Audit Assessment with internal note

Assessment	Company	Month	FYear
Corporate Management Audit	CH Service Ltd.	January	2018-2019

Status	Comencement Date	Completion Date
Submitted	02/01/2021	02/01/2021

Sr No	Sub Section	Process	Sub Process	Assessement Answer	Notes	Internal Notes
1	Quality Management System	Has the organization established and maintained a quality management unit within the overall company?	Organizational chart exists which reflects the current reporting structure. Evidence exists which indicate organizational freedom to exercise authority and responsibility. Job descriptions include responsibilities for supporting quality objectives. There is a management representative with defined authority and responsibility for meeting customer compliance. Qualified technical personnel available for design, process, product, and service support. Quality manual has been developed which details the quality system of policies and procedures. Procedures identify: Who is responsible for action l What has to be done l When the actions are required Responsibility for updating and revising the quality manual and system is defined. Quality manual is supported by top management. Written procedures and instruction define the methods for performing work affecting quality for those: l Managing the work l Performing the work l Verifying the work	Improvement Needed		

2	Quality Management System	Are there corporate goals for continuous quality improvement?	Company quality objectives documented, signed and dated. Quality objectives communicated, understood, and maintained throughout organization. Written procedures address the following types of planning: l Establishment of requirements l Verification of requirements l Acceptance procedures l Quality information systems l Customer satisfaction Ongoing quality improvements are a part of the plant manager's objectives. Quality costs are used for evaluating and planning. Documented evidence that advanced quality planning activities are reviewed with customers. Demonstrated innovation in their techniques to improve quality. Long-term plan is reviewed annually for progress reviews and continuous improvements.	Acceptable		

3	Quality Management System	Is there a periodic review by management of the effectiveness of the quality management systems?	Lead times measured and tracked Total cost of quality tracked Cycle times measured and tracked Annual Quality improvement goals are set by top management Goals are regularly reviewed by top management. System in place to verify meeting objectives and policy. Achievement of quality objectives a high priority in overall performance reviews. Quality manual is regularly reviewed, revised, and communicated throughout the organization. Documented and objective process to measure and track customer satisfaction.	Improvement Needed		
4	Quality Management System	Are internal audits performed and corrective actions implemented?	Internal audits are performed with defined reports/distribution. There is a documented procedure for conducting internal quality audits. Internal audits are conducted semi-annually or scheduled on the basis of status and importance of activity. Audit includes work environment and general housekeeping. Internal audit evaluates effectiveness of activity as well as conformance to procedures. Internal audit results are documented and brought to attention of management. Management reviews are conducted on results of audits. Corrective actions are timely, recorded, and evaluated for effectiveness.	Outstanding		

5	Document and Data Control	Is there a product/process specification control system and does it reflect the evolution of each product. (I.e. Change Control).	Documentation controlled by Revision Level Changes. Design changes controlled by Engineering Change Notices or a similar process (SRN). Written procedures have been developed and implemented for controlling design and document control. Procedures address responsibility and the approval process required to make changes. Design changes documented and approved by authorized personnel before implementation. There is a periodic audit of the process to confirm the specification control system functioning properly.	Acceptable		
6	Document and Data Control	Are current documents (specifications, drawings artworks, etc.) available and readily accessible to all appropriate areas?	Master list of all controlled documents and the revision level are available. Current documents are available and readily accessible in all appropriate areas. There is evidence that the current documents are being referenced and utilized throughout the company to perform the activities required to produce the product. There is a periodic audit of the process to confirm that current specifications are being utilized and the and the process is functioning properly.	Acceptable		

7	Document and Data Control	Are obsolete documents removed from use?	Obsolete documents are removed from use. Written policies and procedures are available to handle obsolete documents. Obsolete documents are being destroyed in a timely and confidential manner. There is a periodic audit of the process to conform that obsolete documents are being withdrawn from use.	Outstanding		
8	Supplier Quality Management	Are criteria for evaluation of suppliers defined, and are the results of these evaluations and follow-up actions recorded?	Supplier visits are made as a result of quality problems and to promote quality improvement. Supplier quality levels are routinely measured and target improvements have been established with supplier. Formal supplier audit program is developed and implemented with audits conducted on critical supplier`s operations. Suppliers have demonstrated and documented their usage of prevention techniques (Capability Studies, SPC, etc.). Supplier actively seeks long-range quality improvement planning from their suppliers. All critical suppliers are in certification program.	Acceptable		
9	Supplier Quality Management	Is there a system that defines approved suppliers?	Approved sources defined and documented on specifications. Unapproved sources are used only with written justification by R&D or procurement. A review system is in place to assure only approved suppliers are used.	Improvement Needed		

