

**TCB  
Audit  
Services**

QUALITY AND INTEGRITY

# Management Systems Assessment Report

for

Heubach Corporation

TCB Number 21003

ISO 9001:2015

Quality Management Systems-Requirements

Prepared by: Eric Hinson  
Date: May 2, 2022

**TCB Audit Services, LLC**

Website: [www.tcbaudits.com](http://www.tcbaudits.com)

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*Disclaimer: It is important to note that auditing is a sampling operation and not every activity or record in your management system will be reviewed; therefore, deficiencies may exist that have not been identified by the audit team. Certification does not absolve you from the responsibility of correcting deficiencies found by yourselves to ensure that compliance with the management system standard is fully maintained. This report should be read in coordination with the Assessment Plan and CAR summary and the audit plan.*

*This assessment report should be read in conjunction with the Assessment Plan & CAR Summary as both documents constitute the entire assessment report*

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## **1 Introduction**

The reporting format follows the selected management system standard elements, and findings are reported as appropriate. Activities that are not in compliance with your own documentation or the standard are reported as Corrective Action Requests (CARs) and are categorized as either Minor or Major.

Major CARs are of a serious nature and relate to the absence of, or the failure to implement and maintain one or more management system elements, or a situation which would, on the basis of available objective evidence, raise significant doubt as to the effectiveness of the management system. For certification assessments Major CARs must be closed out or downgraded to Minor before certification can proceed. For surveillance and recertification assessments all Major CARs must be closed or downgraded within three months.

Minor CARs are those which are not considered to have a serious impact on the effectiveness of the management system implemented by your company and normally relate to isolated non-complying activities. Minor CARs are required to be actioned within three months but formal close-out can be delayed until the next audit visit.

Many Corrective Action Requests can be closed-out by our review of revised documentation and therefore for Major Corrective Action Requests, you should submit copies of such documentation. If follow-up visits to site are required for close-out purposes, we will contact you to arrange a mutually convenient time.

In addition to CARs, the report may contain Observations and Opportunities for Improvement that relate to issues where, although compliance with the management system standard has been achieved, system improvements may be apparent.

TCB Audit Services assessors are assigned to conduct audits according to standards(s), technical competencies and industry expertise related to each client being audited. Each auditor is individually reviewed and if appropriate approved to ensure competence is maintained at all times. Details of such competency reviews are retained in our records as required by ISO 17021-1. All assessments are conducted in accordance with our operational procedures which meet all the applicable criteria, i.e., ISO 17021-1, ISO 19011, IAF MDs, and all other applicable criteria.

Please make sure that you advise us of any changes that may affect your certification or may assist us to keep your contact details or information up to date as required by the TCB Audit Services certification criteria document.

If you have any queries with regard to the contents of this report, please contact your Client Manager or your local office who will discuss the findings in more detail.

## ② Assessment summary

### 2.1 Assessment type

- |                            |                                     |
|----------------------------|-------------------------------------|
| Certification assessment   | <input checked="" type="checkbox"/> |
| Surveillance assessment    | <input type="checkbox"/>            |
| Recertification assessment | <input type="checkbox"/>            |

### 2.2 Assessment visit number

Assessment number 1.0

### 2.3 Assessment objectives

The objective of this assessment is to:

- evaluate the level of compliance with the organization's management system against the standard(s) detailed on the front page of this assessment report.
- determine the ability of the management system to ensure that the organization meets applicable statutory, regulatory and contractual requirements.
- evaluate the effectiveness of the management system to ensure the organization is continually meeting its specified objectives.
- identify areas of potential improvement within the management system.

The output of this assessment is recorded in this Assessment Report and the Assessment Plan and CAR Summary document which contain the recommendations of the assessment team.

### 2.4 Date(s) of assessment

May 2, 2022

### 2.5 Scope of assessment- Sites visited- Make note of any ICT audit activities.

IAF Code(s): 14

Fabrication and conversion of foam and other flexible materials.

2713 Industrial Lane, Garland, TX 75041

## 2.6 Changes

Have there been any changes to the following:

- |                                 |                              |  |
|---------------------------------|------------------------------|--|
| • The Management Representative | YES <input type="checkbox"/> | NO <input checked="" type="checkbox"/> |
| • The Scope of Certification    | YES <input type="checkbox"/> | NO <input checked="" type="checkbox"/> |
| • Address(es)                   | YES <input type="checkbox"/> | NO <input checked="" type="checkbox"/> |
| • Phone Number(s)               | YES <input type="checkbox"/> | NO <input checked="" type="checkbox"/> |
| • E-mail Address(es)            | YES <input type="checkbox"/> | NO <input checked="" type="checkbox"/> |

## 2.7 Assessment team

Team Leader: Eric Hinson

Other Auditor(s):

## 2.8 CAR summary

For details of all CARs and their history refer to the last page in the Assessment Plan & CAR summary that accompanies this Assessment Report.

Number of new major CARs raised 0

Number of new minor CARs raised 1

Number of CARs closed out at this assessment visit 0

Number of outstanding CARs (*from last assessment*) 0

Reason/s for CARs being left open from last assessment (*if applicable*): n/a

## 2.9 Planned date(s) and time(s) for next audit

Late April or early May 2023

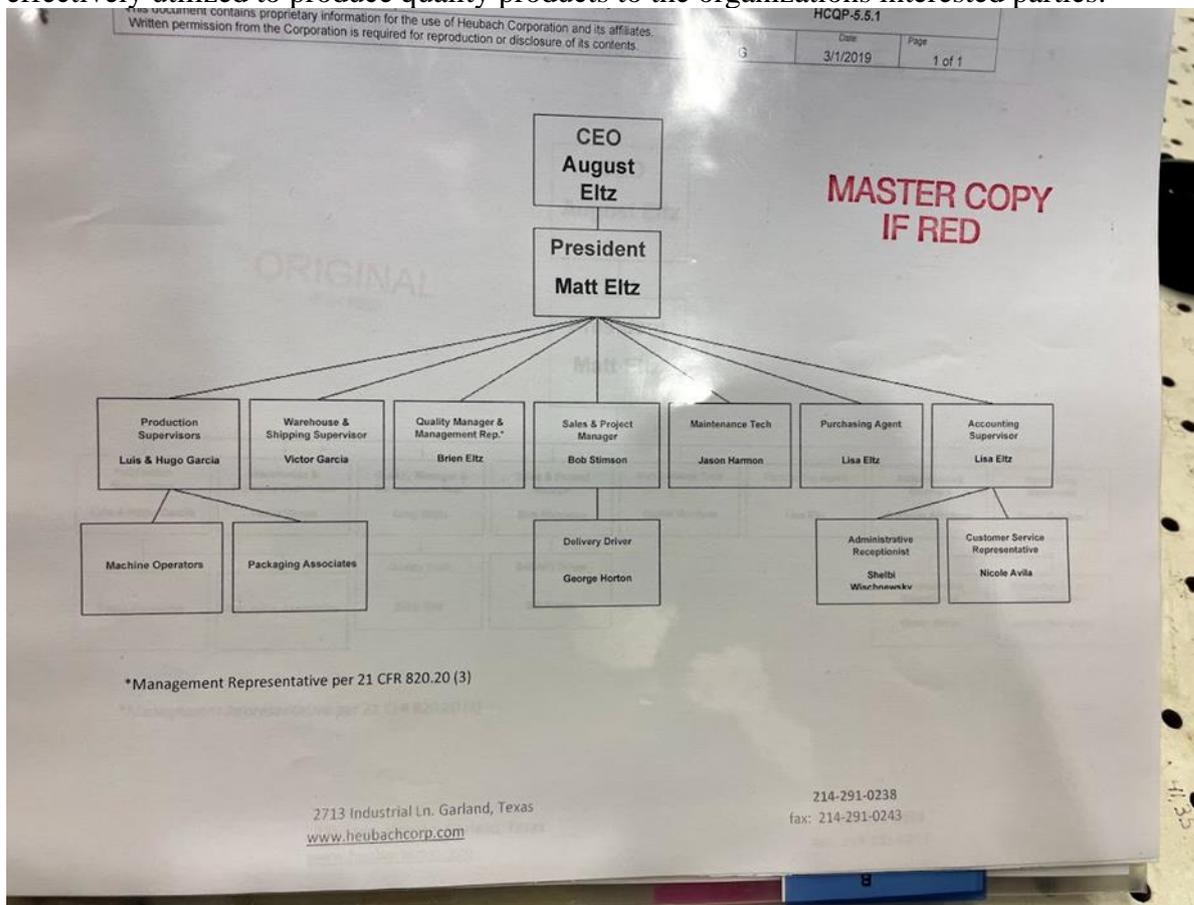
### ③ Compliance summary

The compliance summary is outlined in section 3 of the Assessment Plan & CAR Summary. This not only shows the assessment compliance details but also outlines the assessment plan for the whole three-year certification period.

