CONFIDENTIAL DISCLOSURE RE ABBOTT LABORATORIES' PRODUCTION SITE IN STURGIS, MICHIGAN

I. OVERVIEW[1]

What is alleged in the within complaint is believed to be a series of violations of regulatory requirements relative to the manufacture of infant formula and related products by Abbott Laboratories ("Abbott"). Most of what is alleged is based upon first-hand knowledge [redacted] In a few instances, what is alleged stems from highly credible sources. Complainant stands ready to elaborate on what is alleged, to provide additional information, and to fully cooperate with any federal or state regulatory agency.

It should be emphasized that this complaint is not being filed to retaliate against Abbott.[3] To the contrary, over an extended period the Complainant properly and consistently raised product safety concerns. His protected activity ultimately led to his termination. That wrongful conduct is being appropriately investigated by OSHA.[4] Rather, this complaint stems from his personal knowledge of a litany of violations as well as the knowledge that countless current employees want this information disclosed to enforcement officials. They are rightly fearful of retaliation.

A. BACKGROUND

The Complainant is a former employee of Abbott. During the relevant period, he worked in Quality Systems ("QS"), a subunit of the Quality Assurance organization ("QA") in Sturgis, Michigan ("Sturgis site") as part of Abbott's Nutritional Division ("division"). The Sturgis site was previously a part of Ross Laboratories, a Columbus-based company that was acquired by Abbott. For a number of years, Ross Laboratories remained a separate division of Abbott.

Even though the acquisition took place many years ago, the Sturgis site has never been fully integrated into Abbott's system of internal controls. Unlike other Abbott units, active resistance to a full implementation of electronic records persists. Reliance on paper records for work orders continues to this day. Many of the same people remain in place. Long-term social

[redacted]

friends remain in positions overseeing product safety issues associated with each other.

Against this backdrop, Complainant observed and became increasingly aware of incidents and practices that caused him to be concerned as to the Sturgis site's compliance with the Food and Drug Administration's ("FDA") regulations. As long as one was not inclined to "rock the boat," lax practices, including regulatory violations, were consistently overlooked. Others also raised concerns, some with management but more often among colleagues at the Sturgis site.[5] Given the overriding fear of retaliation, few were as outspoken as the Complainant.[6]

Ultimately, despite an admirable employment record at Abbott and elsewhere,[7] Complainant was terminated based upon his repeated elevation of compliance concerns. That termination is being investigated by OSHA after filing a whistleblower complaint under Section 42 of the Food Safety Modernization Act ("FSMA complaint").[8] The timing of this complaint is prompted by the ongoing nature of the questionable practices and the fear of retaliation by current employees who have raised concerns.[9]

B. THE NATURE OF THE VIOLATIONS

As noted, most of what is reported is based upon Complainant's first-hand observations. In virtually all of these situations, he raised concerns as to regulatory violations with management at the Sturgis site. Most of what he reports has been corroborated through credible sources.

1. ***The Falsification of Records*** – On multiple occasions, and in various ways, records have been knowingly falsified. In most but not all of the situations, information of a material nature was not disclosed. This included testing seals on empty cans; signing verifications without adequate knowledge;

[5]Though far less frequently, officials at the division level were also made aware of Complainant's concerns relative to compliance with relevant FDA regulations.

[6]It must be kept in mind that Abbott's Sturgis site is, in general, the highest paying and largest employer in the immediate area. The loss of one's job is apt to have significant consequences requiring relocation to secure a position with equivalent income and benefits. In an environment where whistleblowers are not protected, raising concerns could put the well-being of families at risk.

[7]Prior to joining Abbott, Complainant's record was stellar both in terms of his academic record and in terms of his employment record. During his time at Abbott, he was never given a bad evaluation. On more than one occasion, he was awarded for being the "Best in Abbott" for carrying out certain aspects of his responsibilities. It was reported that officials at the division level repeatedly complimented him. His situation changed as he became more vocal, especially in challenging the leadership of QS and QA.

