# BOV Solutions
# OTC cGMP Compliance Follow-up Audit

Prepared for:
BOV Solutions
1105 E. Garner Bagnel Blvd.
Statesville, NC 28677

**NSF Health Sciences Pharma Biotech**
Washington, DC

June 5, 2020

**CONFIDENTIAL**

**NSF Health Sciences Pharma Biotech**
2001 Pennsylvania Ave NW, Suite 950, Washington, DC 20006
**T** 202-822-1850 **F** 202-822-1859
**E** pharma@nsf.org **W** www.nsf.org

## TABLE OF CONTENTS

## 1.0 EXECUTIVE SUMMARY

At the request of BOV Solutions (BOV), **NSF Health Sciences Pharma Biotech** (**NSF Pharma Biotech**) conducted a follow-up audit of current Good Manufacturing Practices (cGMPs) as it related to over-the-counter (OTC) products manufactured at their Statesville, NC facility on May 12, 2020. Steven Sharf, Senior Consultant of **NSF Pharma Biotech** conducted the audit. The audit was a completion of follow-up from the **NSF Pharma Biotech** audit conducted in February 2018.

The previous full **NSF Pharma Biotech** audit of BOV (February 2018) deemed the site not in compliance with the requirements of 21CFR Parts 210 and 211. The audit resulted in 28 findings, 20 of which were classified as major. The 2018 findings covered a number of quality system and facility elements. As a result of the 2018 **NSF Pharma Biotech** audit, BOV removed the QA staff and brought in a third party, Dedicated Partners, to assist in remediating their quality system.

In June 2019, **NSF Pharma Biotech** conducted a review of CAPAs from the 2018 audit and determined that two (2) observations were considered open and 10 required a demonstration of effective implementation prior to the observation being considered closed. A summary of those findings closed as well as those that were deemed open and those requiring additional evidence (from the June 2019 audit) is as follows:

| Finding # | Critical / Major / Minor / OFI | Status |
|---|---|---|
| 1 | Minor | Closed. |
| 2 | Major | In-place. In use – TBD |
| 3 | Major | Closed. |
| 4 | Minor | In-place. In use – TBD |
| 5 | Minor | In-place. In use – TBD |
| 6 | Minor | Closed. |
| 7 | Major | In-place. In use – TBD |
| 8 | Major | Closed. |
| 9 | Major | Closed. |
| 10 | Major | In-place. In use – TBD |
| 11 | Major | In-place. In use – TBD |
| 12 | Major | In-place. In use – TBD |
| 13 | Major | In-place. In use – TBD |
| 14 | Major | Closed. |
| 15 | Major | Closed. |

| Finding # | Critical / Major / Minor / OFI | Status |
|---|---|---|
| 16 | Major | Closed. |
| 17 | Minor | Closed. |
| 18 | Major | Closed. |
| 19 | Major | Closed. |
| 20 | Minor | Closed. |
| 21 | Major | In-place. In use – TBD |
| 22 | Major | Closed. |
| 23 | Major | Closed. |
| 24 | Minor | Open. |
| 25 | Major | Closed. |
| 26 | Major | Closed. |
| 27 | Minor | Open. |
| 28 | Major | In-place. In use – TBD |

Each of the findings noted above as 'in-place. In Use – TBD' and 'open' was reviewed and determined to be closed based on evidence presented (described below). The 2018 **NSF Pharma Biotech** audit of BOV can be considered closed and through remediation efforts, BOV can be deemed compliant to the requirements of 21CFR Parts 210 and 211.

If you have questions or require additional information, please contact Maxine Fritz, Executive Vice President, **NSF Pharma Biotech** at (202) 716-9550 or mfritz@nsf.org.

## 2.0 FACILITY INFORMATION

*Facility Identity* BOV Solutions

*Location* 1105 E. Garner Bagnal Blvd.
Statesville, NC 28677

*Phone* 714-696-1473

*Contact Personnel* Ashley Cooper, QA Manager

*Audit Dates* May 12-15, 2020

*Auditor* Steven Sharf, Sr. Consultant, **NSF Pharma Biotech**

## 3.0 OPENING MEETING AND PERSONS INTERVIEWED

| Name | Title |
|---|---|
| Jeremiah Pfaff | SVP, Operations and Compliance |
| Charles Gray | Acting Head, Quality |
| Ashley Cooper | QA Manager |
| Jeremy Johnson | Plant Manager |
| Tonya Wassel* | Quality Systems Specialist |

*Only attended the close-out meeting

## 4.0 FINDINGS

**Status of 2018 NSF Audit Findings**

Only those findings from the 2018 **NSF Pharma Biotech** audit that were not closed during the June 2019 **NSF Pharma Biotech** audit (as noted on pages 3-4 of this report) are included below.