### ④ Executive Summary

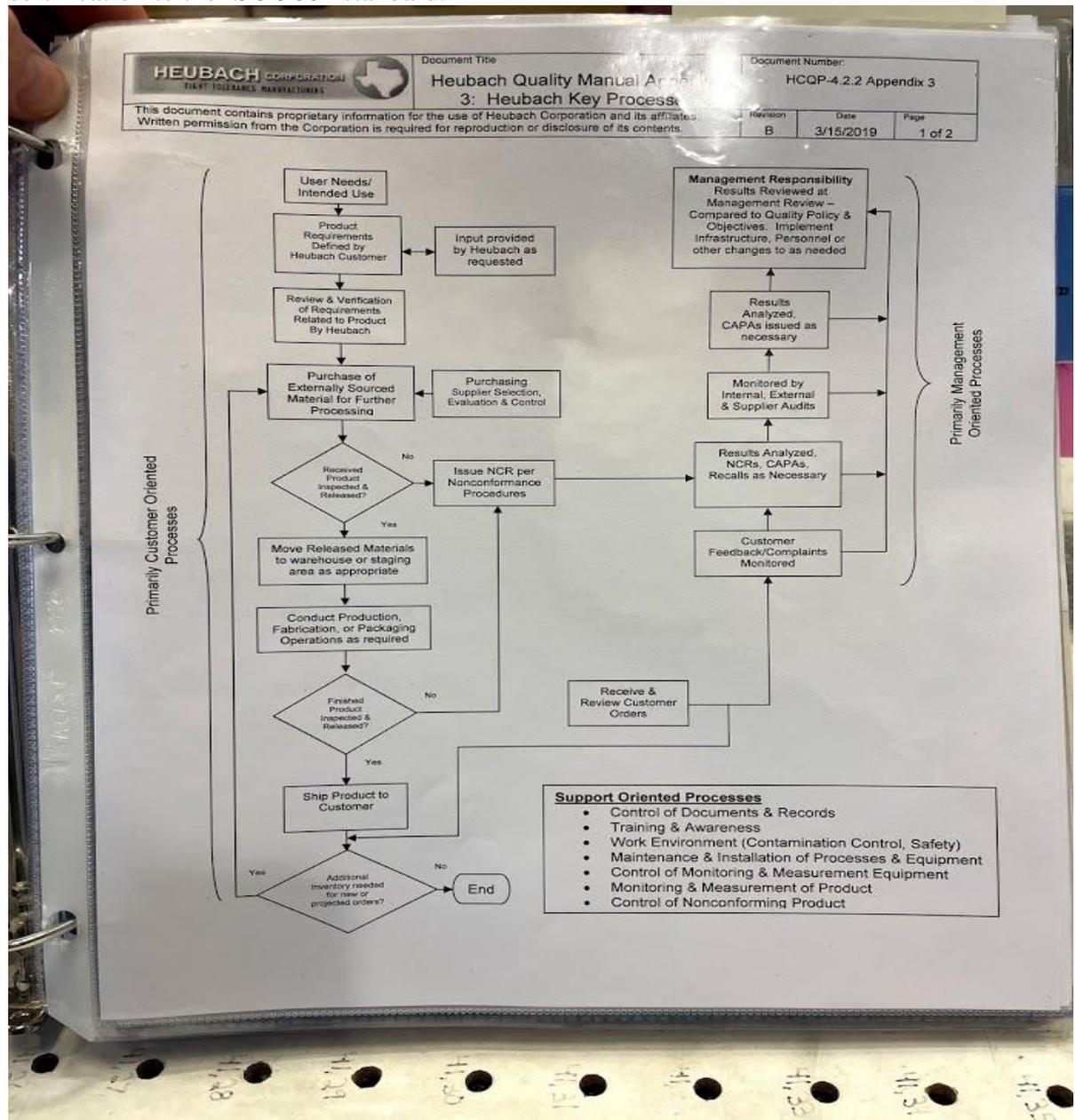
**4.1 Client overview detailing; changes in scope, contact details, processes, or general business changes. Ensure to make note if a remote audit is being conducted the ICT ways and means that this is carried out are mentioned.**

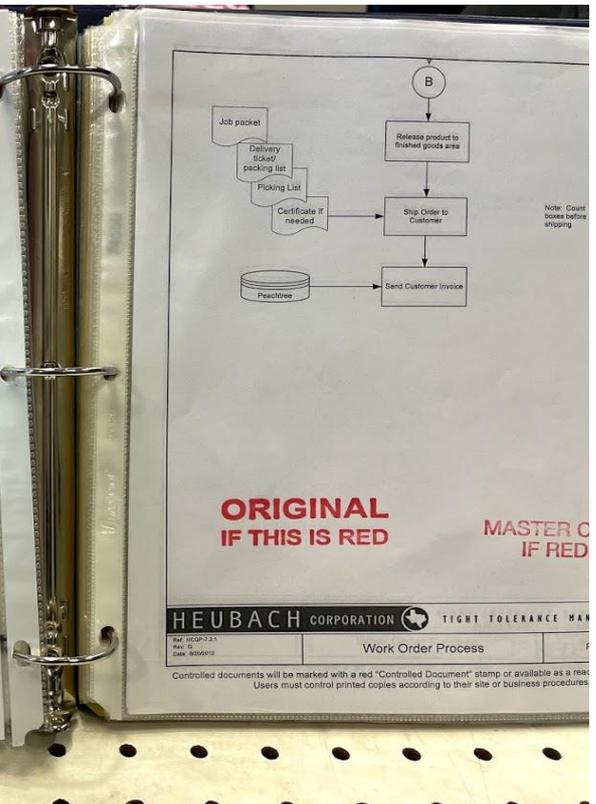
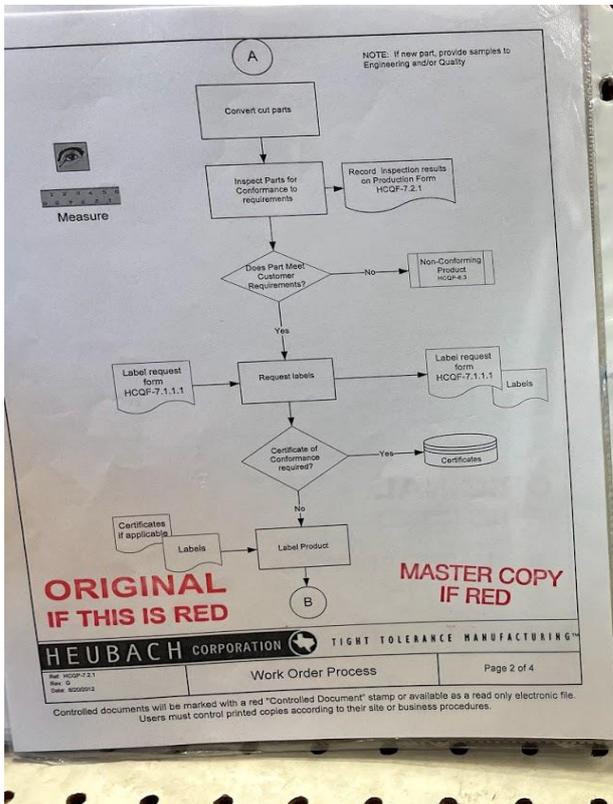
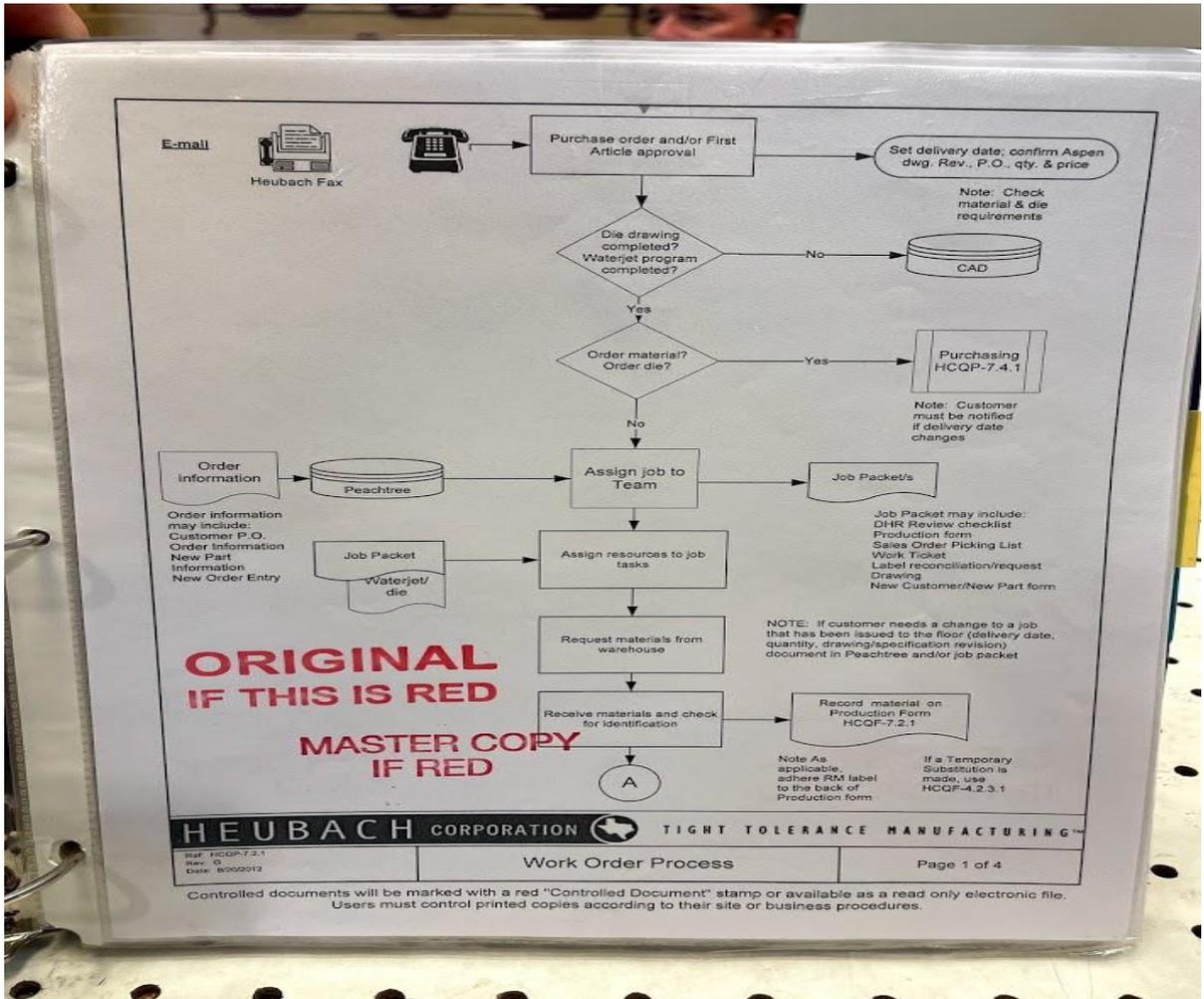
There were no significant issues impacting the audit program and the audit objectives have all been fulfilled appropriately. The scope was seen to be appropriate for the general business conducted by the organization and there were no changes as outlined in section 2.6 of this report. The processes remained the same as the last surveillance assessment with TCB which resulted in no corrective action and this assessment resulted in one minor corrective action. An organizational chart is utilized to outline management responsibilities and helps to determine who is responsible for what and who reports to whom. Top management was seen to be involved with the system processes, business decisions and with the ISO 9001:2015 certification as well as with management reviews, management of issues and OFI's, daily and weekly meetings and with continuous improvement. The QMS and its processes were reviewed in their entirety along with many procedures and policies which were seen to be effectively utilized to produce quality products to the organizations interested parties.