[8]21 U.S. Code § 399d.

[9]After the filing of the FSMA complaint, it is understood that officials at the corporate level seem to be more concerned about identifying employees who have raised concerns than addressing the underlying bases for the concerns. Management officials at the Sturgis site have already engaged in the harassment of individuals known to be friendly with the Complainant as well as those who were likely to provide damaging information arising out of a state investigation relative to shooting a stun gun within a facility at the Sturgis site.

understating or inaccurately describing events so as to limit or avoid oversight; issuing certifications of projection pages bereft of pertinent data; shipping packages with fill weights lower than represented on the labels; failing to maintain accurate maintenance records; and prematurely removing holds in the absence of all requisite approvals.

2. ***Releasing Untested Infant Formula*** – The Sturgis site performed a time code removal after the discovery of microorganisms ("micros") in a batch of infant formula. The remaining portion of the batch outside the time code removal was released without additional testing. On another occasion product was not re-called from the market even after management became aware of a nonconformity ("NC").

3. ***The 2019 FDA Audit*** – Active efforts were undertaken and even celebrated during and after the 2019 FDA audit to keep the auditors from learning of certain events believed to be associated with the discovery of micros in infant formula at the Sturgis site.

4. ***Clean-in-Place Staffing and Practices*** – The Sturgis site has continued to permit lax practices associated with clean-in-place ("CIP") procedures. The Sturgis site failed and continues to fail to have staff in place with sufficient training and experience to review CIP charts. Nor are CIP charts regularly reviewed prior to the release of a batch. CIP checklists do not require signatures of those performing the tasks and are not otherwise subject to audit by QS staff.

5. ***Failure to Take Corrective Measures –*** The Sturgis site has repeatedly failed to undertake reasonable measures to reduce natural or unavoidable defects to the level feasible as mandated by the current Good Manufacturing Practices ("cGMPs").[10] Deficient testing procedures known to be prone to causing mistakes have not been corrected. The Sturgis site continues to rely on staff with insufficient training and experience to interact with third-party labs ("TPL").

6. ***Lack of Traceability*** – The Sturgis site has ongoing problems associated with the traceability of its products. The automatic labeler frequently failed to work properly and led to significant difficulties in retracing product. QS staff never knew with certainty if an affected pallet was retrieved.

[10] *See*, e.g., 21 CFR § 117.110(a).

A remaining and overriding concern is the rather dramatic evidence of inadequate internal controls. The delay in transitioning to electronic records; the absence of adequate procedures to protect employees raising concerns; the pervasive lack of accountability; the questionable incentive structure; and the ongoing failure to address a material contingent liability, among others, are endemic to inadequate internal controls where food safety is paramount. Abbott's financial statements may also suggest regulatory concerns with respect to the inadequacy of its internal controls.[11]

C. THE ONGOING CONCERNS

Most if not all of the concerns raised by the Complainant in his FSMA complaint have been corroborated by others. Complainant also understands that Abbott has been made aware of credible information that corroborates the concerns raised. However, to date, no serious effort has been undertaken to address these concerns. One report suggests a greater interest at the corporate level of identifying the sources of complaints as opposed to addressing the underlying concerns raised.[12]

Aside from the compelling need to protect consumers, Complainant believes that other employees at the Sturgis site are currently at risk.[13] To protect those currently employed at Abbott, Complainant respectfully requests that, for the time being, this report be kept confidential and exempt from disclosure under the Freedom of Information Act ("FOIA"). He is prepared to fully cooperate and provide more specifics, including identifying individuals who can corroborate what is disclosed in this complaint.[14]

II. THE SUSPECTED VIOLATIONS

The suspected violations may be categorized in a variety of ways. But regardless of category, the common thread was and is to conceal the reality of what is taking place at the Sturgis site. The violations are neither inadvertent nor minor in nature. They constitute acts of commission and omission by management. In either case, what has been concealed is, in a number of instances, material information and holds the prospect of putting the ultimate consumer at risk.

[11] 15 U.S.C § 7262.