### 4.1 Major Findings

**Finding #2**

The quality control unit has not been given the responsibility or authority to perform their duties.

*Objective Evidence:*

- Any documents represented as quality control unit duties have not been reviewed or approved by any function outside of the quality unit.
- No clear separation of duties and responsibilities between quality and production. The person with the responsibility for regulatory compliance and quality at BOV is also the VP of Manufacturing.

**BOV Response:** BOV Solutions has hired a consulting company to evaluate and address all regulatory and quality deficiencies. This process is currently in place and this finding is in the process of being addressed. Additional quality personnel are in the process of being hired, including a Quality Director. Anticipated to complete by Q3 2018

**Evidence presented for review:** A quality policy (Doc. PCY-BOV-QA-00001.00) has been implemented and clearly defines the responsibilities of the quality group as well as of the operations group. At the time of the audit, BOV has yet to hire a full-time BOV employee as a Quality Director. On an interim basis, a third party consultant is serving as the acting head of Quality. The BOV org chart indicates that there is one SVP responsible for both quality and operations at the site level. BOV has committed that by the end of 2019, a corporate level head of Quality will be installed. This person will have independence from the operations group at BOV.

**June 2019 Status:** Finding #2 can be considered in-place. This finding cannot be closed until such time as BOV onboards a corporate level head of Quality. This should be confirmed during a subsequent NSF inspection.

**May 2020 Status:** BOV management took the decision to retain the third party consultants that they have been using and also to promote the Quality Systems Specialist to the role of Quality Manager. She is working daily and closely with the third party consultants but is the lead quality BOV employee on site. The Quality Manager reports directly to the Starco Executive Board (Starco being the owner of BOV) and has six (6) direct reports with three (3) more slated to be brought on board during 2020.

**Finding #2 can be considered closed.**

**Finding #7**

Failure to Establish or maintain procedures for internal audits.

*Objective Evidence:*

- The internal audit program as presented is more of a housekeeping inspection. “Internal Audit Policy”, Form # 2031, REV.4 – 10/30/14 does state “BOV Solutions will cover BOV Solutions’ quality systems, facility and equipment, materials control, production, packaging and labeling, and laboratory control.” However the objective evidence provided showed only that housekeeping items were listed or checked. See Internal Audit Reviews dated 03/15/2016 and 03/05/2017. Also, see document titled Audit Walk Through dated 09/01/2017.
- The same person performs all the audits, including areas where they have direct responsibility.

**BOV Response:** BOV Solutions has hired a consulting company to evaluate and address all regulatory and quality deficiencies. This process is currently in place and this finding is in the process of being addressed. The internal audit process is under review and will be completed by Q4 2018

**Evidence presented for review:** SOP BOV-QA-00019-01 *Internal Audit Procedure* is in place and describes the site internal audit program. The SOP requires a schedule be organized and

executed, that personnel conducting audits not be a part of the group they are auditing, and that reports be issued upon audit completion. Audit form 2031 has been obsoleted and replaced with a comprehensive checklist based on CFR requirements. A copy of the 2019 internal schedule was provided. No discrepancies were noted.

Dedicated Partners, the third party contracted by BOV to aid in remediation conducted a site-wide assessment of the operation (February 2019). The assessment resulted in a number of CAPAs that were translated into a BOV project plan with an anticipated completion date of Sept. 30, 2019. No BOV internal audits have been completed to date based on the requirements of BOV-QA-00019-01. The third party audit was used to satisfy SOP requirements; this is provided for in the site SOP.

**June 2019 Status:** The system for conducting internal audits is considered in place. Finding #7 is considered open as no internal audits have been completed by BOV personnel per SOP BOV-QA-00019-01 requirements. The next review of this finding should focus on BOV personnel completing audits per the scheduled SOP requirements, adherence to the internal schedule, and the overall quality of the audits.