**4.2 Effectiveness of the management system and compliance to appropriate standard(s)**

The organization was seen to have maintained an effective management system and compliance to the ISO 9001:2015 standard. After discussions with the organization, a thorough facility tour and review of many items such as the QMS manual, management review meeting minutes, purchase orders, incoming and outgoing invoicing procedures, the CAPA log, the quality policy and objectives, continuous improvement items, and the process flow around the order completion processes it is apparent that the organization is aware of the requirements of the ISO 9001:2015 standard and that they have the necessary personnel in place to ensure that the QMS manual and the supplementing policies and procedures are being utilized to complete orders for their customers appropriately while continually improving their management system as a whole. Various process flowcharts were seen to be utilized and have been represented below. This recertification assessment resulted in one corrective action and the QMS has helped to maintain the foundation to assist the organization in maintaining certification to the ISO 9001 standard.





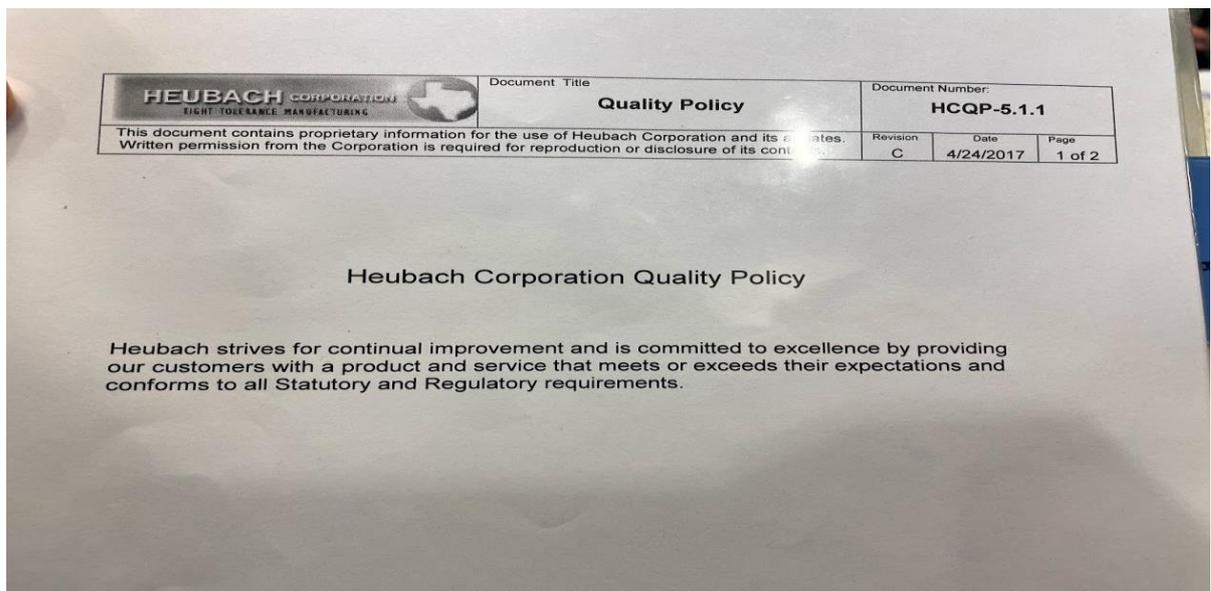
**4.3 Performance and awareness against stated policy and objectives**

The organization continues to monitor and track three quality objectives. These objectives are all ultimately based on customer satisfaction and maintaining ISO certification. The organization has selected proper and fitting objectives and continues to meet these as well. Below are the quality objectives as well as the quality policy statement for the organization. An observation or opportunity for improvement has been added to the end of this report as well

## Previous Quality Objectives

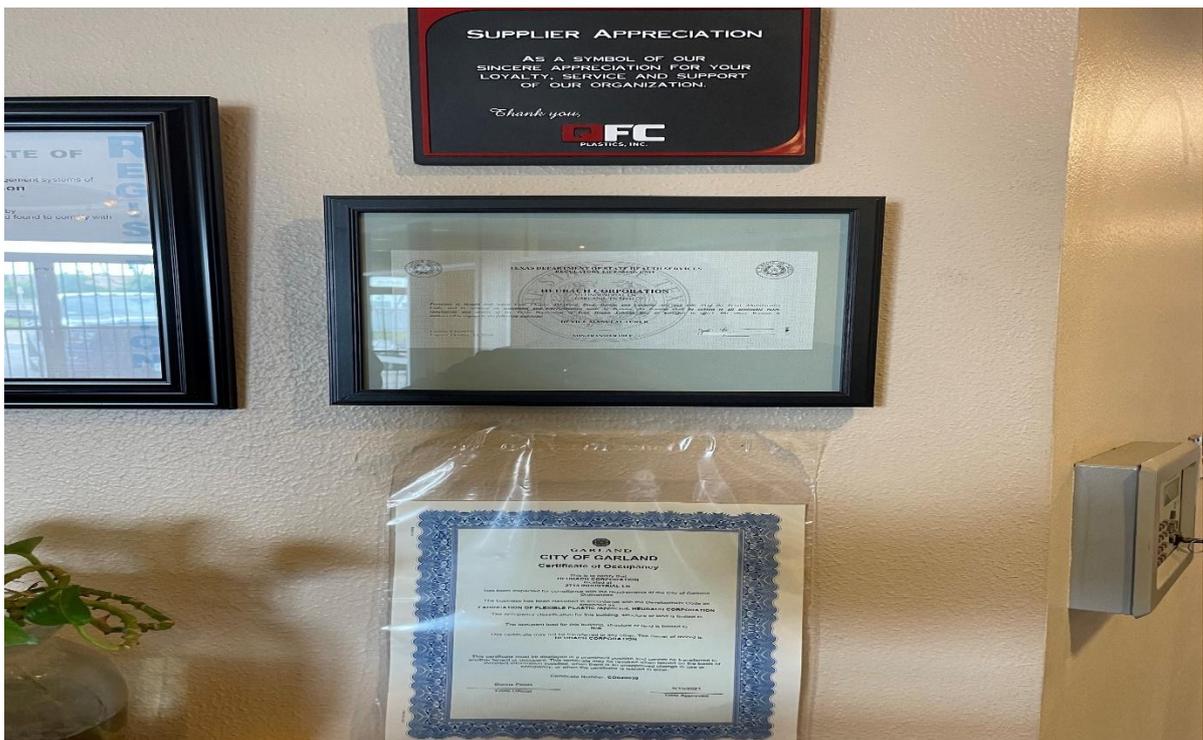
Objective	Target	Actual	Status
Provide high quality products	Less than 1 per \$100,000 sales	2 customer complaints since Jan 1, 2021 0.16/\$100,000	Meets Objective
Responsive customer service	Meets or exceeds 75% on time delivery	Not Determined but 75% or greater on time	Meets Objective*
Management system compliance	Maintain ISO 9001:2015 by 2Q 2022	ISO Certified	Meets Quality Objective**

\*Customer Satisfaction Survey provided positive feedback in Customer Service & Delivery  
\*\*ISO 9001:2015 Compliant



#### 4.4 Compliance to relevant legal/regulatory requirements

There have been no instances of legal or regulatory non-compliance identified by the organization at this time. The organization holds all the proper business licenses and occupancy permits to conduct its business in the city of Garland and in the state of Texas. The organization is compliant with OSHA and EEOC regulations, has proper business licenses, occupancy permits and workers compensation insurance. An annual inspection from the fire department is conducted and there are recycling programs in place. Overall, compliance to all relevant legal/regulatory bodies and/or agencies was seen to be effective for the organization.



#### 4.5 Effectiveness of operational controls

During this certification assessment the following operational controls and areas were reviewed as per the assessment plan and CAR summary; understanding the organization and context, need and expectations of the interested parties, determining the scope of the QMS, the QMS and its processes, leadership and commitment, establishing and communicating the quality policy, organizational roles and responsibilities, actions to address risks and opportunities, quality objectives review, planning of changes, resources, awareness, competence, communication, operational planning and control, requirements for products and or services, control of externally provided processes, products or services, production and service provision, release of products and services, control of non-conforming outputs, monitoring, measurement, analysis and evaluation, internal audits, management reviews, general improvement, nonconformity and corrective action, continual improvement, use of logo and certification marks and legal requirements.

The processes involved around the controls mentioned above were reviewed and discussed with the organization during this assessment visit with the leadership of the organization and during a facility tour. A process approach is utilized while the organization conducts its everyday business and risks are addressed during the quoting and proposal processes, vendor selection, risk assessments, during annual management meetings and at other meetings as well. The process workflow was seen to be followed appropriately and many examples of some of the steps within the process flowchart have been added to this section of the report. A PDCA cycle flow helps identify the interaction within the QMS and overall, the processes around the quoting, proposal processes, vendor selection, order fulfillment and review, and all customer related processes appear to work well for the organization and it could be seen that the organization follows these steps after discussions with top management and a review of the QMS procedures including the product workflow.

The work environment for the organization appears to be safe and no major miss time work related injuries have been reported.



The document retention table has been shown below.

HEUBACH CORPORATION TIGHT TOLERANCE MANUFACTURING		Document and / or Form Title <b>Control of Quality Records</b>	Document Number <b>HCQP-4.2.4</b>	
This document contains proprietary information for the use of Heubach Corporation and its affiliates. Written permission from the Corporation is required for reproduction or disclosure of its contents.			Revision D	Date 6/27/2011
			Page 4	4 of 4

Table 1

Record Description	Retention Time	Type	Disposition
Inspection Records	2 years	Paper	Shred
Production Records	2 years	Paper	Shred
Internal Audits	2 years	Paper & Electronic	Shred & Delete
Management Review Reports	2 years	Paper & Electronic	Shred & Delete
Purchase Orders	2 years	Paper & Electronic	Shred & Delete
Customer Complaints	2 years	Paper & Electronic	Shred & Delete
Corrective and Preventive Actions	2 years	Paper & Electronic	Shred & Delete
Supplier Records	7 years	Paper	Shred
Part Records	7 years	Paper	Shred
Non-conformance Reports	2 years	Paper & Electronic	Shred & Delete
Training Records	5 years	Paper & Electronic	Shred & Archive (electronic)
Quality Plans	7 years or as determined by the customer	Paper	Shred
Customer Property Records	4 years or as determined by the customer	Electronic	Delete

**ORIGINAL IF THIS IS RED**      **MASTER COPY IF RED**

The quality document reference table has been shown below.

