Shotwell Hydrogenics

10001 W. I-20 Suite F-3 Midland, Texas, United States, 79760

C0385215

Audit Type
REGISTRATION

Lead Auditor
Richard Whittington

Registration
ISO 9001:2015

Recommendation
Registration: Recommended; NO CARS

Executive Summary	
	The facility enjoys excellent customer satisfaction rates. Management is visible throughout the facility and personnel are professional in their approach to their assigned duties. Equipment is well maintained and safety is an emphasis items. The IT systems are supportive and stable.

Opportunities	
	The facility is clean, well lighted, and the production flow is logical. Support equipment and systems are robust and interviewed personnel were knowledgeable of their contribution to the satisfying of customer requirements.

Process	
Processes	**Observations**
7: Processes or Activities-01-Company Context, Leadership & Planning	**What is the Objective of the process? Support whether the process is effective or not in meeting its objective(s). Include the performance data you reviewed to verify effectiveness, e.g. on-time delivery, scrap rates, inspection data, internal audit results, etc. Also, list the records that you reviewed during the audit of this process, e.g. procedures and/or work instructions, personnel interviewed, training, quality policy, calibration, responsibility and authority, etc, as applicable.** Company Context, Leadership & Planning The objectives of the processes are for Leadership to achieve policy commitments and take actions to address risks and improve performance. Additionally, Leadership is committed to a productive, safe and healthy working environment, enabling effective risk management, encouraging proactive environmental efforts, assuring conformity of goods and services, conforming to customer requirements and meeting industry and international standards, where required. The processes are effective. Reviewed IMS-MN-01 – Shotwell Integrated Management System Manual – Rev 2 – 8 Aug 18. Discussed Company Context, Leadership & Planning with Michael Puckett. Shotwell Hydrogenics is a standalone company within the BPS Jet family of companies, blending, storage, handling and shipping of chemicals in support of the oil industry. The organizational is influenced by employees internally, and external customers, regulatory agencies, competition and marketing affect the organization. The organization's internal structure includes Production, QA, Receiving, Shipping, Purchasing, and Training. The organization's operational flow is graphically diagrammed in the Integrated Management System Manual, and the Quality Policy is compliant with the ISO 9001:2015 Standard's requirement. The organization has been in business since 2017 and is housed in a 21,000 square foot production facility. The organization employs six personnel in a non-union environment. The organizational Performance Measurements are listed in their specific category. The processes are compliant with the Standard and there were no discrepancies noted.
7: Processes or Activities-02-Resources & Environment	**What is the Objective of the process? Support whether the process is effective or not in meeting its objective(s). Include the performance data you reviewed to verify effectiveness, e.g. on-time delivery, scrap rates, inspection data, internal audit results, etc. Also, list the records that you reviewed during the audit of this process, e.g. procedures**

	and/or work instructions, personnel interviewed, training, quality policy, calibration, responsibility and authority, etc, as applicable. Resources & Environment The objectives of the processes are to recruit, select and train personnel for administrative or production requirements within the organization. Additionally, the training must be monitored for the duration of tenure. The processes are effective. Reviewed SH&E-3.1-002 – Training Procedure – Rev 1 – 17 May 17 and PRD-4.2.001 – On-The-Job Training Procedure – Rev 1 – 1 Feb 18. Discussed Training processes and procedures with Michael Puckett and Tawney Randell Personnel hiring processes are contracted to an outside agency. Upon selection, drug and background checks are performed. After selection, Initial Orientation and Job Training are performed by the organization and Training Records are maintained digitally and hardcopy. Recurring Safety Training requirements are tracked on a spreadsheet and accomplished internally. Reviewed the Training Records for Caswell, Dipetta, and Pipes. Records are concise, well organized, and on line. The Training Program is electronic and tracks extensive requirements for all employees, including the requirement for training on changed documents. Average age of the workforce is 35, and the average tenure is 1 year. The production environment is a non-union workforce with a non-existent turnover rate. Discussed the IT setup. The IT system is supportive of the QMS and the servicing effort. Training Performance Measurements are: Job Competency Rating Goal 100% Qualified – Attained, Initial Training Completion Goal NTE 7 Days - Attained. The processes are compliant with the Standard and there were no discrepancies noted.
7: Processes or Activities-03-Documentation	**What is the Objective of the process? Support whether the process is effective or not in meeting its objective(s). Include the performance data you reviewed to verify effectiveness, e.g. on-time delivery, scrap rates, inspection data, internal audit results, etc. Also, list the records that you reviewed during the audit of this process, e.g. procedures and/or work instructions, personnel interviewed, training, quality policy, calibration, responsibility and authority, etc, as applicable.** Documentation The objectives of the processes are to control creating, approving, disseminating, reviewing, updating, and deleting QMS documentation, and to provide for records processes for proof of conformity. The processes are effective. Reviewed SP-12.1-001 – Document Control Procedure - Rev 1 – 8 Feb 18, SP 12-