10	Supplier Quality Management	Is a system in place to provide assurance that the supplier meets physical, chemical, visual, functional and dimensional requirements?	Statistical data review of supplier data verifying conformance to specifications. Production process verification or validation. Raw material traceability to finished material verified. Supplier rating system uses acceptance/rejection information. Certificates of Analysis and/or Conformance results have been validated.	Improvement Needed		
11	Supplier Quality Management	Quality history, delivery, price and service considered when making sourcing decisions.	Rating program used to demonstrate its inclusion in the procurement process. Rating program with measurement system that demonstrates high effectiveness and continuous improvement.	Improvement Needed		
12	Receiving Inspection	Incoming material is properly received prior to release for production.	Incoming procedures are documented, available at the incoming area, and are properly followed. Packing and shipping requirements are verified when shipments are received. Storage requirements are followed (refrigeration, etc.). A system is in place which segregates and identifies non-inspected received material. A system is in place to report shipping discrepancies (over, short or damaged receipts). Incoming material receives approval from authorized personnel before it moves into storage or production. There is a documented system to verify use status of stored material.	Acceptable		

13	Receiving Inspection	Production material is properly identified and traceable, during all phases of manufacturing and delivery.	Material and product are traced by manufacturing date/lot code. A system is in place to document expiration dates of received materials. Procedures have been developed for material traceability and identification status during processing. Material inspection status is identified by verification of acceptance/rejection, and traceable to inspection location. Traceability control system is manually or electronically controlled with information easily obtained. Material is identified through all phases of manufacturing and delivery. Procedure for releasing urgently required material prior to verification activities is defined, documented, and followed. Procedures are fully developed and implemented for the identification of inspection status and provided for: l Establishment of material conformance l Holding of non-conforming material l Identification and segregation	Acceptable		
14	Receiving Inspection	Incoming materials are sampled using approval plans.	Sampling procedures are defined, followed, and based on recognized standards. Samples are properly identified for traceability through the inspection process. A documented system is in place to allow for reduction in sampling, based on valid criteria. A system is in place to actively work with suppliers to reduce sampling and inspection.	Acceptable		

15	Receiving Inspection	Incoming materials are inspected for adherence to written specifications.	Inspection plans include comparison to an approved standard. Equipment used in the inspection process have calibration or standardization records Test data is recorded according to applicable procedures or regulations. Test methods are documented and referenced on material specifications. Test methods are validated for the materials being tested. There is a formal Material Review Board that routinely meets to make disposition on non-conforming material. A material retain program is defined and utilized. There are written procedures which detail supplier notification/corrective action on rejected materials. Records of test reports, certifications, statistical data, etc., are on file and traceable to specific lots when required. Statistical evidence on specification conformance is required on all critical material. Validation or verification completed on products that are accepted on test or Certificates of Conformance.	Acceptable		

16	Inventory Management	Product/material is properly identified and traceable during all phases of process. (Incoming, production, distribution).	Material and product are traced by manufacturing date/lot code. Material status is identified by verification of acceptance or rejection and is traceable to inspection location. Traceability control system is controlled manually or electronically with information easily obtained. Material is identified through all phases of manufacturing and delivery. Procedure for releasing urgently required material prior to verification activities is defined, documented, and followed. Procedures are fully developed and implemented for the identification of inspection status and provide for: l Establishment of material conformance. l Holding of non-conforming material. l Identification and segregation.	No System		hhhhhhhhhhhhhhhhhhhh

