DEPARTMENT OF HEALTH AND HUMAN SE. .CES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax:(513) 679-2772 Industry Information: www.fda.gov/oc/industry	04/09/2013 - 04/17/2013* FEI NUMBER 1526542

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Walter J. Schum, President

FIRM NAME	STREET ADDRESS
So-Low Environmental Equipment Co. Inc.	10310 Spartan Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cincinnati, OH 45215	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Corrective and preventive action activities and/or results have not been documented.

Specifically, the firm has procedure OP 820.100A titled "Corrective Action" that was issued on 10/22/09. This procedure states that production processes, delivery, training, warranty, customer complaints, and other business related activities will be reviewed for potential problems or failures with a view toward implementing actions to prevent their reoccurrence. Since the last inspection, the firm has no documented review of these data sources. The firm keeps a log titled "Corrective and Preventive Action Log", but the log actually contains a list of complaints and service reports received by the firm, rather than corrective and preventive actions that have been opened as a result of data source analysis.

The firm also has a procedure OP 820.100B titled "Preventive Action" that was issued on 10/22/09. This procedure states that each quarter management will collect and review information to identify recurring problems, unsatisfactory trends with service process performance, problems that could result in nonconforming product or other services, or costly problems. There are no documented reviews of these data sources.

This is a repeat observation from the previous inspection.

OBSERVATION 2

Complaint files are not adequately maintained.

Specifically, the firm records what they consider to be "FDA complaints" related to their medical freezers on a form titled "FDA Service Log". The only complaints documented on these forms are for freezers that are still under warranty; each freezer has a 1-year warranty. Management stated that the life cycle of the device is 8 years.

When asked if they keep any documentation of complaints related to freezers that are no longer under warranty, management stated that they will make notes on the outside envelope that the device history record is enclosed in when the customer calls. These "notes" on the DHR envelopes are not tracked or analyzed as a quality data source.

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	Allison M. Scheck, Investigator	04/17/2013

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The firm's service log indicates that 112 complaints were documented for freezers under warranty since the previous inspection in 2009. During the inspection I reviewed a total of 32 complaints for U80-30 and U85-25 freezers that were under warranty from 2010 until present. Documentation for 3 out of 32 of these complaints was missing. 9 out of 29 of the remaining complaints had no follow-up or "diagnosis" documented.

This is a repeat observation from the previous inspection.

OBSERVATION 3

Procedures for training and identifying training needs have not been adequately established.

Specifically, the firm's Quality System Manual dated 04/05/13 states on page 14 that "trained personnel are assigned to all work affecting quality, based on their *Competency* (*F820.25-2*) which includes appropriate education, background, training, skills, and experience." Form F820.25-2 has sections to describe all of these requirements for each particular job title. The firm has (b) employees total, but has only (b) of these "Competency Requirements" F820.25-2 forms on file. (b) out of (b) Competency Requirements forms on file are incomplete. The firm also has an "Experience Record" (Form F6.2.1-1) attached to each Competency Requirements Form. (b) out of (b) of these Experience Records are incomplete.

Management also stated during the inspection that their employees, along with themselves (including the Management Representative), have not been trained in any of the firm's quality system procedures. No training needs have been identified or documented for the firm's employees.

This is a repeat observation from the previous inspection.

OBSERVATION 4

The organizational structure has not been adequately established and maintained to ensure that devices are produced in accordance with 21 CFR 820.

Specifically, the firm does not have a quality department or an employee(s) dedicated to ensuring devices are produced in accordance with 21 CFR 820.

OBSERVATION 5

Products that do not conform to specifications are not adequately controlled.

Specifically, the firm does not document nonconformances during incoming inspectional activities or during in-process production. The only time instances of non-conforming product are documented is during final product testing. Management stated that if a nonconformance is discovered during in-process or incoming inspection, the problem will be fixed and the unit moves on. No other action is taken.

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The firm is also not following its procedure OP 820.90 titled "Nonconforming Product", dated 10/22/09. This procedure instructs the employee to record the nonconformance on the Internal Nonconformance Report form when corrective action is taken. When asked, management said that they do not use this form. Rather, they fill out a "Problem Unit" form and stick it to the side of the fridge until the problem is resolved. The form is then filed in the Device History Record. When I asked to look at some of these Problem Unit forms, management stated that they are not tracked and they would have to search through each DHR to find them. This also puts the firm in contention with their procedure, which states "The Management Representative shall track all nonconformances" and "the MR shall review the Nonconformance Reports....at a minimum once each month".

This is a repeat observation from the previous inspection.

OBSERVATION 6

A process whose results cannot be fully verified by subsequent inspection and test has not been validated according to established procedures.

Specifically, the firm uses an (b) (4) foam shooting system to inject insulating foam into the frame of their freezers. They use a "Shot Time" worksheet that they created several years ago through "trial and error" that lists the number of seconds foam needs to be shot into each side of the freezer's frame. These times were calculated for all models of freezers that the firm manufactures. This foam shooting process has never been validated.

OBSERVATION 7

Process control procedures that describe any process controls necessary to ensure conformance to specifications have not been adequately established.

Specifically, the firm has not developed any written procedures for the processes used in the manufacture of their medical freezers. The firm has a Form 2315 titled "FDA Control System Process Control Traveler", effective 10/20/09, which gives a brief summary of each step taken to manufacture the freezers. However, there are no details given as to what equipment should be used, process parameters, or product specifications. Management stated that other than this form, there were no additional procedures regarding freezer production.