	1.002 – Document Control Procedure Template – Rev 1 – 8 Feb 18, SP-12.01.003 – Document Control Procedure Policy Template – Rev 1 – 8 Feb 18, QM-12.2.001 – Document Retention Procedure – Rev 2 – 15 Jun 18, and SH&E-10.1.001 – Management of Change – Rev 1 – 13 Feb 18. Discussed Documentation processes and procedures with Michael Puckett. The QMS is digitally on line and protected by password. A Master index is on an Excel Spreadsheet and easily navigated. A corresponding Forms Spreadsheet is also available for use and tracking of versions. The Management of Change Procedure controls updates and changes, and the Document Retention Procedure delineates hold times for all documentation and records. Records are primarily digital and the responsibility of the generating manager. The QMS documentation system is well organized, easily navigated and supportive of the Standard. Documentation Performance Measures are: Documentation Change Processing GOAL NTE 3 Days – Attained The processes are compliant with the Standard and there were no discrepancies noted.
7: Processes or Activities-04-Contract Review & Operations Planning	**What is the Objective of the process? Support whether the process is effective or not in meeting its objective(s). Include the performance data you reviewed to verify effectiveness, e.g. on-time delivery, scrap rates, inspection data, internal audit results, etc. Also, list the records that you reviewed during the audit of this process, e.g. procedures and/or work instructions, personnel interviewed, training, quality policy, calibration, responsibility and authority, etc, as applicable.** Contract Review & Operations Planning The objectives of the processes are to receive customer requests, quote work, receive Purchase Orders, enter the data into QuickBooks. The processes are effective. Reviewed QM-7.1.001 – Product Introduction Process – Rev 1 – 11 Sep 18, SP-7.3.001 – Production Scheduling – Rev 1 – 25 May 18, SP-9.2001 – Estimates Procedure – Rev 1 – 9 Aug 18. Discussed Contract Review and Operational Planning with Nik Dipetta. Customers email requirements for production. These are coordinated internally for capability, risk, timing, etc., and quotes returned. After acceptance of the quote, the customers forward a Purchase Order authorizing the work. The received Purchase Order is entered in QuickBooks and the production requirement is forwarded to the Control Room for Action. Reviewed Requests for Quote 15 Aug 18 for 2 products - 110 gallons each to be delivered by 20 Aug 18. This request became Purchase Order 1146 and was worked

	beginning on 15 Aug 18. The product shipped on 16 Aug 18. Reviewed Requests for Quote (phone) on 11 Sep 18 for 2 Totes – 660 gallons to be picked up by customer. The Purchase Order was 011013 received on 11 Sep 18. This item was in stock and shipped 11 Sep 18. Customer Orders are forwarded to the Control Room for production daily. Contract / Planning Performance Measures are: Quote Return Goal NTE 24 Hrs. – Attained P/O input to Control Room Notification NTE 24 Hrs. - Attained The processes are compliant with the Standard and there were no discrepancies noted.
7: Processes or Activities-05-Purchasing & Suppliers	**What is the Objective of the process? Support whether the process is effective or not in meeting its objective(s). Include the performance data you reviewed to verify effectiveness, e.g. on-time delivery, scrap rates, inspection data, internal audit results, etc. Also, list the records that you reviewed during the audit of this process, e.g. procedures and/or work instructions, personnel interviewed, training, quality policy, calibration, responsibility and authority, etc, as applicable.** Purchasing & Suppliers The objectives of the processes are to procure raw material for production, and to qualify and monitor Suppliers. The processes are effective. Reviewed IMS-MN-01 – Shotwell Integrated Management System Manual – Rev 2 – 8 Aug 18, PRD-6.1.001 – Supplier Scorecard Procedure – Rev 1 – 25 Apr 18, PRD-6.1.002 – Raw Material Handling and Material Control – Rev 1 – 4 Jun 18, and SP-6.1-003 – Purchase Requisition Procedure – Rev 1 – 6 Nov 17. Discussed Purchasing processes and procedures with Tawney Randell, Nik Dipetta and Ben Caswell. Reviewed Purchase Requisition 19 Jul 18 which became Purchase Order 1206. This was a blanket Purchase Order for raw material. Quality requirements were on the Purchase Order and the raw material arrived on 6 Sep 18. The material was accompanied by a Bill of Lading and Certificate of Analysis for Lot #86777. After receiving the material, QA tested the material and passed it on 6 Sep 18. The Orion A-216 was used as well as the STIR Comparator. Checked Calibration on Density Meter 82480103 – Self Calibrating – with Factory Documentation. Reviewed Purchase Request 1222 on 10 Sep 18 for Warranty Extension. There are less than 10 suppliers in the database and one sole source. The longest lead time for material/components is 6 weeks. Purchasing Performance Measures are: Initial Request to P/O Goal – 3 Days – Attained.