17	Inventory Management	Product is properly segregated and identified (accepted, waiting inspection, rejected, etc.) for Incoming Materials, Work in Progress, and Finished Goods. (status control)	Procedures developed to distinguish the status of material. (quarantined, rejected, approved) Procedures are documented and available in applicable areas that define possible stock status. Non-conforming materials are properly identified (tags or electronic) and segregated from good material. Material status can only be changed by QA or by their authorization. QA must approve any material released under deviation. Document trail is available and maintained for rejected material. Records are maintained that allow for review and traceability of materials from incoming through to final distribution.	No System		sdzfgc ghvuuyhv

18	Inventory Management	Is product properly handled and stored to prevent damage, contamination, and/or loss?	Where applicable the following measures should be found: l Pest control system in place, sheets from outside agency on file and up to date. l Structure of building suitable and intact. (No cracks/loose bricks, no leaks in roof, etc.) l Adequate floor drainage (flood potential). l Windows intact and with screens if they open. l Entry points are closed and secured from the inside. l Production/mix area has protection from accidental breakage of light bulbs/tubes. l Storage racks are set away from the building wall. l Temperature sensitive products are being stored in an environmentally controlled room. (Temperature/Humidity) l Flammable products are being stored in an XP room. l Trucks and sea containers are cleaned and treated with insecticide before loading.	Acceptable		

19	Inventory Management	Are outside/contact warehouses used to store product.	Where applicable the following measures should be found: l Pest control system in place, sheets from outside agency on file and up to date. l Structure of building suitable and intact. (No cracks/loose bricks, no leaks in roof, etc.) l Adequate floor drainage (flood potential). l Windows intact and with screens if they open. l Entry points are closed and secured from the inside. l Storage racks are set away from the building wall. l Temperature sensitive products are being stored in an environmentally controlled room. (Temperature/Humidity) l Flammable products are being stored in an XP room. l Trucks and sea containers are cleaned and treated with insecticide before loading.	Acceptable		
20	Inventory Management	Is the inventory system audited? (inventory accuracy)	Actual inventory count is taken once per year. Procedures are published to define the need and frequency to perform inventory cycle counts. Stock is being rotated on a FIFO basis unless otherwise defined. Obsolete/expired inventory is disposed in a timely manner. Cycle count accuracy is 98 percent or greater (preferably verified by a third party).	Acceptable		

21	Inventory Management	Is there a system to monitor, finalize, disposition, and follow-through on distressed material?	QA leads the disposition of rejected material and has final sign-off on any material release. There is formal Material Review Board that routinely meets to make disposition on non-conforming material. There are written procedures that detail supplier notification/corrective action on rejected material. Full records are maintained detailing the initial rejection through to the final disposition of the material.	Outstanding		
22	Process Control	Processes are documented and quality procedures have been developed and implemented within manufacturing operations.	Documented process and quality instruction procedures, including applicable standards, are located at work stations and reflect current practices. Sampling plans are utilized as a part of the quality inspection plan. Quality inspection sampling plans utilize acceptance criteria targeted at zero defects. All instruction procedures are controlled documents and are signed off by appropriate personnel. A formal procedure exists, which details the responsibility for procedure development and approval processes. All written instruction procedures are routinely reviewed for application of processing methods and accuracy of quality requirements.	Outstanding		

23	Process Control	There are procedures for controlling manufacturing process changes.	Manufacturing process changes are documented on all key operations. Process change procedure breaks responsibility down to affected department responsibility level. Process F.M.E.A.`s (Failure Mode & Effects Analysis) are reviewed and updated for changes made to key operations. Evaluation studies for quality specifications are required on process changes made to key operations. All process changes are documented, reviewed, and approved by appropriate personnel before change is made. All manufacturing process changes are promptly communicated to customer. New processes are not implemented without customer knowledge and approval.	Acceptable		

24	Process Control	Control plans are developed which detail quality planning activities required to ensure conformance to quality requirements.	Supplier control plans satisfy customer driven quality requirements. Control plans have been developed on all customer material. Process instruction procedures agree with control plan. Control plans are controlled documents. Authority to stop the manufacturing process in the case of non-conforming product is defined. Control plans are actively used throughout all operations and have been developed on 100% of key process operations. Supplier utilizes control plan for quality planning activities on new and change processes. Control plans are routinely reviewed for effectiveness and updated as required.	Acceptable		
25	Process Control	In-process quality expected to be achieved through superior process controls.	Consistently meets/exceeds quality goal. Deficient processes are immediately identified and actions implemented for improvement. Quality goals are regularly reviewed and supported by top management. Annual quality goals are revised by top management. SPC is used for in-process inspection.	No System		yrcjicvy