[12] In a related investigation arising out of the shooting of a stun gun within the facilities at the Sturgis site, it is known that the corporate officials disclosed the identity of the source of the complaint. [redacted]

[14] Given the credible fear of retaliation, Complainant emphasizes that a number of employees will be reluctant to come forward or speak candidly in the presence or even the knowledge of Abbott officials.

A. FALSIFICATION OF RECORDS

Complainant has first-hand knowledge of practices associated with the falsification of records on a regular and ongoing basis. He has reason to believe that these practices are not limited to what he personally observed. Most often the falsification took the form of material omissions. Sometimes a situation was incorrectly categorized. Other times, the records were simply falsified. In virtually all of the situations, the conduct was intentional and designed to conceal the reality of what was actually taking place at the Sturgis site.

1. Seam Testing of Empty Cans

The cGMPs and 21 CFR § 106.40(f)(3), in particular, provides:

> Any ingredient, container, or closure that has not been manufactured, packaged, labeled, or held under conditions to prevent adulteration under section 402(a)(1) through (a)(4) of the Federal Food, Drug, and Cosmetic shall not be approved and released for use.

The Sturgis site has had ongoing problems with seam integrity with powdered products. On an episodic basis, powder would become enmeshed in the seam thereby jeopardizing the integrity of the seal and product safety. Instead of addressing the underlying problem, the testing process was altered to test empty cans instead of sealed cans containing the product. To the Complainant's knowledge, this questionable practice was never disclosed or referenced in records that came to his attention.[15] He has reason to believe that the questionable practice has *not* ceased and, as well, has not been disclosed to FDA officials.

a. Recall of Calcilo XD

The cGMPs for infant formula and 21 CFR § 106.100, in particular, provides in pertinent part:

* * * * *

> (e) For each production aggregate of infant formula, a manufacturer shall prepare and maintain records that *include complete information* relating to the production and control of the production aggregate.

* * * * *

[15] In addition, the practice also appears to have violated 21 CFR § 106.40(d)(4), which requires in pertinent part that a manufacturer "[e]nsur[e] that each container of finished product is properly sealed."

> (2) Any deviations from the master manufacturing order and any corrective actions taken because of the deviations.
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> * * * * *
>
> (o) *The manufacturer shall maintain quality control records that contain sufficient information to permit a public health evaluation of any production aggregate of infant formula*.[16]

In 2019, Abbott recalled a batch of Calcilo XD for discolored powder and rancid smell. It was caused by powder being in the seam on the Abbott-applied end of the can.[17] A large portion of several batches of Calcilo XD produced after the recall had the same problem.[18] Complainant has direct knowledge that the work order was changed to suggest that the Sturgis site was doing everything necessary to prevent powder from getting into the seams.

As an example, the frequency of the seam checks was increased by the terms of the work order. It was made to appear that the Sturgis site had increased its oversight to correct for the deficiency that had been discovered with respect to seam-integrity issues. But what actually took place in terms of testing was not fully disclosed. Critically, instead of directly addressing the underlying problem, seam checks were performed on empty cans. Performing seam checks on empty cans was the only way to achieve passing results without finding powder in the seam. Management at the Sturgis site directed that the checks be performed in this manner.

In addition, during the rework, instead of "tearing down" the cans to verify whether there was any powder in the seams, the operators were directed to weigh each can to show that the correct amount of powder was in the can. However, it was well known that if the powder is too fluffy, the can may fall within the acceptable weight range and powder can still be in the seam.

These decisions were made because leadership knew powder would be found in the seam. They did not want to discard the entire batch. A number of production operators raised concerns with Complainant and others. They reported that they were being directed to perform seam checks

[16]Emphasis added.

[17]When powder gets in the seam, the seal is not as tight as it should be. Air, moisture, and bacteria can get into the can thereby leading to the powder becoming discolored and rancid.