HEUBACH CORPORATION TIGHT TOLERANCE MANUFACTURING		Document and / or Form Title <b>QUALITY DOCUMENT INDEX &amp; CROSS-REFERENCE</b>			Document and / or Form Number <b>DOCUMENT INDEX</b>	
This document contains proprietary information for the use of Heubach Corporation and its affiliates. Written permission from the Corporation is required for reproduction or disclosure of its contents.					Revision N/A	Date 4/22/2019
					Page 1	1

DOC #	DOCUMENT NAME	REV.	APPLICABLE ISO SECTION	APPLICABLE FDA QSR SECTION	TAB
HCQP-4.2.1	Emergency & Disaster Policy	A	7.1.4	\$820.70	A
HCQP-4.2.2	Quality Manual	F	4.4.1	\$820.5, \$820.20(e)	A
Appendix 1	Internal & External Issues of Strategic Importance	A	4.1	\$820.1	A
HCQP-4.2.2 Appendix 2	Interested Parties within the Context of the Organization	A	4.2	\$820.1	A
HCQP-4.2.2 Appendix 3	Interaction of Processes	B	4.4.1	\$820.5	A
HCQP-5.1.1	Quality Policy	C	5.2.1	\$820.20(a)	A
HCQP-5.4.1	Quality Objectives	E	6.2	\$820.20(a)	A
HCQP-5.5.1	Organization Chart	E	6.3	\$820.20(b)	A
HCQP-4.2.3	Document Control	F	7.5.3	\$820.40	B
HCQP-4.2.3.003	Good Documentation Practices	B	7.5.3	\$820.40	B
HCQP-4.2.4	Control of Quality Records	D	7.5.3	\$820.180	B
HCQP-5.6	Management Review	D	9.3	\$820.20(e)	B
HCQP-6.2.2	Competence, Awareness and Training	D	7.2	\$820.25	B
HCQP-6.3	Scheduled & Unscheduled Maintenance	E	7.1.3, 8.5.1	\$820.70(g)	C
HCQP-6.4	Work Environment	F	7.1.3, 8.5.1	\$820.70(h)	C
HCQP-7.1	Planning for Product Realization	D	8.2.2, 8.2.3	\$820.70(a)	C
HCQP-7.1.1	Failure Mode and Effects Analysis	B	8.2.2, 8.2.3	\$820.70(a)	C
HCQP-7.2.1	Work Order Process	G	8.2.2, 8.2.3	\$820.70(a)	C
HCQP-7.2.2	Change Control	A	8.5.6	\$820.70(a)	C
HCQP-7.2.3	First Article/Samples	C	8.2.2, 8.2.3	\$820.70(a)	C
HCQP-7.4.1	Purchasing Process	H	8.4	\$820.70(b)	C
HCQP-7.4.1.1	Approved Supplier List	A	8.4	\$820.70(b)	C
HCQP-7.4.3	Receiving Process	H	8.5.1	\$820.80(b)	C
HCQP-7.5.1.1	Labeling and Packaging Procedure	E	8.5.2	\$820.120, \$820.130	C
HCQP-7.5.3	Identification & Traceability	E	8.5.2	\$820.60, \$820.65, \$820.95	C
HCQP-7.5.4	Control of Customer Property	D	8.5.3	\$820.140, \$820.150	C
HCQP-7.6	Control of Monitoring and Measuring Devices	E	7.1.5	\$820.72	D
HCQP-7.6.1	Instructions for Calibrating a Steel Tape Measure	A	7.1.5	\$820.72	D
HCQP-7.6.2	Instructions for Calibrating a Caliper Micrometer	A	7.1.5	\$820.72	D
HCQP-8.1	Monitoring, Management, Analysis & Improvement	A	9.1	\$820.20, \$820.250	D
HCQP-8.2.2	Internal Quality Audits	E	9.2	\$820.22	D
HCQP-8.2.4	Monitoring and Measurement of Product/Process Release	C	8.6	\$820.80(c & d)	D
HCQP-8.3	Control of Non-conforming Product/Material	E	8.7	\$820.90	D
HCQP-8.5	Customer Complaints	D	10.2	\$820.198	E
HCQP-8.5.1	Medical Device Reportable	A	8.5.5	\$803.3	E

DOC Name: Quality Document Index

An example of a PO to a vendor has been shown below.

ORDERED BY:  
HEUBACH CORPORATION  
2713 INDUSTRIAL LANE  
GARLAND, TX 75041  
USA

Purchase Order  
Purchase Order No.  
17436  
Date Issued  
4/4/22

To:  
FROST INNOVATIVE PKG, LLC  
2900 WELLS STREET  
MARSHVILLE, MI 49840  
USA

Ship To:  
HEUBACH CORPORATION  
2713 INDUSTRIAL LANE  
GARLAND, TX 75041  
USA

Send invoices to: lisa@heubachcorp.com

Deliver By	Ship Via	Account No.	Terms
4/5/22	Heubach		Net 30 Days

Quantity	Unit	Item	Description	Unit Cost	Amount
100.00EA		PE-SHT-0061	100+ BLK 2W 2 X 18 X 108	31.956	3,195.00
				<b>Total</b>	<b>\$ 3,195.00</b>

\*\*\*Please label part before delivery with part # / Lot #\*\*\*

Authorized Signature \_\_\_\_\_

The receiving log has been shown below.

HEUBACH CORPORATION  
TIGHT-TOLERANCE MANUFACTURING

RECEIVING LOG

DATE	HEUBACH LOT #	SUPPLIER	PART NO. OR DESCRIPTION	SUPPLIER LOT #	QTY	PO#	RECEIVED BY	LABELS MADE?
4/25/22	425220052	CARPENTER FOAM	CHARCOAL 32X87X108 CHARCOAL 32X87X108	PS-90185CH PS-90185CH	2 BUO	17452	V.G.	
4/25/22	425220053	ALLIED Plastic	WHITE HIMPACT PL-SHT-0064 STYRENE	845034	75 PCS	17457	H.G.	
4/25/22	425220054	LIBERTY PACKAGING	Trigger COR-BOX-0115	1700316	2 Packets	17417	H.G.	
4/28/22	428220055	II	COR-Box 0063-	1512028	125 Packets	17398	H.G.	
4/28/22	428220056	II	COR-Box-0084- 4-09 EPS-1450X60X961#	1512029	75 Packets	17398	H.G.	
4/28/22	428220057	CARPENTER DALLAS	EPS BLOCK 50X50X96	95242104	5 Blocks	17451	V.G. HG	
4/28/22	428220058	Rosco PACKAGING INC	COR-SHT-0069	6076176	40 Packets	17450	H.G.	
4/28/22	428220059	PREMIER FOAM	PJ-BUN-0073 Biocide 20065-710 GREEN BUNS	411682	15 BUN	17456	V.G. HG	
4/29/22	4/29220060	CHANDLER RESOURCES	4mmPS F-156990-SS-SC-BL1	14019	2,500 FT.	17444	V.G.	

HCDF-7.4.3 Receiving Log Rev C

DATE: 0.

An example of a bill of lading has been shown below.

**Pregis Innovative Pkg LLC, Straight Bill of Lading-Original-Not Negotiable**

RECEIVED subject to indubitably determine rates or contracts that have been agreed upon in writing between the carrier and shipper, reference to the usual classifications and rules that have been established by the carrier and are available to the shipper on request. The shipper hereby certifies that herein is true and correct with all the terms and conditions of the ABCD Uniform Freight Bill of Lading including those on the back thereof and the said terms and conditions are hereby agreed to by the shipper and accepted by the carrier and its agents.

<b>SHIPPER</b> Pregis Garland Plant 2901 W KINGSLEY RD GARLAND TX 75041 Telephone No.: (903)874-1775		<b>CONSIGNEE</b> HEUBACH CORPORATION 2713 INDUSTRIAL LN GARLAND TX 75041		DATE 04/05/2022 BOL# 476297-0001 CARR CUSTOMER PICK UP TRLR# SEAL# PCOF# Freight Terms COLLECT
--	--	---	--	--

No. Packages	HTS RATE	DESCRIPTION OF ARTICLES, SPECIAL MARKS AND EXCEPTIONS - HWFC	WEIGHT in LBS	CLASS	Notes
100		EXPANDED PLASTIC ARTICLES (IF * 2WCUFFI-1573226UR2)	1413	300	Subject to section 7 of conditions of application of bill of lading to be delivered to the consignee without recourse on the carrier/the carrier will accept the following statement: The carrier, agent, or consignee of the shipment without payment of freight and all other lawful charges per (Signature of Consignor)
100		Pregis Order# Customer Pick Consignee Po# 776792 17436	1,413		

Notes:  
RECEIVING HOURS  
8 AM - 4 PM  
214-291-0238

COC AND COA IS REQUIRED WITH EACH SHIPMENT.  
SHIPMENTS CANNOT BE RECEIVED IF A CERTIFICATE IS NOT PROVIDED. IF SHIPMENTS CANNOT BE RECEIVED, INVOICES WILL NOT BE PAID.

SHIPPER SIGNATURE: [Signature]

DRIVER SIGNATURE: [Signature]

DATE: [Date]

CARRIER: [Carrier]

2, Carrier Copy

An example of a packing list from a vendor has been shown below.

**Pregis Packing List**

Ship Date	Shipment#	Page
04/05/2022	476297	1 of 1

**Bill-To:**  
 HEUBACH CORPORATION  
 2713 INDUSTRIAL LN  
 GARLAND TX 75041

**Ship-To:**  
 HEUBACH CORPORATION  
 2713 INDUSTRIAL LN  
 GARLAND TX 75041

Order#	Delivery#	Customer PO#/Date	Cons.PO#	Ship-To#	Freight Carrier	Freight Terms
776702	81165805	17436 / 04/04/2022		1040982	CPUP	CPU

Line	Qty Orderd	Qty BO	Qty Shipped	UOM	Item#	Description
10	100	0.00	100.00	EA	476265	PE LAM RNW 1.7# BK 2X48X108 Notes:
			100.00			

Notes:  
RECEIVING HOURS  
8 AM - 4 PM  
214-291-0238

COC AND COA IS REQUIRED WITH EACH SHIPMENT.  
SHIPMENTS CANNOT BE RECEIVED IF A CERTIFICATE IS NOT PROVIDED. IF SHIPMENTS CANNOT BE RECEIVED, INVOICES WILL NOT BE PAID.