**May 2020 Status:** A copy of the 2020 internal audit schedule was provided and reviewed. The schedule includes all elements of an internal audit program that would be expected. A total of eleven (11) employees, including the third party consultant, are approved to participate in audits, while two (2) are trained as lead auditors. Evidence was provided that audits are being completed per the 2020 schedule and reports are issued per SOP requirements. It was noted during the review that reports are not generated in a consistent format; BOV committed to creating a template to ensure consistent reporting moving forward.

**Finding #7 can be considered closed.**

**Finding #10**

Failure to maintain a change control process for equipment, systems and processes.

*Objective Evidence:* The only change control process at BOV is for Document Control only; there is nothing in place for equipment, systems and processes.

**BOV Response:** For clarification, BOV Solutions does have a process for documenting changes to documentation (FORM#2050 REV 2. 08/29/16). The process documents a description of a change, and the annual review process. However, we recognize the deficiencies noted and are committed to remediating the process.

BOV Solutions will create a procedure for the documentation and approval of change controls. The procedure will, at a minimum, include:

- Controlled documents (procedures, specifications, etc.)
- Controlled engineering drawings

- All modifications to equipment or facility
- Establishing individual and unique (non-repeating) identifiers for each change
- Detailed instructions for justification of a proposed change
- Implementation of a change consensus participant approval
- Quality pre and post approval

The procedure will be effective by the end of Q3 2018.

In the interim, we will continue to use the current procedure to support changes to documents (i.e., policies, procedures, etc.). An interim system to capture changes or potential changes to equipment and facility will be used. All captured changes will be required to have:

i. Justification for why the change is taking place

ii. Potential product impact

iii. Quality pre-approval

iv. Individual sequential numbering

v. Review of implemented change and Quality post-approval

**Evidence presented for review:** SOP BOV-QA-00070-01 *Change Control Procedure* is in place and provides guidelines for change controls regarding all GMP documentation, processes, and procedures at BOV. The SOP describes the initiation of a change control request, completion of the change control request form, assessment of a proposed change, implementation of a change, and the closure of a change request. Evidence was provided of a standing agenda item called 'Pending Change Controls' during the site semi-monthly Quality Board meeting. A review of the last three (3) Quality Board meeting minutes issued demonstrates that open changes controls are discussed.

One change control (CCR 19087) was reviewed for a product change executed at BOV. The change was documented in-line with the requirements of SOP BOV-QA-00070-01.

**June 2019 Status:** The system for handling and processing changes is in-place. Due to change control being a key QMS element, effective implementation (through review of additional change controls) should be determined during a subsequent NSF inspection.

**May 2020 Status:** Beginning in April 2020 and in addition to the semi-monthly Quality Board review, BOV has implemented a monthly change control meeting during which any open change controls are discussed and updates are provided by personnel responsible for specific changes. Change control logs were provided for 2019 and 2020. It was noted that the vast majority of change controls (>90%) are related to document changes and the introduction of new products. Change control metrics are provided quarterly to the Quality Review Board. Three (3) change controls from 2020 were reviewed (CCR20003 for a packaging change, CCR20008 for creation of documents resulting from a new product introduction, and CCR20029 for document updates)

and it was determined that each was handled and documented per the requirements of SOP-BOV-QA-00070-01.

**Finding #10 can be considered closed.**

**Finding #11**

Failure to establish or maintain procedures for CAPA.

*Objective Evidence:*

- Corrective Action Plan, Form # 2028, REV.2, 02/01/18 was represented as the "CAPA procedure", however this procedure does not meet Quality System requirements.
- For the past two years BOV had objective evidence of only three Corrective Action Forms. These Forms were identified by date and product name. 07-21-17, Alba HWN Sunscreen; 08-01-16, UltraShield EX 15 oz.; and 08-01-16, Hot Shot 7 oz. spray. All concluded that no issue could be found however, all showed documentation that "Action was Implemented".

**BOV Response:** BOV Solutions has hired a consulting company to evaluate and address all regulatory and quality deficiencies. This process is currently in place and this finding is in the process of being addressed.

**Evidence presented for review:** A CAPA SOP, BOV-QA-00051-04 has been put in place to describe the CAPA process at BOV. CAPAs can be generated as a result of internal and external audits, customer complaints, or an investigation. The SOP discusses development of CAPA plans, the use of a CAPA log, provisions for effectiveness checks, and the requirements that need to be met in the event an extension is needed.

Three (3) CAPAs were selected for review as evidence of effective implementation of the SOP. Each was handled in accordance with SOP BOV-QA-00051-04.