[18]It is understood that this continues to be an ongoing problem.

on empty cans.[19] He has reason to believe that the practice of testing empty cans continued after his departure.[20] He also believes that the FDA has never been apprised of this practice.

b. Similac

The cGMPs and 21 CFR § 106.70(d), in particular, provides:

> A production aggregate of infant formula, including a reprocessed or reconditioned production aggregate, that does not meet the nutrient requirements of section 412(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(i)) or that has not been manufactured, packaged, labeled, and held under conditions to prevent adulteration under sections 402(a)(1) through (a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) through (a)(4)) *shall not be approved and released for distribution*.[21]

During the week of August 17, 2020, and possibly earlier, seam integrity issues were discovered in multiple batches of Similac Sensitive for Spit Up ("Similac"). Roughly half of the affected product remained within the control of the Sturgis site. The other half had been shipped. Even though management was aware of what occurred, product was not called back for inspection.

Complainant raised his concerns as to what was taking place with other members of QA leadership. Complainant was told that the Sturgis site was required to notify officials at the division level that a nonconforming product had been released. It is Complainant's understanding that there is a "grading" scale based on severity that Abbott uses in these situations. However, despite the objections of staff, he was told by those directly involved that the Sturgis site intentionally misrepresented the severity of the issue to division officials.[22]

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[19]Complainant recalls that during the production of the Calcilo XD batch(es), two powder packaging operators came to QS and raised concerns as to the seam checks being performed without any powder in the cans. [redacted] Complainant confirmed the accuracy of what was reported with a colleague in the powder packaging unit. He received conflicting information as to whether this was an isolated event. [redacted] Including himself, Complainant is aware of at least six individuals outside of management who were knowledgeable as to what occurred. Complainant saw the work order associated with the Calcio XD batch(es) and knows that the work order did not disclose that the testing was performed on empty cans.

[redacted]

[21]Emphasis added.

[redacted]

More than three months after the problem was discovered, the product still under Abbott's control was destroyed.[23] However, no recall was issued for the shipped product that was already in the marketplace. Generally, products are destroyed only when deemed to be non-compliant or unsafe for the consumer. Yet no action of any kind was taken for the product already in the marketplace.

2. Signing Verifications without Adequate Knowledge

At various stages of the production process, a need arises to verify that certain steps were taken or to explain corrective actions taken. At times two signatures are required. At other times, only one signature is required. However, in each instance, it was Complainant's understanding that a verification required first-hand knowledge or an independent and credible basis upon which to sign the verification. Relying exclusively on the word of others was insufficient.

a. Line Clearance

The cGMPs for infant formula and, 21 CFR § 106.100(f)(4), in particular, provides that the manufacturer of infant formula shall maintain

> [r]ecords, in accordance with § 106.30(f), on equipment cleaning, sanitizing, and maintenance that show the date and time of such cleaning, sanitizing, and maintenance and the production aggregate number of each infant formula processed between equipment startup and shutdown for cleaning, sanitizing, and maintenance. *The person performing and checking the cleaning, sanitizing, and maintenance shall date and sign or initial the record indicating that the work was performed*.[24]

What is referred to as "line clearance" is the process of clearing a packaging line at the end of a batch. At the Sturgis site, the process begins by placing a colored can on the line at the beginning of the packaging line and then following the can through every process or stage of the packaging process. Once the colored can arrives at the end of the packaging line, it can be assumed that the product and cans, or both, from the previous batch have been removed from the line. The risk of any product (powder) making it into the next batch is largely eliminated.

Along with clearing the line, other items are checked as well. Among others, can size, label, cap, shipping container, scoop (these are all commodities) can differ from batch to batch. Changes may need to be made to ensure that whatever is required for the next batch can be accommodated. In every work order for each batch, a "line clearance" section is included with critical subparts requiring verification/signatures by two operators or managers.

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[23]It is understood that much of the shipped product was at Abbott-owned or affiliated distribution centers.

[24]Emphasis added.