	The processes are compliant with the Standard and there were no discrepancies noted.
7: Processes or Activities-06-Product Realization, ID, Traceability & N/C	**What is the Objective of the process? Support whether the process is effective or not in meeting its objective(s). Include the performance data you reviewed to verify effectiveness, e.g. on-time delivery, scrap rates, inspection data, internal audit results, etc. Also, list the records that you reviewed during the audit of this process, e.g. procedures and/or work instructions, personnel interviewed, training, quality policy, calibration, responsibility and authority, etc, as applicable.** Product Realization, ID, Traceability & N/C The objective of the process is to formulate product to customer specifications. The process is effective. Discussed production processes and procedures with Nik Dipetta, Michael Puckett, and Pipes. Reviewed SP-7.3.001 – Production Procedure – Rev 1 – 25 May 18, PRD-5.1.001 – Blending Procedure – Rev 1 – 15 Feb 18, PRD-5.1.003.4 – F-Mixer Blending Procedure – Rev 1 – 6 Feb 18, PRD-5.1.005 – Splash Blending Procedure – Rev 1 – 6 Feb 18, and PRD-5.1.006 – P-Mixer Blending Procedure – Rev 1 – 6 Feb 18. Production requirements are delivered daily to the Control Room and posted on the production board. Both on-going production for blanket Purchase Orders and non-blanket Purchase Orders are listed. The production operation blends multiple fluids into customer specifications as listed on the Purchase Order and recorded on the Batch Sheet. The Batch Sheet lists the raw material, batch #, Start and Stop Times, the target weight/volume and the actual weight/volume attained. Reviewed Batch Sheet for Product SHSFX-1000 – Batch SHO72718-2 – 27 Jul 18. The Kahler System controls the mixing and also generates control data which is attached to the Batch Sheet for Records purposes. All mixed product is tested prior to release by QA. Checked calibration on the Density Meter, Ph Meter, and the FTIR. The instruments are either "Self-Calibrating" or "Calibrate before use". Checked the calibration process for the "Calibrate Before Use", and documentation for the "Self-Calibrating" instruments. Production Performance Measures are: First Pass Yield Accuracy Goal 100% - Attained 98% The processes are compliant with the Standard and there were no discrepancies noted.
7: Processes or Activities-07-Shipping & Receiving	**What is the Objective of the process? Support whether the process is effective or not in meeting its objective(s). Include the performance data you reviewed to verify effectiveness, e.g. on-time delivery, scrap rates, inspection data, internal audit results, etc. Also, list the records that you reviewed during the audit of this process, e.g. procedures**