**June 2019 Status:** The system for handling CAPAs can be considered in-place. Due to CAPAs being a key QMS element, effective implementation (through review of additional relevant CAPAs) should be determined during a subsequent NSF inspection.

**May 2020 Status:** The CAPA SOP, BOV-QA-00051-4 does not require a CAPA be initiated for every deviation or investigation. While this concept is not reflected in BOVs current CAPA SOP it was noted that each deviation/investigation does include CAPAs as needed. A total of 21 formal CAPAs were initiated in 2019 (59 investigations were initiated in 2019) and two (2) formal CAPAs have been initiated thus far in 2020 (16 investigations have been initiated so far in 2020). It was determined that BOV is initiating CAPAs as needed, however the process should be more clearly documented in the CAPA SOP.

**Finding #11 can be considered closed.**

**Finding #12**

Failure to ensure that any deviation from the written procedures shall be recorded and justified.

*Objective Evidence:* Non-conformance / Deviation Policy, Form # 2035, Rev. 4, 02/02/18 is the BOV Standard Operating Procedure (SOP) to demonstrate compliance with this clause, but it does not provide the direction necessary to process to capture, document, investigate or correct a non-conformance / deviation.

**BOV Response:** BOV Solutions will create a procedure that governs the initiation and investigation process. The procedure will, at a minimum, include:

- Establishing individual and unique (non-repeating) identifiers for each investigation
- Instructions for personnel on how to initiate an investigation for a non-conforming event
- Instructions for root cause analysis (e.g., five why's)
- Guidance on reviewing impact to non-conforming lot and how to extend the investigation into reviewing all potential other lots impacted
- Providing a Quality disposition and final approval for closure

In the interim, BOV Solutions' Quality Director will be responsible for documenting non - conforming events that address the bullet points above (at a minimum) using a "white paper" system. In addition to this response, BOV Solutions will create a policy on Quality Management Review. The policy will detail how key process indicators and/or non-conformances will be reviewed and trended on a daily, monthly, quarterly, and annual basis.

The procedure and policy will be effective by the end of Q3 2018

**Evidence presented for review:** SOP BOV-QA-00039-01 *Procedure for Performing Investigations* defines the process for documenting non-conformances and deviations. The SOP provides examples of non-conformances, definitions of planned and unplanned deviations, deviation classifications (critical, major, minor), and steps needed to close an investigation. All investigations require closure within 30 business days of initiation or an interim report for those that cannot be closed.

One planned and two unplanned deviations were reviewed. The planned deviation was completed with a specific timeframe for the deviation. The two non-conformances (unplanned deviations) were completed per SOP but did not provide robust investigations so as to adjudicate the issue and determine appropriate CAPAs and next steps.

**June 2019 Status:** The system for generating and investigating deviations can be considered in-place. Effective implementation (review of additional investigations) should be determined during a subsequent NSF inspection. Consideration should be given to providing training to production management and QA personnel on investigation writing.

**May 2020 Status:** Each of the 16 investigations initiated in 2020 were reviewed. It was determined that the investigations are clearly written and define the problem as well as immediate actions taken to correct the issue or prevent recurrence. Each investigation was written in line with the requirements of SOP BOV-QA-00039-01.

**Finding #12 can be considered closed.**

**Finding #13**

Failure to establish and follow written procedures for the handling of all written and oral complaints regarding a drug product.

*Objective Evidence:*

- Corrective Action Plan, Form # 2028, REV.2, 02/01/18 was represented as the "complaint handling procedure", however this procedure does not meet the requirements of 21CFR Sec. 211.198.
- No objective evidence that any official agreement or process exists for customers / clients to provide information for any complaint to BOV.
- No objective evidence that non conformances discovered by BOV against a supplier are feed back into the suppliers system for an investigation.

**BOV Response:** BOV Solutions has hired a consulting company to evaluate and address all regulatory and quality deficiencies. This process is currently in place and this finding is in the process of being addressed.

**Evidence presented for review:** SOP BOV-QA-00023-04 *Customer Complaint Procedure* describes a formal process for handling customer complaints at BOV. Complaints are received by BOV from retailers and require investigations and corrective actions (as needed) per SOP.