An example of a PO to a vendor has been shown below.

ORDERED BY:  
HEUBACH CORPORATION  
2713 INDUSTRIAL LANE  
GARLAND, TX 75041  
USA

Purchase Order  
Purchase Order No  
17436  
Date Issued  
4/4/22

To:  
PREGIS INNOVATIVE PKG, LLC  
2700 MILLS STREET  
MARYSVILLE, MI 48040  
USA

Ship To:  
HEUBACH CORPORATION  
2713 INDUSTRIAL LANE  
GARLAND, TX 75041  
USA

Good Thru	Ship Via	Account No.	Terms
4/3/22	Heubach		Net 30 Days

Quantity	Item	Description
100.00	PE-SHT-0031	1.7# BLK RNW 2 X 48 X 108

An example of an invoice to a customer has been shown below.

HEUBACH CORPORATION  
2713 INDUSTRIAL LANE  
GARLAND, TX 75041  
USA

Voice: 214-291-0238  
Fax: 214-291-0243

SALES PICKUP  
**INVOICE**  
Invoice Number: 59636  
Invoice Date: Apr 21, 2022  
Page: 1  
Duplicate

EMAILED  
APR 22 2022

Bill To:  
ACUMEN  
4101 W. Green Oaks #305-233  
ARLINGTON, TX 76016  
USA

Ship to:  
ACUMEN  
2743 PLEASANT HILL RD.  
Grand Prairie, TX 75052  
UNITED STATES

Customer ID	Customer PO	Payment Terms	
ACUMEN	000082523	Net 30 Days	
Sales Rep ID	Shipping Method	Ship Date	Due Date
	Heubach	4/21/22	5/21/22

Quantity	Item	Description	Unit Price	Amount
300.00	ACU-Bottle Holder	70 130 PU Char 12" x 6" x 2.75" Thk Insert W/ 6 cut outs. Shave 5 bottle slugs to .75" Thk and re insert. .5" thick loose Lid. No base. SET = Insert and Lid.	4.72000	1,416.00
1.00		TAX (8.25%)	116.82000	116.82
1.00		DELIVERY FEE	45.00000	45.00
Subtotal				1,577.82
Sales Tax				
Freight				
Total Invoice Amount				1,577.82
Payment/Credit Applied				
<b>TOTAL</b>				<b>1,577.82</b>

Check/Credit Memo No:

An example of a sales order pick list for a customer has been shown below.

**HEUBACH CORPORATION**  
2713 INDUSTRIAL LANE  
GARLAND, TX 75041  
USA

Voice: 214-291-0238  
Fax: 214-291-0243

**SALES ORDER PICKING LIST**  
Sales Order Number: 000082523  
Sales Order Date: Apr 4, 2022  
Ship By: Apr 15, 2022  
Page: 1

**To:**  
ACUMEN  
4101 W. Green Oaks #305-233  
ARLINGTON, TX 76016  
USA

**Ship To:**  
ACUMEN  
2743 PLEASANT HILL RD.  
Grand Prairie, TX 75052  
UNITED STATES

Customer ID	PO Number	Payment Terms	Sales Rep Name
ACUMEN	000082523	Net 30 Days	
Customer Contact	Shipping Method	Freight Amt	Ship Date
Darren Taylor	Heubach		

Quantity	Item	Description	Shipped Prior	This Shipment
300.00	ACU-Bottle Holder	70 130 PU Char 12" x 6" x 2.75" Thk Insert W/ 6 cut outs. Shave 5 bottle slugs to 75" Thk and re insert. 5" thick loose Lid. No base. SET = Insert and Lid.		300 sets
1.00		TAX (6.25%)		
1.00		DELIVERY FEE		

HEUBACH DELIVERY  
APR 27 2022  
RCVD BY: *[Signature]*

An example of a payment to a vendor has been shown below.

HEUBACH CORPORATION / 2713 INDUSTRIAL LN, GARLAND, TX 75041

Customer Name: ACUMEN  
Customer ID: ACUMEN

Receipt Number: 58636  
Date: 4/26/22  
Reference: 042622CC-1

ITEM / INVOICE	DESCRIPTION	QUANTITY	UNIT PRICE	AMOUNT
58636				1,577.82

Payment Method: VISA  
XXXXXXXXXXXX6302  
05706D

Subtotal: 1,577.82  
Sales Tax: 0.00  
1,577.82

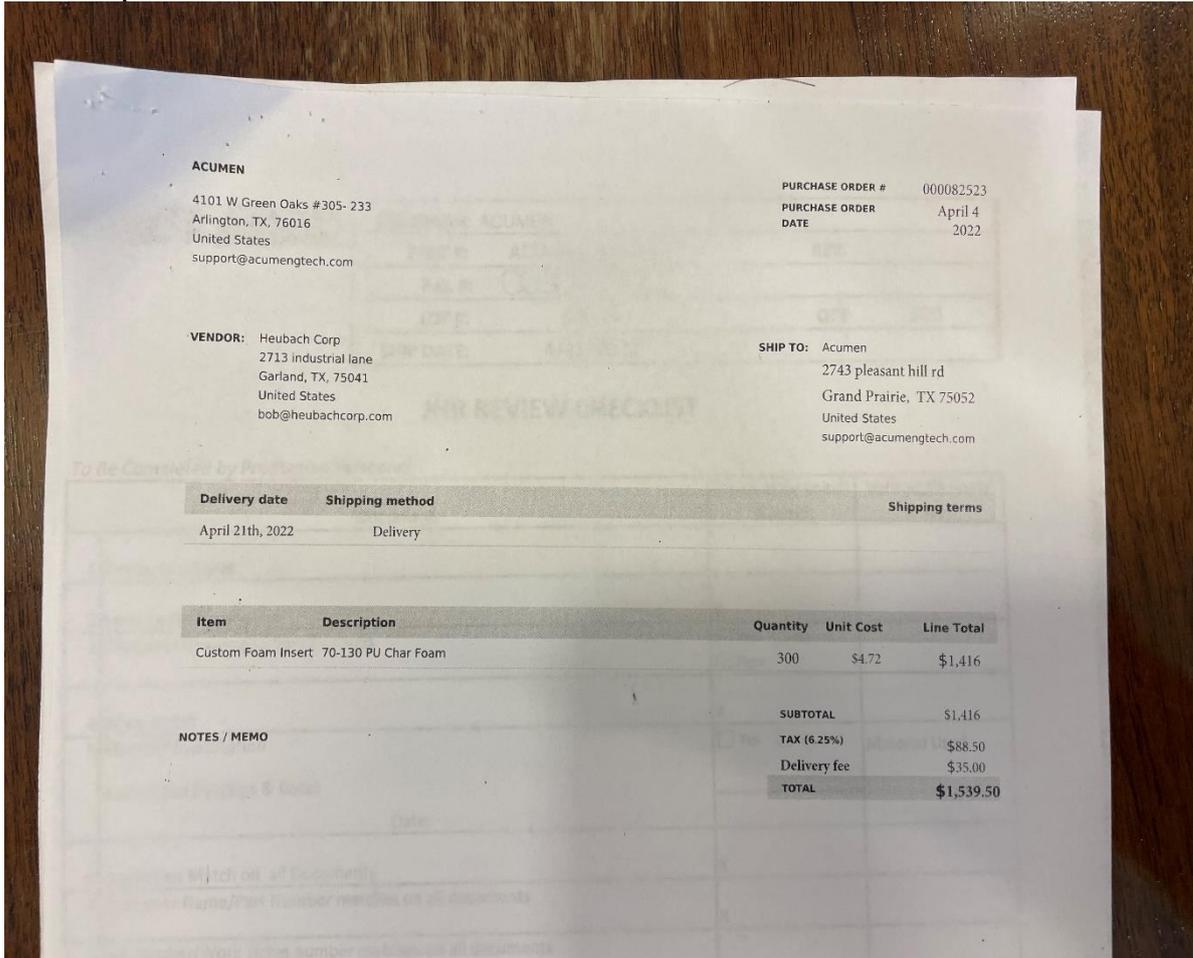
Receipt Number: 58636  
Date: 4/26/22  
Reference: 042622CC-1

ITEM / INVOICE	DESCRIPTION	QUANTITY	UNIT PRICE	AMOUNT
58636				1,577.82

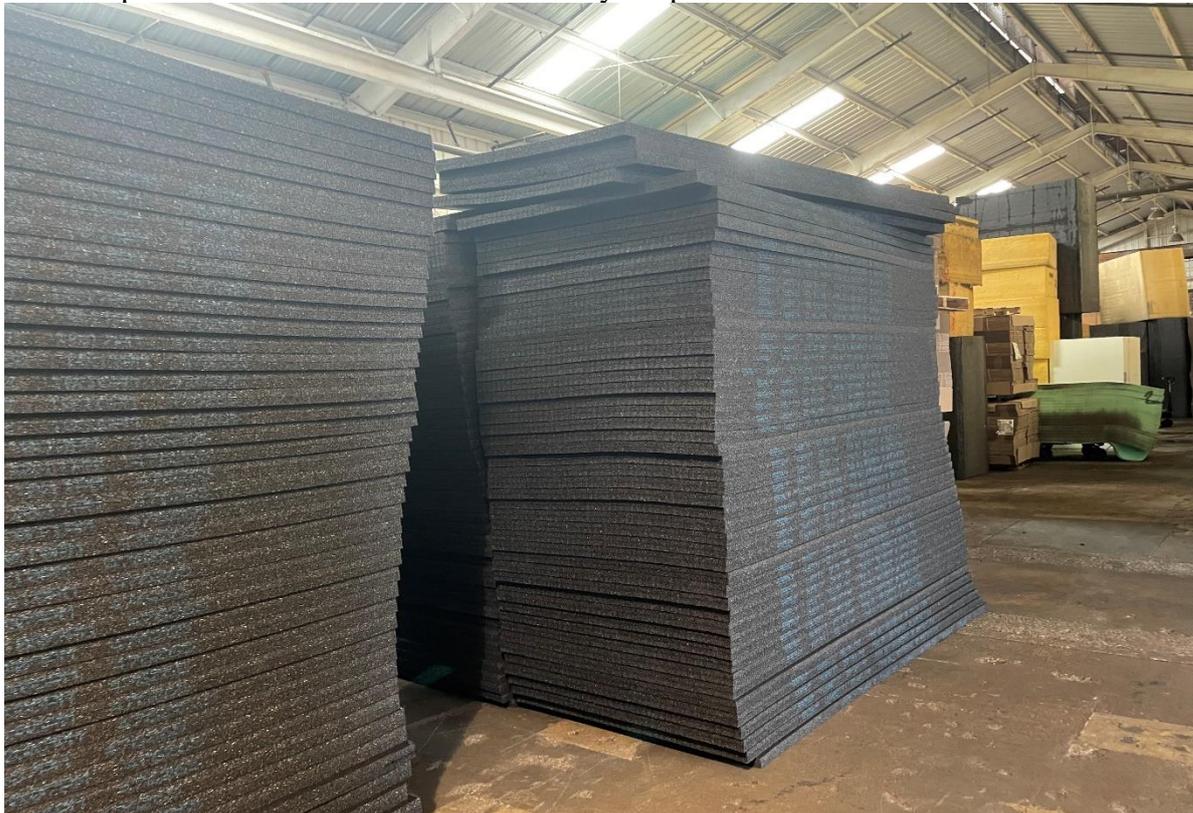
Payment Method: VISA  
XXXXXXXXXXXX6302  
05706D

Subtotal: 1,577.82  
Sales Tax: 0.00  
1,577.82

An example of a PO from a vendor has been shown below.