26	Process Control	Manufacturing quality systems achieved through Total Quality Control philosophies.	Uses SPC or other effective processes to control manufacturing processes. Proactively implements effective quality and reliability programs. Operates under total quality control principles, including validation. All processes documented. Supplier evaluates equipment for capability.	Acceptable		
27	Process Control	A preventive maintenance program has been documented and implemented.	Plant wide preventive maintenance program is in place and operational. Preventive maintenance "procedures" are available which were supplied from the original equipment manufacturer or have been developed if not available Complete preventive maintenance and repair records are readily available for all process equipment. Records indicate that high wear parts, for critical processes, are kept in stock. Preventive maintenance program is reviewed on a routine basis and includes the effects of process changes. Where necessary, preventive maintenance is concluded with a process capability study to verify conformance. Preventive maintenance program is structured and performed based on time requirements.	Acceptable		

28	Product Inspection	Inspections and tests are performed at appropriate points throughout manufacturing operations.	Inspection coverage is available on all operating shifts. Quality Assurance has the prime responsibility for evaluating production material. If manufacturing is responsible for quality within the manufacturing operations, Quality Assurance has the prime responsibility for auditing quality system conformance. Process flow diagrams are available which show necessary quality checkpoints. Procedures are written for re-inspection and testing of defective material. Sampling and retain plans are written and consistently followed. Inspection/test plans are periodically reviewed for effectiveness. Statistical sampling methods are used to perform final product audits. Statistical process control is the prime tool used for controlling manufacturing operations. Continuous reduction in process variation is pursued actively by manufacturing personnel. Written procedures exist for the prompt retrieval of nonconforming material found during manufacturing.	Outstanding		

29	Product Inspection	Quality and reliability expectations are for defect-free materials/products.	No quality or reliability problems exist. Exceptional quality and reliability goals are established for all areas to ensure defect-free materials. Management reviews are held on products/processes for manufacturing and non-manufacturing areas in all major areas.	Outstanding		

30	Product Inspection	Calibration program is utilized for the identification and control of all inspection, measurement, and test equipment. (Typically this is an electronic system.)	Written procedures exist which address the control and calibration of inspection, measurement, and test equipment. Gauge control and calibration stickers are attached to inspection, measurement, and test equipment. All inspection, measurement, and test equipment is individually traceable throughout the system. All calibration masters are included as a part of the calibration system and are traceable to manufacturer`s recommendations. All certified documents are kept on file. Historical records are maintained indicating that inspection, measurement, and test equipment are recertified at regular intervals. Inspection, measurement, and test equipment are properly handled and stored to maintain calibration and fitness for use. All inspection, measurement, and test equipment are calibrated and up-to-date as to the correct revision level of product being manufactured. Records exist for recalibration of part-specific inspection, measurement, and test equipment following engineering changes.	Acceptable		

31	Product Inspection	Test methods and equipment have been validated for their use.	Validation is performed on all test methods and equipment. Validation is documented. Written validation procedures are available for all test methods and equipment. All products have been validated for the test method or equipment used. System in place to provide review and revalidation of test methods or equipment.	Improvement Needed		
32	Corrective Action	Does the company maintain a root cause corrective action system that provides for prompt identification and correction of conditions adverse to quality?	Written Corrective Action procedures are documented as part of the quality manual. Corrective Action reports address basic information for identification of problem. Written Corrective Action procedures address: l Analyzing data to determine root cause of non-conformance. l Documenting and reporting corrective action. Non-conformance reports (e.g. product quality, deviation, audit results, quality records, etc.) used to develop preventive actions. Supplier maintains a historical database for all Corrective Actions. Corrective Action procedures are reviewed regularly for continuous improvement.	Improvement Needed		
33	Corrective Action	Is follow-up action performed to verify the effectiveness of corrective action?	Written Corrective Action procedures address verification for effectiveness of corrective action. Effectiveness of Corrective Action is verified and documented. Effectiveness of Corrective Action is verified by routine audits of original problem.	Acceptable		