Often, an operator or manager did not sign his or her portion verifying the line clearance. Some portions of the work order are required to be double verified. Complainant regularly resisted management efforts to pressure him to sign the second verification for which he had no personal knowledge as to whether the task had been actually performed. QS staff were told by management that the sole purpose of the second signature was to verify the existence of the first signature. No independent verification was required.[25]

b. Technical Equipment/Engineering Issues

The cGMPs for infant formula and 21 CFR § 106.40(d), in particular, provides:

> A manufacturer shall develop written specifications for ingredients, containers, and closures used in manufacturing infant formula and shall develop and follow written procedures to determine whether all ingredients, containers, and closures meet these specifications. *When any specification is not met, an individual qualified by education, training, or experience shall conduct a documented review, shall determine whether a failure to meet such a specification could result in an adulterated infant formula, and shall make and document a material disposition decision to reject the ingredient, container, or closure or the affected infant formula; to reprocess or otherwise recondition the ingredient, container, or closure or the affected infant formula; or to approve and release the ingredient, container, or closure or the affected infant formula for use*.[26]

From time to time, Plant Information Reports ("PIR") from production were sent to QS to report an issue with a piece of machinery. The purpose of the PIR is to identify any deviations from the work order that occur during the manufacturing of a batch and, if applicable, the steps taken to correct the deviation. Frequently, no one in QS had the requisite knowledge to know whether the steps taken were acceptable.

In order to address the PIR, someone with QA had to explain why the corrective action was acceptable or, if not, what steps needed to be taken to appropriately address the issue. Complainant's supervisor would typically not address the PIR. Instead, she would relay the information to Complainant and ask him to sign the PIR without affording him an opportunity to undertake his own review before signing the PIR.

[25]Complainant was directly involved with the line clearance verifications as he repeatedly refused to verify what occurred without adequate information. [redacted] Members of management were well of aware of this practice of having verifications completed by individuals who lacked the requisite knowledge.

[26]Emphasis added.

These situations usually resulted in an argument where Complainant refused to sign the PIR due to his lack of personal knowledge.[27] Complainant had no fundamental objection to the verification or certification process.[28] The issue was whether he and others had sufficient knowledge to attest to the appropriateness of the action taken. Asking others to sign off as a matter of course was pervasive at the Sturgis site with the full knowledge and participation of management. Complainant has reason to believe the practice remains ongoing.

c. Signing Off on Nonconforming Product

The cGMPs for infant formula and 21 CFR § 106.60(a), in particular, provides:

> A manufacturer shall examine packaged and labeled infant formula during finishing operations to ensure that all containers and packages in the production aggregate have the correct label, *the correct use-by date*, and the correct code established under § 106.80.[29]

Meeting metrics frequently took precedence over product safety at the Sturgis site. Complainant is aware of multiple situations where PIRs were approved despite the product being out of specification ("OOS"). The OOS information was documented in a PIR. This should have initiated a potential nonconformity ("PNC") or an NC. However, officials at the division level would have been almost assuredly made aware of the designation of a PNC or NC.

To make a problematic situation less likely to be tracked and monitored by officials at the division level, management at the Sturgis site often moved OOS batches into a category known as "quality assessment." A PNC or a NC required certain individuals from the division level to sign off. Once division signed off, then the Sturgis site could move forward. However, by categorizing a problem or situation as a quality assessment, those within the QA organization at the Sturgis site could resolve an issue without the approval of division officials.[30]

In some instances, this meant that further testing or some sort of rework was not performed. It also meant that product was knowingly released where the expiration date of the product may

[27]In addition to members of management, Complainant [redacted] have direct knowledge of this practice. [redacted]

[28]For example, when his supervisor was unavailable, he did participate in the process. At those times, he was able to make an independent determination based on his own inquiry as to whether the actions taken were appropriate.

[29]Emphasis added.