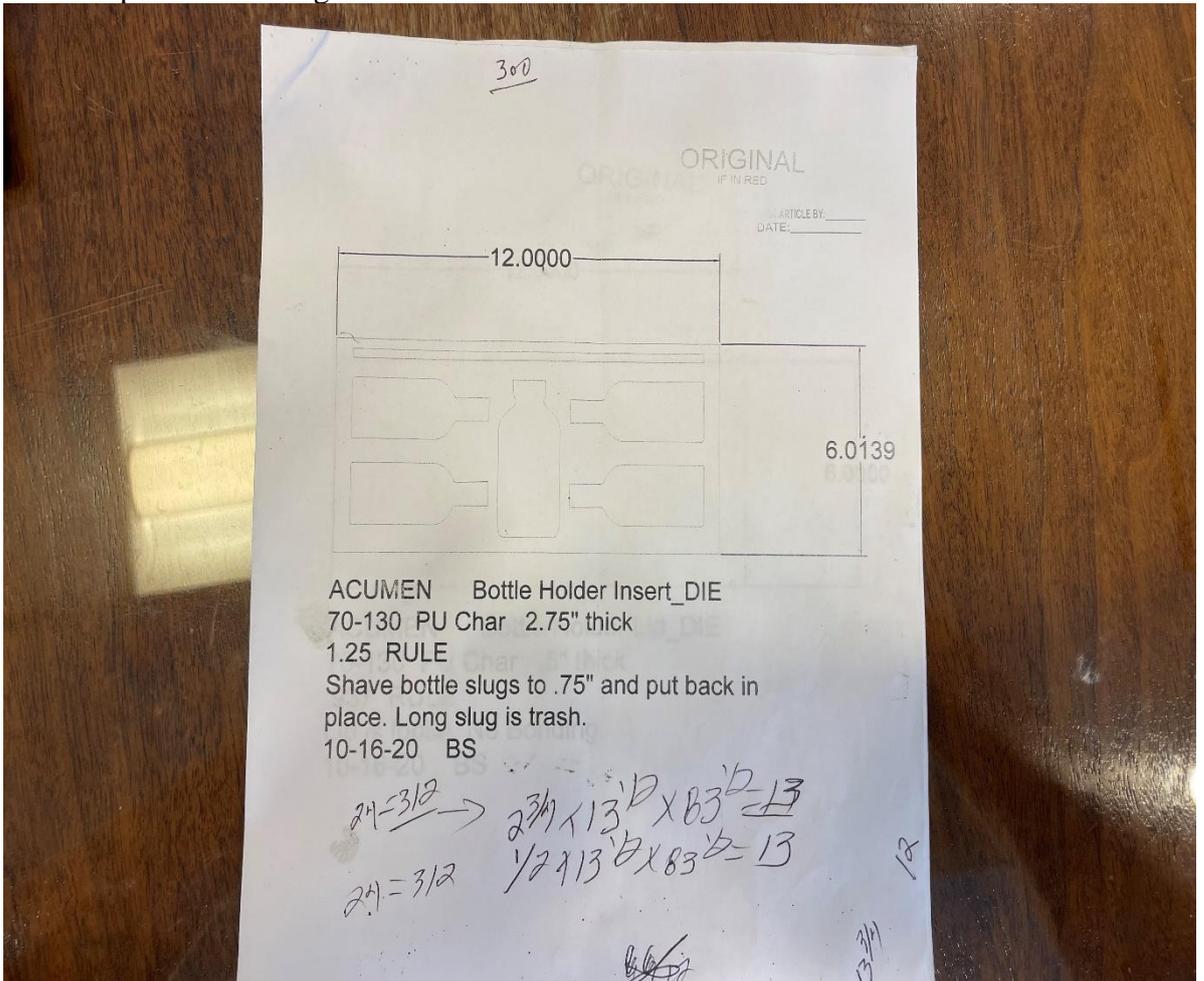
An example of raw materials sheeted and ready for production run has been shown below.



An example of completed goods ready for shipment have been shown below.



An example of a drawing for an order has been shown below.



An example of a request/label request for an order has been shown below.

6 @ 50 Inserts  
1 @ 300 Lids  
4-14-22

**HEUBACH CORPORATION**  
HEUBACH INNOVATIVE PACKAGING

**LABEL REQUEST/RECONCILIATION FORM**

Product Code/Number	ACU-Bottle Holder
Customer PO	000082523
Lot No.	57565
No. of Labels needed	<del>4000</del> 1000
No. of Labels issued	1
Signature/date of issuer	ll 4/14/22
Verified by and date	
No. of labels used	
No. of labels scrapped	
No. of labels returned	
No. of labels for overages	
Total of labels used, scrapped and returned	
Difference, if any	
Product verification signature and date	
Quality approval and date	

Heubach Corporation  
2713 Industrial Lane  
Garland, Texas 75041

Ship Date: 04/14/22

**TO: ACUMEN**  
2743 PLEASANT HILL RD  
GRAND PRAIRIE, TX 75052

**PURCHASE ORDER: 000082523**  
**PART NUMBER: ACU - BOTTLE HOLDER**  
**DESCRIPTION: INSERTS**  
**QUANTITY: 50**      **LOT#: 57565**

An example of an invoice from a vendor has been shown below.

**Pregis**

**Invoice**

<b>Sold-To Party</b>		<b>Payment Information</b>	
HEUBACH CORPORATION 2713 INDUSTRIAL LN GARLAND TX 75041		Doc. No./Invoice Date	91125135 / 04/05/2022
<b>Ship-To Party</b>		Ship Note No./Ship Date	476297 / 04/05/2022
HEUBACH CORPORATION 2713 INDUSTRIAL LN GARLAND TX 75041		Order No./Date	776702 / 04/04/2022
<b>Conditions</b>		PO #	17436
Payment	Up to 05/05/2022 without deduction	Customer	1040982
<b>Delivery</b>		Currency	USD
Delivery	CPU - CPU COLLECT	Invoice Amount	3,195.00
Shipped Via	CPU COLLECT - CPU COLLECT	Contact	BEN BURTON
PRO Number	CUSTOMER PICK UP	Contact Phone	810-320-7350
		Consignee PO#	

<b>Weight - Volume</b>			
Gross Weight		1,413.000 LB	
Net Weight		1,413.000 LB	
Volume		747.500 FT3	

**NEW REMITTANCE INFORMATION**

Item	Material Description	Quantity	Unit Price	Extended Price
000910	476285	100 EA	31.95	3,195.00

PE LAM RNW 1.7# BK 2X48X108  
Plant: Pregis Garland Plant

TOTAL	USD	3,195.00
TAX		0.00
INVOICE AMOUNT		3,195.00

(Handwritten initials)

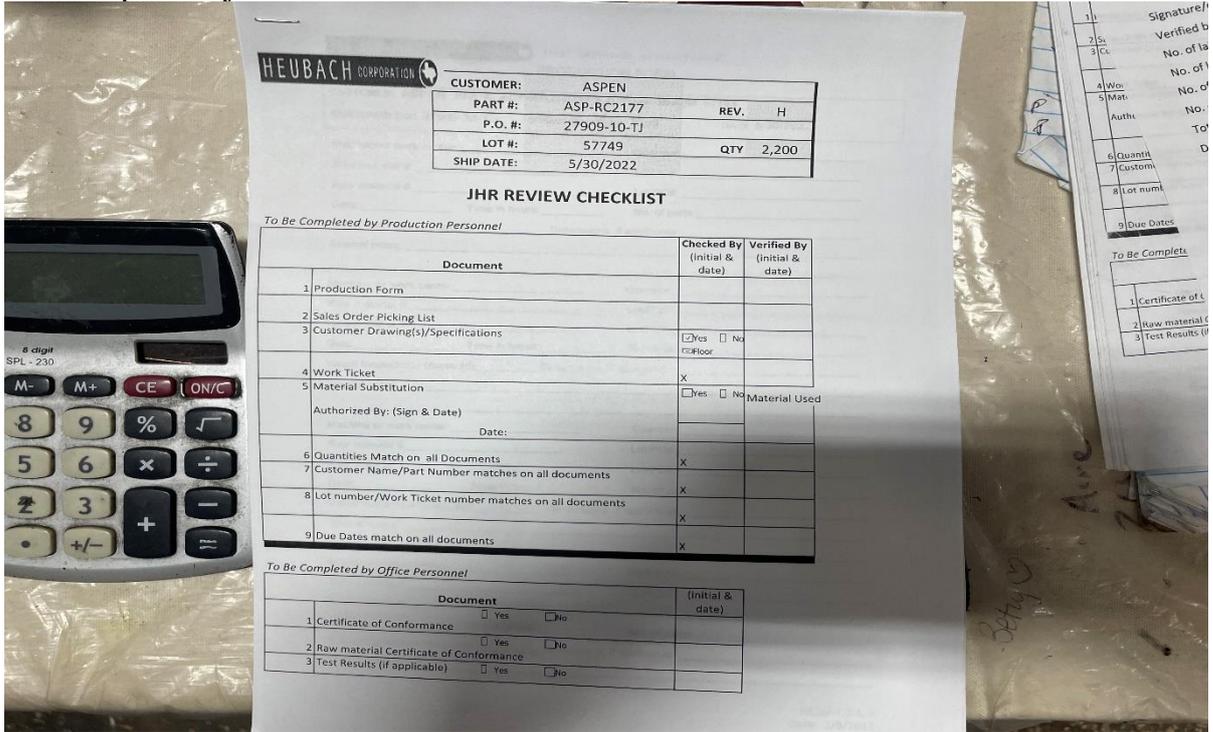
Heubach Corp/2713 Industrial Ln  
Pregis Innovative Pkg

Check Number 20465      020465  
Check Date Apr 26, 2022

Check Amount	\$36,045.37
Discount Taker	Amount Paic

Item to be Paid - Description	
91125134	15,889.75
91125135	3,195.00
91129451	15,960.62

An example of a job review checklist has been shown below.