This is a repeat observation from the previous inspection.

OBSERVATION 8

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been established.

Specifically, the firm's Quality System Manual dated 04/05/13 states on page 16 that "all suppliers that provide product for production are approved prior to use and are listed in the Active Supplier's List". When asked, management stated that no such list exists and it would be very difficult to come up with a complete list of all the firm's suppliers. The Quality System

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Manual also states that New Key Suppliers shall be added in one of four ways;

- After a trial based on at leasl (b) successful shipments
- Passing an e-mail or mailed audit survey to the satisfaction of Purchaser
- Supplier registered to the current ISO 9001 standard and can produce acceptable performance data for on-time delivery and minimal customer complaints
- On-site assessments, as appropriate.

Management stated that they do not assess any of their suppliers in this way. They simply order from the supplier, and if everything works out they will use them again in the future if needed.

The Quality System Manual says on page 16 that the Purchasing Agent will track the performances of key suppliers that include at a minimum

- On-time delivery
- Short shipment
- Wrong or damaged materials

Management stated they do not document or track this information for their suppliers.

The firm also does not have any written or verbal agreements with their suppliers. There is no agreement that states suppliers will notify So-Low of changes in the product or service being provided.

The only documentation of Purchasing Controls at the firm are the purchase orders which are stored in tabbed binders.

OBSERVATION 9

Acceptance activities were not adequately documented.

Specifically, the firm's Quality System Manual dated 04/05/13 states that "So-Low has established and maintains procedures for acceptance of incoming product. Incoming product shall be inspected, tested, or otherwise verifed as conforming to specified requirements." When asked, management stated that they do not have any written procedures for inspection of incoming product. They stated that the product is given an overall visual inspection, but there is no documentation of its acceptance or rejection.

In addition, in-process acceptance activities are not consistently documented. 34 device history records were reviewed for the U80-30 and U85-25 freezers. 19 out of 34 device history records were missing sign-off signatures from required personnel.

This is a repeat observation from the previous inspection.

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OBSERVATION 10

Written MDR procedures have not been developed, maintained, and implemented.

Specifically, the firm does not have a written procedure addressing how they will identify and handle events that meet the criteria for MDR reporting.

This is a repeat observation from the past two inspections of the firm.

OBSERVATION 11

Management with executive responsibility has not reviewed the suitability and effectiveness of the quality system at defined intervals.

Specifically, the firm's Quality System Manual, dated 04/05/13, states on page 12 that Executive Management will meet at least once per calendar year to review and ensure the continuing suitability and effectiveness of the Management System. The only documented management review meeting since the previous inspection in 2009 was held on 04/08/2013, one day prior to the start of the current inspection.

This is a repeat observation from the previous inspection.

OBSERVATION 12

Quality audits were not performed at defined intervals to determine whether the quality system activities and results comply with quality system procedures.

Specifically, the firm has a procedure OP 820.22 titled "Internal Audit" that was issued on 10/20/09. This procedure states that "the management representative will establish and coordinate an annual audit program that covers all activities, processes, work environment, services, systems, procedures and instructions within the Quality System Manuals and all appropriate elements of the Code of Federal Regulations Title 21 Subchapter H - Medical Devices." The most recent audit schedule was developed in 2013. Prior to 04/05/2013, there were no documented quality audits.

This is a repeat observation from the previous inspection.

OBSERVATION 13

Procedures to ensure equipment is routinely calibrated and maintained have not been established.

Specifically, the firm uses (b) pressure gauges to monitor several processes during the manufacture of their freezers. The firm does not keep track of these individual pressure gauges and does not calibrate them. Rather, they will "zero" the gauges

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before use. Additionally, the firm uses an (b) (4) foam shooting system to inject foam into the frame of their freezers. Management stated that the supplier of the system will perform maintenance on it approximately 4 times a year; when asked, management at the firm said they were not sure of the type of maintenance performed. No documentation of this maintenance was on file. The firm also uses (b) (4) temperature recorders to monitor the temperatures of the freezers during final product testing. No documentation of calibration/maintenance on these devices is kept.

OBSERVATION 14

Procedures to control labeling activities have not been adequately established.

Specifically, procedures ensuring label integrity, labeling inspection, labeling storage, and labeling operations were not established. The release of labeling after examination and approval is not documented.

This is a repeat observation from the previous inspection.

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Observation Annotations

Observation 1:	Under consideration.	Observation 2:	Under consideration.
Observation 3:	Under consideration.	Observation 4:	Under consideration.
Observation 5:	Under consideration.	Observation 6:	Under consideration.
Observation 7:	Under consideration.	Observation 8:	Under consideration.
Observation 9:	Under consideration.	Observation 10:	Under consideration.
Observation 11:	Under consideration.	Observation 12:	Under consideration.
Observation 13:	Under consideration.	Observation 14:	Under consideration.

*** DATES OF INSPECTION:**
04/09/2013(Tue), 04/10/2013(Wed), 04/11/2013(Thu), 04/12/2013(Fri), 04/15/2013(Mon), 04/17/2013(Wed)

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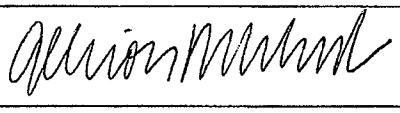
	Allison M. Scheck, Investigator 	04/17/2013