acceptance or rejection of components	820.80	
Procedures for finished device inspection and sampling plans	820.80	
Documentation of testing of computer software programs for calibrating, inspecting, and checking measurement equipment	820.84	
Procedures for calibration, inspection, and checking of measurement equipment	820.84	
Procedures and limits for accuracy and precision in calibration of measurement equipment	820.84	
Records documenting traceability of calibration standards	820.84	
Records of calibration, inspection, and checking of measurement equipment	820.84	
Records of calibration of measurement equipment	820.84	
Procedures for reprocessing of devices or components	820.90	
Record (implied) of final inspection of reprocessed device	820.90	

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Records of the disposition of obsolete, rejected, or deteriorated components	820.90	
Records of investigation of failure of device or components after release for distribution	820.100	
Procedures for warehouse control and distribution of finished devices Where necessary, system to assure that oldest approved devices are distributed first	820.124	
Record of examination of labeling materials	820.162	
Device Master Record	820.181	
Device History Record	820.184	
Record of critical operations in device history records by responsible individual	820.184	
Records of written and oral complaints	820.198	
Record of complaint investigation or reason no investigation was done	820.198	
Complaints pertaining to injury, death, or any hazard to safety	820.198	
Servicing procedures, records, and record evaluations	820.200	
Statistical techniques: identification of valid techniques, sampling plans, adequacy	820.250	

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Upper Confidence Level		0 out of:	1 out of:	2 out of:
A	≤30%	11	17	22
B	≤25%	13	20	27
C	≤20%	17	26	34
D	≤15%	23	35	46
E	≤10%	35	52	72
F	≤5%	72	115	157