[30]The "Low-Fill Weights" scenario described on pages 12-13 is a prime example of this practice. In that situation, in addition to management, the Complainant, [redacted] other individuals have direct knowledge of what occurred. ABTRAQ should show an audit trail whereby the PNC was initiated for the low-fill weights and then cancelled with a quality assessment being initiated to replace the PNC. ABTRAQ requires justification for each of these steps.

have been well before the date disclosed on the label.[31] Complainant has reason to believe that this practice has not ceased and continues to this day.

d. Overriding Quality Assessments to Meet Metrics

The mandate of the cGMPs and 21 CFR § 117.110(a), in particular, require that "[t]he manufacturer, processor, packer, and holder of food must *at all times* utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.[32] Furthermore, 21 CFR § 117.305 requires that records must:

> (b) *Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities*;
>
> (c) Be *accurate*, indelible, and legible; . . . .[33]

In addition, 21 CFR § 106.40(d) provides:

> A manufacturer shall develop written specifications for ingredients, containers, and closures used in manufacturing infant formula and shall develop and follow written procedures to determine whether all ingredients, containers, and closures meet these specifications. *When any specification is not met, an individual qualified by education, training, or experience shall conduct a documented review, shall determine whether a failure to meet such a specification could result in an adulterated infant formula, and shall make and document a material disposition decision to reject the ingredient, container, or closure or the affected infant formula; to reprocess or otherwise recondition the ingredient, container, or closure or the affected infant formula; or to approve and release the ingredient, container, or closure or the affected infant formula for use*.[34]

For the majority of the adverse events that arise during production, Abbott has a procedure known as the Standard Quality Evaluation ("SQE") procedure. The procedure covers a multitude of scenarios. It directs how certain issues are to be addressed. Each scenario has a number or code associated with it. As part of evaluating the PIRs and the Quality Assessments,

[redacted]

[32]Emphasis added.

[33]Emphasis added.

[34]Emphasis added.

Complainant and others would apply these codes referencing the SQE procedure as justification for the adverse event being acceptable.[35]

Increasingly over the last 12 months of Complainant's time at Abbott, management directed him and others to misuse the SQE procedure in order to meet metrics for the Sturgis site. The misuse primarily occurred with the application of SQE 6.16 in lieu of SQE 6.12. Both of these SQEs relate to missed checks at the packaging/finished product stage.

SQE 6.12 pertains primarily to missed visual inspections and seam integrity checks. Often, in order to meet the criteria of SQE 6.12, it is time consuming and costly as reworking the product tends to be the resolution. SQE 6.16 pertains to, among others, missed oxygen checks, "overcap" inspections, and outgoing package quality checks. For the most part, the criteria for resolving SQE 6.16 is found within the work order.

In order to meet metrics and, at times, over the objection of Complainant and others, management started directing Compliment and others to document SQE 6.12 events as SQE 6.16 events. At times, Complainant and others objected.[36] Indeed, on occasion, managers were repeatedly confronted and questioned as to the appropriateness of the directive being given.

3. Low-Fill Weights

FDA regulations and 21 CFR § 101.7(g), in particular, provides, in pertinent part, that

> [t]he declaration shall *accurately* reveal the quantity of food in the package exclusive of wrapper and other material packed therewith . . . .[37]

Sometime during 2019, the eight-ounce liquid packaging line had issues with low-fill weights. Over the course of several hours, the fill weights of cans were below the weight listed on the label. Instead of shutting down the line to correct the problem, the decision was made to keep filling the cans.

The initial plan was to destroy the cans where the weight was not consistent with the label.

[35]For example, based on his recollection, Complainant recalls that SQE 6.13, in effect, states that if a nutrient or mineral is OOS in-process, it must test within specification at finished product or project within specification at finished product. Once it is verified that the mineral or nutrient tests or projects within finished product specifications, then the SQE can be applied and the event is determined as acceptable.

[36]In addition to at least two members of management, Complainant [redacted] were knowledgeable of this practice. [redacted]

[37]Emphasis added. It is suspected that conduct may have violated other provisions of 21 CFR part 101.

The Sturgis site initiated a PNC for the incident. This was required by Abbott's Corrective Action Preventative Action ("CAPA") policy. However, management at the Sturgis site later cancelled the PNC and initiated a quality assessment to keep the situation less visible from officials at the division level.