	and/or work instructions, personnel interviewed, training, quality policy, calibration, responsibility and authority, etc, as applicable. Shipping & Receiving The objectives of the processes are to receive customer material and components into the system and prepare and ship finished product as required by the customer. The processes are effective. Reviewed SP-7.3.002 – Shipping Procedure – Rev 1 – 11 Sep 18, and PRD-5.1.007 – Truck Loading/Unloading Procedure – Rev 1 – 8 Feb 18. Discussed Shipping and Receiving processes and procedure with Michael Puckett, Nik Dipetta and Ben Caswell. Product received and shipped range in quantity from 1 gallon to tanker lots. Received raw material and components are inspected for proper quantity, weight, and matching Lot Numbers. Samples are then taken to the laboratory and tested against the received COA and specification. If acceptable, Receiving enters the material into inventory. Reviewed B/L for load 272826060 received on 17 Aug 18 against P/O 1207 – Lot# 0814182 x 7 totes and 0814181 x 7 totes. Product to be shipped is an email notification to Shipping. Shipping will prepare the product for the size of the shipment. The customer may provide the transportation (upwards of 80% of product shipped). Shipping & Receiving Performance Measures are: Received Goods Entered into Inventory Goal NTE COB – Attained Shipping in Full on time Goal 100% - Attained The processes are compliant with the Standard and there were no discrepancies noted.
7: Processes or Activities-08-Internal Audits & CA/PA/IA	**What is the Objective of the process? Support whether the process is effective or not in meeting its objective(s). Include the performance data you reviewed to verify effectiveness, e.g. on-time delivery, scrap rates, inspection data, internal audit results, etc. Also, list the records that you reviewed during the audit of this process, e.g. procedures and/or work instructions, personnel interviewed, training, quality policy, calibration, responsibility and authority, etc, as applicable.** Internal Audits & CA / PA / IA The objectives of the processes are to verify that the procedures established by the QMS are being followed, and to highlight deviations from established work processes. Additionally, the processes provide a method of formally addressing error correction. The processes are effective. Reviewed QM-14.001 – Internal Audit Procedure – Rev 1 – 22 May 18. SP-11.001

	- Procedural Non-Conformance – Rev 1 - 9 Feb 18 Discussed Internal Audits and Corrective / Preventive / Improvement processes and procedures with Michael Puckett. Reviewed the current Audit Schedule and audits accomplished for the ISO 9001:2015 registration audit. Reviewed the 5 Jul 18 Audit Report. There were 5 findings during that audit – all closed. Audits are performed by an outside Auditor. A full system audit is required annually, with specific tasks audits required as deemed necessary. The organization uses the "5 Whys" for analysis and resolution of error. Findings are tracked to closure using the Audit Checklist, which provides space for such tracking. There have been 5 Improvement / Preventive Actions YTD. Internal Audit Performance Measures are: Audit Accomplished to Schedule Goal 100% - Attained. Repeat CAR Findings Goal 0 – Attained The processes are compliant with the Standard and there were no discrepancies noted.
7: Processes or Activities-09-Management Review & Customer Satisfaction	**What is the Objective of the process? Support whether the process is effective or not in meeting its objective(s). Include the performance data you reviewed to verify effectiveness, e.g. on-time delivery, scrap rates, inspection data, internal audit results, etc. Also, list the records that you reviewed during the audit of this process, e.g. procedures and/or work instructions, personnel interviewed, training, quality policy, calibration, responsibility and authority, etc, as applicable.** Management Review & Customer Satisfaction The objectives of the processes are to review the results of operations under the control of the Quality Management System to verify the QMS's ability to control operations as designed. Additionally, the Management Review looks at customer data to see how improvements can be made in satisfaction of requirements. The processes are effective. Reviewed IMS-MN-01 – Shotwell Integrated Management System Manual – Rev 2 – 8 Aug 18. Discussed the Management Review and performance of the organization with Michael Puckett. The ISO 9001:2015 required subjects were included in the Review and objectives established for the next cycle. Customer Satisfaction is very good and all other measurables are stable or trending improvement. There were no internal or external issues relevant to the QMS. The cycle's internal

	audits resulted in 5 findings. Those are all closed. The Quality Policy was reviewed for suitability and applicability – still current. Process performance was discussed, and procedural issues to document process risk was assigned as an action item. New objectives were established in the areas of Key Performance Measures. There were 5 Improvement Opportunities, and all are closed. Analysis of data indicates all goals have been achieved during this cycle. Supplier performance is stable. The upcoming installation of SharePoint will greatly aid in internal communication and data tracking. Performance Measures are: First Pass Yield Accuracy Goal 100% - Attained 98% Down Time Goal NTE 1% – Attained 0 The processes are compliant with the Standard and there were no discrepancies noted.