34	Corrective Action	Is there a system to notify customers when non-conforming product may have been inadvertently shipped?	Documented system in place with defined roles and responsibilities and is used consistently. Returned product from customer is analyzed and corrective actions initiated as appropriate. Documented system reviewed periodically for continuous improvement Records of inadvertent shipments of non-conforming product maintained in corrective action database.	System Deficient		
35	Corrective Action	Are customer or field complaints received, reviewed, and investigated?	Customer field complaints are addressed, recorded, and maintained in a corrective action database. Verification of customer satisfaction is recorded after corrective action has been implemented.	Improvement Needed		

36	Records	Are inspection and production records maintained in accordance with governmental regulations and/or company policy?	Quality records and related documentation are retained for a specified time period. There are documented record keeping rules. Quality records are legible and readily retrievable for a specified time. Centralized filing system (hardcopy or electronic) is maintained in an appropriate environment to prevent deterioration, damage or loss. Quality documentation is retained and easily accessible to verify achievement of required quality and effective operation of the quality system. Timely and periodic purging of the file system takes place to keep record keeping system up to date with current information.	Acceptable		
37	Records	Do inspection records include the following?	Inspection records are consistently maintained, Procedures and work instructions detailing inspection record requirements are available. Appropriate review and sign-off is noted on the inspection records. Inspection records include the following: l Item (Stock Keeping Unit). l Date of inspection. l Acceptance criteria. l Characteristic measured. l Number and description of non-conformities found. l Disposition of inspected material. l Reference of action taken on non-conformities (Corrective Action). l Reference to DMDO.	Improvement Needed		

38	Records	Is there a system in effect to assure that inspection and production records are reviewed?	Records are reviewed on a schedule as defined in a procedure or work instruction. Records are reviewed for the purpose of the following: l Process refinement/improvement l Testing reduction for the purpose of manpower efficiencies and cost reduction.	System Deficient		
39	Personnel Training	Have procedures been established and used for identifying training needs?	Training procedures exist for training all levels of the organization, including hourly, technical, and management staff, in quality philosophies and techniques. Training procedures cover all of the following: l Part-time and temporary employees. l Language of employees. l Safety. l Equipment. l Procedures/Work Instructions. l Workmanship Standards. l GMP`S and GLP`S. Training procedures address future training requirements, retraining, and refresher training. Training effectiveness is periodically evaluated. Annual reviews of training procedures and requirements are performed. Annual training plans are addressed in budget requirements.	Outstanding		

40	Personnel Training	Are qualification and training records maintained for all personnel?	Qualification and training records are maintained for all personnel and include all of the following: l Type of training-equipment, method, procedure, or subject. l Date of training. l Results of training. l Date of refresher training, if required. Training records and results are used as management reviews to assure that training requirements are met.	Improvement Needed		
41	Plants and Grounds	Does the supplier practice good housekeeping?	The following good housekeeping points are practiced: l Facilities are clean with no trash around. l Food is not allowed outside the cafeteria or breakroom. l Bathrooms contain soap for washing and paper towels or blowers for drying hands. l Clean toilet facilities, which are readily accessible, in good sanitary and repair conditions, with self-closing doors that do not open into areas where materials are exposed to airborne contamination. l Equipment is stored properly after cleaning. l Proper apparel is worn for the technology. (eg...Hair nets, beard covers, gowns, aprons, gloves.) l Wastes are disposed of properly and in a timely manner.	Acceptable		