Management at the Sturgis site then made the decision to "shuffle the deck." Cases of under-filled product were spread throughout the batch. Pallets were unstacked and restacked with the correct number of under-filled cases to get each pallet to the same weight. The object was to avoid any discrepancies in weight so that distribution centers would not be able to detect whether they were receiving noncomplying product.[38]

Complaints were made to management at the Sturgis site. Even members of QA leadership were also reported to have expressed concerns to the Complainant. One member of QA leadership went so far as to suggest to Complainant the "criminality" of the decision to proceed in this manner.

4. <u>False Certifications</u>

The cGMPs and, 21 CFR § 117.305, in particular, requires that records must:

* * * * *

(b) *Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities*;

(c) Be *accurate*, indelible, and legible;

(d) Be created concurrently with performance of the activity documented;

(e) *Be as detailed as necessary* to provide history of work performed; and

(f) Include:

> (1) Information adequate to identify the plant or facility (e. g., the name, and when necessary, the location of the plant or facility);
>
> (2) The date and, when appropriate, the time of the activity documented;
>
> (3) *The signature or initials of the person performing the activity;* and

[38]Complainant has knowledge of this incident as he was directly involved with the batch. In addition to at least two members of management, [redacted] As noted in footnote 30, ABTRAQ should show an audit trail with respect to this incident.

> (4) Where appropriate, the identity of the product and the lot code, if any.[39]

It was not unusual for management to disregard situations involving severe breaches of the most basic regulatory requirements. In July of 2020, Complainant became aware of projection pages missing test results associated with nine batches of product. For each batch, a projection page missing test results was approved by three analytical lab chemists and one QS auditor. In essence, the certifications as to the test results were patently false as the test results were not included.

What occurred represented a major and serious breakdown in the controls designed to ensure that the product met specification.[40] Management at the Sturgis site was aware of what occurred, that is, 36 serious performance errors for nine batches of product in a short period of time. Signing off on projection pages with missing test results was repeated multiple times. This was neither inadvertent nor isolated. It meant that a complete breakdown had occurred.

Despite the blatant nature of what occurred, and its egregiousness in terms of putting consumer safety at risk, management took no corrective action in terms of discipline. Nor were remedial measures put in place to reduce the likelihood of a recurrence.

5. Inaccurate Maintenance Records

The cGMPs and 21 CFR § 106.30(f), in particular, provides in pertinent part that:

> [a] manufacturer shall ensure that equipment and utensils used in the manufacture of infant formula are cleaned, sanitized, and *maintained* at regular intervals to prevent adulteration of the infant formula.
>
> > (1) An individual qualified by education, training, or experience to conduct such a review shall review all cleaning, sanitizing, and *maintenance* to ensure that it has been satisfactorily completed.
> >
> > (2) A manufacturer shall make and retain records on equipment cleaning, sanitizing, and *maintenance*, in accordance with § 106.100(f)(4).

[39]Emphasis added.

[40]Complainant discovered this situation. A very large number of individuals were made aware as it affected multiple job functions. Most of the QS staff was aware. A large number of members of the analytical lab were made aware. In addition to management, at least 10 people, including the Complainant, have knowledge of this episode. If proper procedures were followed for making corrections to the projection pages, a record should exist showing a signature for a previous date. If the projection pages signed in this manner are no longer in the batch records, then the batch records were falsified to conceal what occurred.