The complaint handling SOP has been put in place, however a review of sample complaint records indicates that investigations lack context, are not robust and/or don't appear to take into account all factors leading to a given complaint. For example, complaint CST19007 was issued as a result of a customer receiving leaking cans, dirty cans, partially filled cans, and cans with partial lot codes. The (complaint) investigation at BOV did not consider the filling operation (i.e. line speed during filling), however it was noted on the complaint investigation that 'the manufacturing investigation noted…'. It is not known what is meant by that statement nor what is meant by '…at the speeds the production line was running…'

**June 2019 Status:** The system for handling complaints be considered in-place. Effective implementation (additional complaint investigations) should be determined during a subsequent NSF inspection. Consideration should be given to providing training to production management and QA personnel on investigation writing.

**May 2020 Status:** BOV has received a total of 18 customer complaints since January 2019. Each of the complaints is for products that are toll-manufactured by BOV for various customers. In each case, because BOV is not the product owner, only a review of batch production and lab records was completed by BOV and the results reported to the specific customer. This is in line with current BOV requirements as defined

**Finding #13 can be considered closed.**

**Finding #21**

Failure to properly review production batch records.

*Objective Evidence:* Certificate of Analysis for Work Order # BO00132, Lot # 306H1 has three results that are out of range:

% Avobenzone, Min=2.90, Max=3.0, Result=3.17
% Octocrylene, Min=7.90, Max=8.10, Result=8.37
% Octisalate, Min=4.90, Max=5.00, Result=5.01

CoA was reviewed and released by QA.

**BOV Response:** Effective immediately; the acting Quality Director in conjunction with a 3rd party Quality and Consulting firm will be performing all Final Release reviews on all batch records processed. The final review responsibilities will require a review of each batch record to ensure the document is complete, all signatures are accounted for chronologically/contemporaneously, and that all testing data is passing prior to bulk being released or finished product to be distributed.

**Evidence presented for review:** Two (2) SOPs are in place related to record review and product release. SOP BOV-QA-00006-00 *Procedure for Record Review* details the process for reviewing and approving batch records. The SOP states what must be reviewed during the record review process and what to do if mistakes are identified.

Policy BOV-QC-00005-00 *Product Release Policy* dictates the policy at BOV for releasing finished goods. All finished product is quarantined by QA prior to release. QA is also required to review the final CoA prior to product release.

**June 2019 Status:** The system to review production batch records can be considered in place. Effective implementation (additional completed batch records reviewed) should be determined during a subsequent NSF inspection.

**May 2020 Status:** The current process at BOV is for the Compliance Systems Specialist (CSS) to complete the final review and release of batches. The records for the last two (2) batches of product released at BOV were reviewed. It was noted that the CSS completed all required reviews. An interview with the CSS also demonstrated a good understanding of the

requirements a batch must meet prior to release. The CV and job description of the CSS were also reviewed.

**Finding #21 can be considered closed.**

**Finding #28**

Failure to monitor storage conditions for samples used for testing.

*Objective Evidence:* Shelf Life Stability Form # 2053, Rev.6 02/02/18 documents temperature and humidity specifications for the area where the stability samples are held. There is no objective evidence that the room is monitored or has been validated.

**BOV Response:** See finding 27, evaluation underway and expected by Q4 2018

**Evidence presented for review:** Since February 2019, BOV has contracted out their stability program to SpeedLabs (Norcross, GA). A site visit to SpeedLabs is scheduled for July 2019.

**June 2019 Status:** The monitoring of storage conditions for samples can be considered in-place. The next audit of BOV should include a review of the BOV audit of SpeedLabs as well as the quality agreement that will be implemented between the two companies.

**May 2020 Status:** BOV conducted an audit of SpeedLabs in August 2019 to determine their capability for conducting stability sample storage and stability testing. It was determined by BOV that SpeedLabs is in fact qualified to conduct stability testing and to store stability samples in qualified chambers. As of the time of this audit, BOV is also pursuing Precision Stability Storage as a secondary contractor for storing stability samples. An on-site visit to Precision was scheduled for 2Q2020, however due to the global pandemic, the visit was postponed until later in 2020.

**Finding #28 can be considered closed.**

### 4.2 Minor Findings

**Finding #4**

The GMP Training is insufficient.

*Objective Evidence:* The GMP Training Modules are a copy and paste of the definitions from the CFR and nothing else. The training does not provide the information necessary to assure that employees remain familiar with CGMP requirements applicable to them nor does it cover the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions.

**BOV Response:** BOV Solutions has hired a consulting company to evaluate and address all regulatory and quality deficiencies. This process is currently in place and this finding is in the process of being addressed. All training programs are under review and are expected to be completed by Q4 2019.