42	Plants and Grounds	Are lighting and utilities sufficient to perform the required operations?	Acceptable lighting is found in all areas: Electrical supply is sufficient to handle production requirements. Where applicable, backflow connections for process water. Where applicable, potable water supplied at adequate temperature and pressure, which meets EPA 40 CFR part 141 (city water report). Back-up generators are installed to handle power outages.	Acceptable		
43	Plants and Grounds	Is the working environment safe?	Production guards and lockout devices are in place and functioning. Safety glass/equipment used as appropriate. Flammable materials stored in XP room. Safety procedures are fully developed. Fire alarm system is place. Exit doors are clearly marked and lock from the inside. OSHA reports are all acceptable or issues have been resolved. No environmental pollution potential.	Acceptable		
44	Customer Service	Is there evidence of a Customer Service System?	Quality issues are communicated through the supplier`s designated Quality Assurance contact. Supplier contacts are provided across functional lines for Purchasing, Quality Assurance, R&D, and Planning.	Outstanding		
45	Customer Service	Is there a process for requesting samples or information?	The supplier can provide samples and the following information: l Certificates l Test Results l Delivery Status l Purchase Order Status l MSDS information	Acceptable		

46	Quality Management System	Has the organization established and maintained a quality management unit within the overall company?	Organizational chart exists which reflects the current reporting structure. Evidence exists which indicate organizational freedom to exercise authority and responsibility. Job descriptions include responsibilities for supporting quality objectives. There is a management representative with defined authority and responsibility for meeting customer compliance. Qualified technical personnel available for design, process, product, and service support. Quality manual has been developed which details the quality system of policies and procedures. Procedures identify: Who is responsible for action l What has to be done l When the actions are required Responsibility for updating and revising the quality manual and system is defined. Quality manual is supported by top management. Written procedures and instruction define the methods for performing work affecting quality for those: l Managing the work l Performing the work l Verifying the work	Improvement Needed		

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66	Inventory Management	Is there a system to monitor, finalize, disposition, and follow-through on distressed material?	QA leads the disposition of rejected material and has final sign-off on any material release. There is formal Material Review Board that routinely meets to make disposition on non-conforming material. There are written procedures that detail supplier notification/corrective action on rejected material. Full records are maintained detailing the initial rejection through to the final disposition of the material.	Outstanding		
67	Process Control	Processes are documented and quality procedures have been developed and implemented within manufacturing operations.	Documented process and quality instruction procedures, including applicable standards, are located at work stations and reflect current practices. Sampling plans are utilized as a part of the quality inspection plan. Quality inspection sampling plans utilize acceptance criteria targeted at zero defects. All instruction procedures are controlled documents and are signed off by appropriate personnel. A formal procedure exists, which details the responsibility for procedure development and approval processes. All written instruction procedures are routinely reviewed for application of processing methods and accuracy of quality requirements.	Outstanding		

68	Process Control	There are procedures for controlling manufacturing process changes.	Manufacturing process changes are documented on all key operations. Process change procedure breaks responsibility down to affected department responsibility level. Process F.M.E.A.`s (Failure Mode & Effects Analysis) are reviewed and updated for changes made to key operations. Evaluation studies for quality specifications are required on process changes made to key operations. All process changes are documented, reviewed, and approved by appropriate personnel before change is made. All manufacturing process changes are promptly communicated to customer. New processes are not implemented without customer knowledge and approval.	Acceptable		

69	Process Control	Control plans are developed which detail quality planning activities required to ensure conformance to quality requirements.	Supplier control plans satisfy customer driven quality requirements. Control plans have been developed on all customer material. Process instruction procedures agree with control plan. Control plans are controlled documents. Authority to stop the manufacturing process in the case of non-conforming product is defined. Control plans are actively used throughout all operations and have been developed on 100% of key process operations. Supplier utilizes control plan for quality planning activities on new and change processes. Control plans are routinely reviewed for effectiveness and updated as required.	Acceptable		
70	Process Control	In-process quality expected to be achieved through superior process controls.	Consistently meets/exceeds quality goal. Deficient processes are immediately identified and actions implemented for improvement. Quality goals are regularly reviewed and supported by top management. Annual quality goals are revised by top management. SPC is used for in-process inspection.	No System		yrcjicvy