An example of completed goods packaged and ready for pick up has been shown below.



More completed goods have been shown below which are ready for shipment.



Customer and vendor satisfaction is reviewed at planned intervals. It was seen to be done regularly with the top customers and vendors for the organization and overall positive responses were seen for both. Examples of these have been shown below.

**HEUBACH CORPORATION**  
DIECT • TOLERANCE • MARKETING

Page 1 of 4

**Heubach Supplier Self Assessment Form**

**Section 1: Company Information**

Company Name Amcor Flexibles North America	<input type="checkbox"/> Distributor <input checked="" type="checkbox"/> Manufacturer	Web site: <a href="https://www.amcor.com/">https://www.amcor.com/</a>
Billing Address 2200 Badger Ave, Oshkosh WI, 54904		Phone 1-800-544-4672 Fax
Primary Manufacturing Address 1350 N. Fruitridge Avenue, Terre Haute, IN 47804 United States	% Capacity 0	Phone 812-466-2213 Fax
Additional Manufacturing Site: Name/Address, if applicable		Phone Fax
Additional Manufacturing Site: Name/Address, if applicable		Phone Fax

**Section 2: Contacts (Please attach organizational chart)**

Function	Name	Title	Phone (with extension)	Email address
Customer Service	Trista Volkman	Account Specialist	920-527-7362	trista.volkman@amcor.com
Sales	Dillon Kempen	Account Manager Associate I	O: 920-527-5654 M: 920-385-8362	Dillon.kempen@amcor.com
Quality	Assigned per Quality Issue			

**Section 3: Products and Services** Give a brief description of types of products, services or technologies offered. Attach brochure if available.

Amcor manufactures cast, extruded, barrier, and metalized films, in addition to rigid trays/roll stock, extrusion laminates, 3-and 4-ply foil structures, a large variety of pouch styles and shrink bags.

In addition, Amcor has several world-class innovation centers, where customers can work hand-in-hand with Amcor to develop market-disrupting packaging:

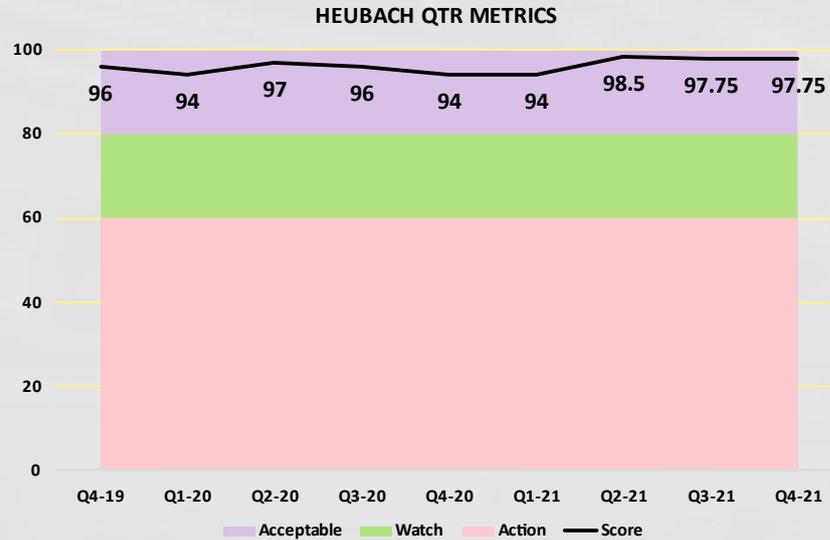
- Innovation Center in Neenah, Wisconsin, is our state-of-the art center where we accelerate your packaging ideas through collaboration, rapid prototyping, and hands on research.
- Ghent Innovation Center, Belgium, where we coordinate global R&D efforts to manufacture increasingly sustainable flexible packaging.
- Manchester Engineering & Innovation Center, Michigan, where experts work with customers to design, engineer, prototype, and test rigid containers.
- Inova Innovation Center, Brazil

**Section 4: Medical Device Customers** List other medical device companies with whom the company does business.

Amcor considers existing customer information proprietary, however we are the worldwide leader in flexible packaging. We provide services to clients of all scales, from small businesses to Fortune 500 companies.

Form #HCQF-7.4.1.003  
Revision A

# Customer Feedback Aspen Medical



# Customer Feedback Aspen Medical

Supplier Scorecard – Heubach 2021 – Q4						
Element	Rating	Weight	Score	%	Performance	Rationale
On-Time Shipments	5	3.0	5	15	Percentage of PO's delivered on time per the requested delivery date.	Percentage of PO's delivered on time per the requested delivery date.
Accuracy of Shipping Documents and Products	5	3.0	5	15	No issues for Q4	Number of errors in Shipping Documentation: Revisions, Quantity, PO number, SKU number
Supply chain responsiveness	5	4.0	5	20	No Issues	Responds to emails and phone calls within 24 hrs. Quality issues addressed within 24 hrs.
Scrap Levels	5	3.0	4.25	12.75	0.743%	MRB material disposition
Nonconforming Material	5	3.0	5	15	No NMRs for Q4	0 NMR For Q4
SCAR's Issued	5	4.0	5	20	No SCARs for Q4	0 SCAR ForQ4
Score			97.75%			

Human resources and training are minimal for the organization. In the event that a position needs to be filled the organization will take the necessary steps to post the job, collect applications and resumes, review the candidates, offer positions, start orientation, complete the required and pertinent paperwork such as employment eligibility I-9 forms, tax information, drug testing background checks, and wage and payroll information and conduct proper OTJ training and other safety trainings. Training is handled as needed, and overall, the human resources functions appear to work well for the organization. An example of a employee performance review has been shown below and an OFI has been added to the end of this report as well.

**HEUBACH CORPORATION**  
Employee Performance Review

**EMPLOYEE INFORMATION**

Name	Hugo Garcia	Employee ID	
Job Title	Production Supervisor	Date	4/26/22
Department	Production	Manager	Math Eltz
Review Period	to		

**RATINGS**

	1 = Poor	2 = Fair	3 = Satisfactory	4 = Good	5 = Excellent
<b>Job Knowledge</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Comments					
<b>Work Quality</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Comments					
<b>Attendance/Punctuality</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Comments					
<b>Initiative</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Comments					
<b>Communication/Listening Skills</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Comments					
<b>Dependability</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Comments					
<b>Overall Rating</b> (average the rating numbers above)	5				

**EVALUATION**

ADDITIONAL COMMENTS: Very hard worker

GOALS (as agreed upon by employee and manager)

**VERIFICATION OF REVIEW**

By signing this form, you confirm that you have discussed this review in detail with your supervisor. Signing this form does not necessarily indicate that you agree with this evaluation.

Employee Signature	Victor H. Garcia	Date	4/26/22
Manager Signature	Matthew Eltz	Date	4/26/22

Planning of jobs is done daily during stand-up meetings and other production meetings. Once orders are received from customers the job is printed out and sent to the production floor. Orders that need to be completed quickly may be considered a “hot order” and done prior to other scheduled work. Daily, the production manager will sort and plan the jobs according to due dates. All jobs were seen to be planned and scheduled as necessary.

Calibration of micrometers and tape measures are to be completed; however, it is noted that this is currently a work in progress and will need to be addressed as soon as possible. An observation or opportunity for improvement has been added to the end of this report in regards to calibration and maintenance.

A process approach is used when conducting everyday operations and this was seen to be utilized as well as a risk-based thinking approach. Risks are addressed during the quoting and proposal processes, during vendor selection and during management reviews as well. A PDCA cycle was seen to be followed and overall, the process approach and how the organization identifies and manages risks appears to work well for the organization. An example of some of the risks identified has been shown below.

**Appendix 1 Internal & External Issues of Strategic Importance**

External Issues:

- Raw Material Costs – Foam Slabstock pricing
- Labor Costs – Limited Availability of Qualified Labor
- General trend by customers to push cost and inventory reduction on suppliers

Strategic Issue	Risk	Opportunity
<b>Internal</b> Recruiting & Retaining Talent	<ul style="list-style-type: none"> <li>• Slow growth of business due to lack of labor or skill sets</li> <li>• Cause quality errors and lower efficiency</li> <li>• Overreliance on dwindling pool of retained labor</li> </ul>	<ul style="list-style-type: none"> <li>• Drive Growth &amp; Efficiency</li> <li>• Expand opportunity to capitalize on new opportunities</li> </ul>
Ineffective or inefficient Operating Processes	<ul style="list-style-type: none"> <li>• Lower Efficiency &amp; Profitability</li> </ul>	<ul style="list-style-type: none"> <li>• Competitive Advantage if Improved</li> </ul>
Equipment Upkeep & Maintenance	<ul style="list-style-type: none"> <li>• Loss of productivity, both in output and efficiency</li> <li>• Shipping Delays, Late Shipments</li> <li>• Repair costs</li> <li>• Increased Safety issues</li> </ul>	<ul style="list-style-type: none"> <li>• Improved Productivity</li> <li>• Better On Time Shipping Performance</li> <li>• Lower overall machine maintenance cost</li> <li>• Fewer Safety Issues</li> </ul>
Production Scheduling & Material Planning	<ul style="list-style-type: none"> <li>• Late Shipments</li> <li>• Higher production costs (labor &amp; machine time) due to inefficient loading of shop</li> <li>• Lower capacity, slowing growth or increasing cost of growth</li> <li>• Additional front office staffing</li> </ul>	<ul style="list-style-type: none"> <li>• Improved delivery performance</li> <li>• Higher productivity and capacity</li> <li>• Improved Front Office Productivity</li> </ul>

#### 4.6 Effectiveness of management reviews

The organization conducted the most recent management review meeting on 4/25/2022. The meeting agenda and attendees were noted in the management meeting PowerPoint presentation and the agenda included the necessary inputs and outputs from the ISO 9001 standard. Overall, the organization has a proper and fitting management review procedure as outlined in the QMS and completes the meetings effectively.