**Evidence presented for review:** Policy PCY-BOV-QA-00015-00 *Training Policy Program* and local site SOP BOV-QA-00016-00 *Employee Training Program* are in place to define the BOV training program. All new employees require job specific training as well as introductory GMP training (and annually after that). Training can be provided via observation or read/understood. Each job function in the plant has a job description.

**June 2019 Status:** The system for providing training can be considered in-place. A subsequent NSF audit should review additional training records (including GMP and OTJ training). This should include a specific review of GMP training given to the site on an annual basis.

**May 2020 Status:** The 2019 GMP training presentation was reviewed. It contained all the necessary elements expected in a GMP training presentation. Evidence was also reviewed that all employees received annual GMP training in 2019 as required by SOP BOV-QA-00016.

**Finding #4 can be considered closed.**

**Finding #5**

Failure to properly qualify personnel by assigned functions.

*Objective Evidence:* All personnel at BOV receive the same training. There is nothing that distinguishes an operator from a supervisor or a manager.

**BOV Response:** BOV Solutions has hired a consulting company to evaluate and address all regulatory and quality deficiencies. This process is currently in place and this finding is in the process of being addressed. As stated in Finding 4, all training programs are under review and completion is expected by Q4 2018

**Evidence presented for review:** Policy PCY-BOV-QA-00015-00 *Training Policy Program* and local site SOP BOV-QA-00016-00 *Employee Training Program* are in place to define the BOV training program. All new employees require job specific training as well as introductory GMP training (and annually after that). Training can be provided via observation or read/understood. Each job function in the plant has a job description.

**June 2019 Status:** The system for providing training can be considered in-place. A subsequent NSF audit should review additional training records (including GMP and OTJ training).

**May 2020 Status:** Training records were reviewed for a production operator, a lab analyst, and a QA line technician. Each position on the org. chart has with it a training matrix that identifies each of the requirements for the specific job function.

**Finding #5 can be considered closed.**

**Finding #24**

Failure to clean and maintain equipment and utensils as appropriate for the nature of the drug.

*Objective Evidence:* There are three tanks that are cleaned with spray balls. Disassembly, cleaning and inspection of these spray balls is not part of routine or preventive maintenance for the tanks.

**BOV Response:** Evaluation of the cleaning process is underway and will be evaluated. Completion expected by Q3 2018

**Evidence presented for review:** BOV is currently still in discussion with their vendor regarding the appropriate level of cleaning and maintenance required for the spray balls.

**June 2019 Status:** Finding #24 will be left open until such time as BOV has completed discussions with their vendor regarding the cleaning and maintenance of the spray balls and takes appropriate actions.

**May 2020 Status:** Since the last NSF audit, BOV has engaged in discussions with the supplier of the spray balls and determined that in using the current procedure for cleaning of compounding tanks, the spray balls are considered 'small parts'. As such, the spray balls (as with any 'small part') are cleaned in the sanitation room per the requirements of SOP BOV-OPS-00039 *Product Contact Parts and Utensils Cleaning.*

**Finding #24 can be considered closed.**

**Finding #27**

Failure to control conditions of temperature and/or humidity.

*Objective Evidence:*

- The Raw Material Ingredient Storage Room was under different conditions of temperature and humidity; however there was no monitoring of these conditions other than individual thermostatic for each of the two units.
- No justification for the different conditions other than antidotal information. It is understood that this area did not contain any drug products, but there is the potential for a drug product to enter this area.

**BOV Response:** Evaluation of temperature and humidity controls is underway in consultation with our consulting team. Completion expected Q4 2018

**Evidence presented for review:** Currently, the Raw Material Ingredient Storage Room has dataloggers that record temperature and humidity readings daily during production. These loggers have been in place since February 2019 and the site continues to gather data to better understand the actual conditions in the area on a daily (and seasonal) basis.

**June 2019 Status:** Finding #27 will be left open until such time as BOV has collected all their data and completed a full assessment of the raw materials being stored in the area to determine if additional controls are needed.

**May 2020 Status:** Since the last NSF audit, BOV collected data on the raw materials stored in the Raw Material Warehouse and compiled a report (dated 12May2020) demonstrating that all raw materials are being stored in their appropriate conditions (as defined on specific raw material labels). The additional controls to be implemented for raw material storage are to monitor materials that are held over from the previous season (from a temperature and humidity perspective).

**Finding #27 can be considered closed.**