71	Process Control	Manufacturing quality systems achieved through Total Quality Control philosophies.	Uses SPC or other effective processes to control manufacturing processes. Proactively implements effective quality and reliability programs. Operates under total quality control principles, including validation. All processes documented. Supplier evaluates equipment for capability.	Acceptable		
72	Process Control	A preventive maintenance program has been documented and implemented.	Plant wide preventive maintenance program is in place and operational. Preventive maintenance "procedures" are available which were supplied from the original equipment manufacturer or have been developed if not available Complete preventive maintenance and repair records are readily available for all process equipment. Records indicate that high wear parts, for critical processes, are kept in stock. Preventive maintenance program is reviewed on a routine basis and includes the effects of process changes. Where necessary, preventive maintenance is concluded with a process capability study to verify conformance. Preventive maintenance program is structured and performed based on time requirements.	Acceptable		

73	Product Inspection	Inspections and tests are performed at appropriate points throughout manufacturing operations.	Inspection coverage is available on all operating shifts. Quality Assurance has the prime responsibility for evaluating production material. If manufacturing is responsible for quality within the manufacturing operations, Quality Assurance has the prime responsibility for auditing quality system conformance. Process flow diagrams are available which show necessary quality checkpoints. Procedures are written for re-inspection and testing of defective material. Sampling and retain plans are written and consistently followed. Inspection/test plans are periodically reviewed for effectiveness. Statistical sampling methods are used to perform final product audits. Statistical process control is the prime tool used for controlling manufacturing operations. Continuous reduction in process variation is pursued actively by manufacturing personnel. Written procedures exist for the prompt retrieval of nonconforming material found during manufacturing.	Outstanding		

74	Product Inspection	Quality and reliability expectations are for defect-free materials/products.	No quality or reliability problems exist. Exceptional quality and reliability goals are established for all areas to ensure defect-free materials. Management reviews are held on products/processes for manufacturing and non-manufacturing areas in all major areas.	Outstanding		

75	Product Inspection	Calibration program is utilized for the identification and control of all inspection, measurement, and test equipment. (Typically this is an electronic system.)	Written procedures exist which address the control and calibration of inspection, measurement, and test equipment. Gauge control and calibration stickers are attached to inspection, measurement, and test equipment. All inspection, measurement, and test equipment is individually traceable throughout the system. All calibration masters are included as a part of the calibration system and are traceable to manufacturer`s recommendations. All certified documents are kept on file. Historical records are maintained indicating that inspection, measurement, and test equipment are recertified at regular intervals. Inspection, measurement, and test equipment are properly handled and stored to maintain calibration and fitness for use. All inspection, measurement, and test equipment are calibrated and up-to-date as to the correct revision level of product being manufactured. Records exist for recalibration of part-specific inspection, measurement, and test equipment following engineering changes.	Acceptable		

76	Product Inspection	Test methods and equipment have been validated for their use.	Validation is performed on all test methods and equipment. Validation is documented. Written validation procedures are available for all test methods and equipment. All products have been validated for the test method or equipment used. System in place to provide review and revalidation of test methods or equipment.	Improvement Needed		
77	Corrective Action	Does the company maintain a root cause corrective action system that provides for prompt identification and correction of conditions adverse to quality?	Written Corrective Action procedures are documented as part of the quality manual. Corrective Action reports address basic information for identification of problem. Written Corrective Action procedures address: l Analyzing data to determine root cause of non-conformance. l Documenting and reporting corrective action. Non-conformance reports (e.g. product quality, deviation, audit results, quality records, etc.) used to develop preventive actions. Supplier maintains a historical database for all Corrective Actions. Corrective Action procedures are reviewed regularly for continuous improvement.	Improvement Needed		
78	Corrective Action	Is follow-up action performed to verify the effectiveness of corrective action?	Written Corrective Action procedures address verification for effectiveness of corrective action. Effectiveness of Corrective Action is verified and documented. Effectiveness of Corrective Action is verified by routine audits of original problem.	Acceptable		

79	Corrective Action	Is there a system to notify customers when non-conforming product may have been inadvertently shipped?	Documented system in place with defined roles and responsibilities and is used consistently. Returned product from customer is analyzed and corrective actions initiated as appropriate. Documented system reviewed periodically for continuous improvement Records of inadvertent shipments of non-conforming product maintained in corrective action database.	System Deficient		
80	Corrective Action	Are customer or field complaints received, reviewed, and investigated?	Customer field complaints are addressed, recorded, and maintained in a corrective action database. Verification of customer satisfaction is recorded after corrective action has been implemented.	Improvement Needed		