## Agenda

- Quality Metrics
  - Quality Objectives
  - Complaints
  - Customer Feedback
- Quality Audit Results
- Status of Corrective & Preventive Actions
- Product & Process Conformance Trends
- New or Revised Regulatory Requirements
- Planned Changes Affecting the Quality System
- Recommendations for Improvements
- Management Output – Review of Quality Policy & Objectives

#### 4.7 Effectiveness of internal audits

The organization has yet to conduct the 2022 internal audit. This has been made a minor corrective action; however, they have shown effective internal audits in the past and have a plan in place to get the audit completed in 2022. See the assessment plan and CAR summary for details.

#### 4.8 Effectiveness of the corrective action system and how non-conformance and complaints are handled

The organization uses a CAR log, as shown below, to monitor and track issues. The issues that arise are minimal but they are tracked as necessary. Overall, the way in which the organization manages the internal and external issues appears to work well for the organization, however an observation or opportunity for improvement has been added to the end of this report. Examples have been added below.

CORRECTIVE ACTION /PREVENTIVE ACTION REQUEST LOG							
CA OR PA?	CAPA NO.	DATE	INITIATOR	REASON OR PROCESS	TARGET CLOSE DATE	DATE CLOSED	
CA	21-001	9/24/21	Brien Eltz	Maintenance logs need to be reworked and updated to most current machines. Distribute to and train Maintenance Technician	7/31/22		
CA	21-002	10/21/21	Key Surgical	Preventative and periodic maintenance not been completed or recorded since 2019.		10/29/21	
CA	21-003	10/21/21	Key Surgical	SCAR 513 not recorded in CAPA Log, Retraining for SCAR 513 not evident. Entries in NCMR Log not recorded properly.		10/29/21	
CA	21-004	11/5/21	Purple Surgical (SCAR 522)	SCAR issued for failed surgical pads. Slitting in liner caused adhesive to stick to liner.		11/13/21	
CA	21-005	12/1/21	Brien Eltz Sent to Berry Global	PSA received for Purple surgical pads had slitting in liner causing parts to fail.			Berry Global failed to return SCAR, Refund received.
CA	21-006	6/11/21	Purple Surgical	Liner of parts tearing and being sent due to worn out die not cutting all the way through paper.		6/13/21	

Form #HCQF-8.5.2.002  
Revision A

<b>Supplier Corrective Action Request (SCAR) Form</b>		
<b>SECTION 1: Information Provided - To be completed by Purple Surgical</b>		
Supplier Corrective Action Request Reference Number	SCAR 522	
Product Supplier	Heubach Corporation	
Product Description	Blue Sponge for EL-101/AF-031	
Purple Surgical Part Number	FFS001	
Supplier Part Number (if different to above)	N/A	
Supplier LOT Identification No.	54270	
Date Goods Received	13/07/2021	
Quantity Received from Supplier	119,980	
Quantity Rejected	119,980	
Purple Surgical NCR Reference No.	NCR 913	
Purple Surgical Person raising this SCAR	Emily Yip	
Date SCAR was raised	27/07/2021	
Purple Surgical Quality Email address for return of the completed form with supplier CAPA details input.	Return completed form to: <a href="mailto:Emily.yip@puplesurgical.com">Emily.yip@puplesurgical.com</a>	
Nature of Complaint/ Defect	<i>*Include Photographs of the Defective Product if they are helpful to communicate the fault</i>	
<p>During the Goods In inspection the above product failed the functionality test.</p> <p><b>Pad tests</b></p> <ul style="list-style-type: none"> <li>Remove backing paper on the foam and ensure it removes smoothly without tearing.</li> <li>Check the adhesive underneath is suitably tacky and a radio-opaque thread is present under the tape.</li> </ul> <p>When removing the backing paper, the adhesive double side film stayed stuck on the backing paper and the sponge peeled off, completely or partially. Even when the sponge removed without damage, it was not smooth and easy to peel.</p>		
		

A	B	C	D	E	F	G	H
Complaint Number	Date	Customer	Customer Part Number	PO #/Lot #	Description	Status	Comments
21-01	11/30/2021	Linerz	Linerz18us	Undetermined	Customer had asked to expedite order. Linerz14us (1/4" Thick) was skived to 1/8" to create Linerz18us to be shipped. Parts were already printed with Linerz14us screen and part number.	accepted	Print issue was made aware to the customer prior to shipping.
21-02	10/12/2021	Breg	ED0037XX	55993	Variation on part Length and width changes depending on ambient temperature the part was cut in.	accepted	Breg tolerances determined to be too tight and a new range was specified.

**4.9 Evidence of the continued effectiveness of corrective actions from the previous assessment visit**

As this is technically an initial assessment this area is not applicable. It is noted that some of the OFI's from previous assessment have been addressed.

**4.10 Evidence of continuous improvement**

The organization has continued to improve its operations and business as well as made upgrades to its QMS. After discussions with the organization the following areas were discussed with top management and considered to be continuous improvement items; potential buyout from main owner, added new staff, added new machines, completed employee surveys, reorganization of warehouse and more capabilities added. The organization utilizes a risk-based thinking approach and a PDCA cycle to plan, do, check and act upon issues, daily operations and when considering new business. It can be seen that the organization looks for ways to improve its operations consistently as well as the QMS as a whole.

## Planned Changes Affecting the Quality System

- Continue Deploying Safety Program
- Implementing Raw Material Inspection and ID tagging, and In process and final inspections for finished Medical Devices
- Continue implementation and improvement to ISO 9001:2015 Quality Management System standard
- Consider making Job Packets digital someday.

HEUBACH CORPORATION TIGHT TOLERANCE MANUFACTURING™

## AREAS OF IMPROVEMENT

- Old unused stock moved to the back of the warehouse from the front. Usable workspace increase.
- Scrap machine moved to new location; workflow should no longer be impeded by scrap in main work areas.
- Employee performance evaluations conducted for each Heubach employee.

### 4.11 Use of logos and certification marks

There has been no noted misuse of logos and certification marks. Two OFI's have been made at the end of this report however.



#### 4.12 Validity of the non-applicable elements of the management system standard(s)

The organization has identified that section 8.3, design and development of products or services, is not-applicable to its QMS. This was seen to be valid during the certification assessment visit.

#### 4.13 Recertification assessments – overview of performance of the previous 3-year period

As this is an initial certification this area is not applicable.

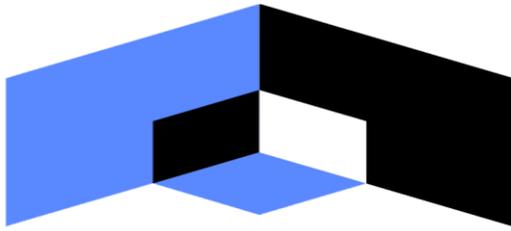
#### 4.14 Certification recommendation

The assessment team recommends this organization for:

- Initial certification (*certification assessments*)
- Continuation of existing certification (*surveillance assessments*)
- Recertification (*recertification assessments*)
- Certification only after closure or downgrading of MAJOR CARs (*certification or re-certification assessments*)
- Suspension of certification due to non-closure of CARs

## **⑤ Observations and opportunities for improvement**

- 5.1 It will be an improvement to update the certificate and logos utilized as well as to update the company website.
- 5.2 It would be an improvement to post the updated quality objectives in the break room.
- 5.3 It will be an improvement once the foam bailer is up and running to recycle the major quantity of foam currently waiting to be processed throughout the facility.
- 5.4 It would be an improvement to update the address on the website.
- 5.5 It will be an improvement once the annual safety training is completed and LOTO is implemented.
- 5.6 It will be an improvement once the bun ID system is created.
- 5.7 It may be an improvement to move to paperless job sheets.
- 5.8 It will be an improvement once the maintenance program has been created and begun.
- 5.9 It may be an improvement to move away from using the glue for Tige.
- 5.10 It will be an improvement once all calibrated equipment has been added to a calibration log and a new tape measure has been purchased.
- 5.11 It may be an improvement to have all staff sign off an acknowledgement of the ISO/QMS certification and its processes during onboarding.



**TCB  
Audit  
Services**

QUALITY AND INTEGRITY

## ⑥ Customer Satisfaction Survey

As an extremely valued customer of TCB Audit Services, LLC we encourage and appreciate your open and honest feedback. Please help us improve our products and our service to you by completing this quick survey. Please complete this form and forward it via e-mail to [eric@tcbaudits.com](mailto:eric@tcbaudits.com).

Company name: \_\_\_\_\_ (not mandatory)

Completed by: \_\_\_\_\_ (not mandatory)

### 6.1 What is your overall satisfaction rating with our company?

Dissatisfied  - Neither Satisfied nor Dissatisfied  - Satisfied

### 6.2 Would you recommend our service to a friend or colleague?

Yes  - Maybe  - No

### 6.3 Did you receive the assessment plan in a timely manner prior to the audit?

Yes  - No

### 6.4 Was the auditor punctual in arriving at your premises?

Yes  - No

### 6.5 Did the auditor conduct the assessment in a professional manner?

Yes  - No

### 6.6 Did the auditor make your staff feel at ease and were they non-confrontational?

Yes  - No

### 6.7 At the exit meeting, were the findings clearly explained?

Yes  - No

### 6.8 Did you receive the audit report and updated assessment plan in a timely manner?

Yes  - No

### 6.9 Were audit findings useful in terms of benefits to your organization?

Yes  - No

### 6.10 Are you happy to continue being audited by your current assessor?

Yes  - No

If you have extra comments or feedback simply include the detail in the e-mail with this survey. All feedback is confidential and any corrective actions that we may make resulting from your comments are approached in a global manner as opposed to focusing on any one client or auditor.

*This assessment report should be read in conjunction with the Assessment Plan & CAR Summary as both documents constitute the entire assessment report*