81	Records	Are inspection and production records maintained in accordance with governmental regulations and/or company policy?	Quality records and related documentation are retained for a specified time period. There are documented record keeping rules. Quality records are legible and readily retrievable for a specified time. Centralized filing system (hardcopy or electronic) is maintained in an appropriate environment to prevent deterioration, damage or loss. Quality documentation is retained and easily accessible to verify achievement of required quality and effective operation of the quality system. Timely and periodic purging of the file system takes place to keep record keeping system up to date with current information.	Acceptable		
82	Records	Do inspection records include the following?	Inspection records are consistently maintained, Procedures and work instructions detailing inspection record requirements are available. Appropriate review and sign-off is noted on the inspection records. Inspection records include the following: l Item (Stock Keeping Unit). l Date of inspection. l Acceptance criteria. l Characteristic measured. l Number and description of non-conformities found. l Disposition of inspected material. l Reference of action taken on non-conformities (Corrective Action). l Reference to DMDO.	Improvement Needed		

83	Records	Is there a system in effect to assure that inspection and production records are reviewed?	Records are reviewed on a schedule as defined in a procedure or work instruction. Records are reviewed for the purpose of the following: l Process refinement/improvement l Testing reduction for the purpose of manpower efficiencies and cost reduction.	System Deficient		
84	Personnel Training	Have procedures been established and used for identifying training needs?	Training procedures exist for training all levels of the organization, including hourly, technical, and management staff, in quality philosophies and techniques. Training procedures cover all of the following: l Part-time and temporary employees. l Language of employees. l Safety. l Equipment. l Procedures/Work Instructions. l Workmanship Standards. l GMP`S and GLP`S. Training procedures address future training requirements, retraining, and refresher training. Training effectiveness is periodically evaluated. Annual reviews of training procedures and requirements are performed. Annual training plans are addressed in budget requirements.	Outstanding		

85	Personnel Training	Are qualification and training records maintained for all personnel?	Qualification and training records are maintained for all personnel and include all of the following: l Type of training-equipment, method, procedure, or subject. l Date of training. l Results of training. l Date of refresher training, if required. Training records and results are used as management reviews to assure that training requirements are met.	Improvement Needed		
86	Plants and Grounds	Does the supplier practice good housekeeping?	The following good housekeeping points are practiced: l Facilities are clean with no trash around. l Food is not allowed outside the cafeteria or breakroom. l Bathrooms contain soap for washing and paper towels or blowers for drying hands. l Clean toilet facilities, which are readily accessible, in good sanitary and repair conditions, with self-closing doors that do not open into areas where materials are exposed to airborne contamination. l Equipment is stored properly after cleaning. l Proper apparel is worn for the technology. (eg...Hair nets, beard covers, gowns, aprons, gloves.) l Wastes are disposed of properly and in a timely manner.	Acceptable		

87	Plants and Grounds	Are lighting and utilities sufficient to perform the required operations?	Acceptable lighting is found in all areas: Electrical supply is sufficient to handle production requirements. Where applicable, backflow connections for process water. Where applicable, potable water supplied at adequate temperature and pressure, which meets EPA 40 CFR part 141 (city water report). Back-up generators are installed to handle power outages.	Acceptable		
88	Plants and Grounds	Is the working environment safe?	Production guards and lockout devices are in place and functioning. Safety glass/equipment used as appropriate. Flammable materials stored in XP room. Safety procedures are fully developed. Fire alarm system is place. Exit doors are clearly marked and lock from the inside. OSHA reports are all acceptable or issues have been resolved. No environmental pollution potential.	Acceptable		
89	Customer Service	Is there evidence of a Customer Service System?	Quality issues are communicated through the supplier`s designated Quality Assurance contact. Supplier contacts are provided across functional lines for Purchasing, Quality Assurance, R&D, and Planning.	Outstanding		
90	Customer Service	Is there a process for requesting samples or information?	The supplier can provide samples and the following information: l Certificates l Test Results l Delivery Status l Purchase Order Status l MSDS information	Acceptable		