In terms of records, 21 CFR § 106.100(f)(4) requires that

> [r]ecords, in accordance with § 106.30(f), on equipment cleaning, sanitizing, and maintenance that show the date and time of such cleaning, sanitizing, and maintenance and the production aggregate number of each infant formula processed between equipment startup and shutdown for cleaning, sanitizing, and maintenance. *The person performing and checking the cleaning, sanitizing, and maintenance shall date and sign or initial the record indicating that the work was performed.*[41]

In addition, the cGMPs for infant formula and 21 CFR § 106.35, in particular, provides in pertinent part that:

> (b) All systems shall be designed, installed, tested, and *maintained* in a manner that will ensure that they are capable of performing their intended function and of producing or analyzing infant formula in accordance with this subpart and subpart C of this part.
>
> > (1) A manufacturer shall ensure, at any point, step, or stage where control is necessary to prevent adulteration of the infant formula, that all hardware is routinely inspected and checked according to written procedures and that hardware that is capable of being calibrated is routinely calibrated according to written procedures.
> >
> > * * * * *
> >
> > (3) A manufacturer shall ensure that each system is validated prior to the release for distribution of any infant formula manufactured using the system.[42]
>
> (c) A manufacturer shall make and retain records, in accordance with § 106.100(f)(5), concerning mechanical or electronic equipment.

In terms of records, 21 CFR § 106.100(f)(5) requires that

> [r]ecords, in accordance with § 106.35(c), on all mechanical and electronic equipment used in the production or quality control of infant formula. These records shall include:
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> * * * * *

[41]Emphasis added. It should be noted and emphasized that the Sturgis site *did not and does not* require "the person performing and checking the cleaning, sanitizing, and maintenance" to "date and sign or initial the record indicating that the work was performed."

[42]Emphasis added.

> (iii) Records that document installation, calibration, testing or validation, and maintenance of the systems used;

The maintenance department at the Sturgis site is responsible for making sure the equipment at the Sturgis site is maintained and functioning properly. In order to do this, the maintenance department has their own tasks to complete on a scheduled basis. Once a maintenance technician physically completes a task, he or she is required to indicate the completion of the task in the web-based program. Complainant was advised on multiple occasions by credible sources that certain maintenance technicians regularly indicate on the web-based program that tasks have been completed when in reality they have not been completed.

It has also been reported to the Complainant that supervisory staff in the maintenance department have been known to falsify root causes when participating in CAPA investigations.[43] One credible source reported that an incident was blamed on an operator when further investigation demonstrated a mechanical issue. Management and maintenance officials looked the other way despite evidence of a mechanical failure.[44] As opposed to accepting responsibility for mechanical and other failures associated with equipment, it is not uncommon for maintenance supervisors to blame others instead of addressing the root cause.

6. Premature Release of Holds

The mandate of the cGMPs and 21 CFR § 117.110(a), in particular, require that "[t]he manufacturer, processor, packer, and holder of food must *at all times* utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.[45] Furthermore, 21 CFR § 117.305 requires that records must:

[43]As an example, Complainant became aware of a situation where one of the seamers was seaming two ends to a can instead of seaming one end to a can. When two ends are seamed to a can this causes significant seam integrity issues. Maintenance technicians were able to prove this was directly caused by the feeder that feeds can ends to the seamer. Maintenance management did not want to take the blame as they were responsible for the seamer functioning properly. Maintenance management blamed the issue on the powder packaging operator who set up the seamer. The particular seamer was able to seam two different can diameters. When changing can sizes, the seamer had to be reconfigured. If not done properly, it would cause seam integrity issues. However, it would not cause the seamer to apply two ends to a can. Both QA and maintenance management knew that the operator did not make a mistake, but they chose to blame him/her anyway.

[44]Complainant has reason to believe that management was aware of the original findings of an equipment failure. However, to appease the maintenance manager, management changed the root cause. [redacted] However, it was also the Complainant's experience, which was shared by colleagues, that management sought to avoid calling into question the performance of others as they feared that there would be retaliatory disclosures as to improprieties associated with their own conduct. This was particularly prevalent among senior members of management and long-term employees.

[45]Emphasis added.

* * * * *

> (b) *Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities*;
>
> (c) Be *accurate*, indelible, and legible; . . . .[46]

In addition, 21 CFR § 106.40(d) provides:

> A manufacturer shall develop written specifications for ingredients, containers, and closures used in manufacturing infant formula and shall develop and follow written procedures to determine whether all ingredients, containers, and closures meet these specifications. *When any specification is not met, an individual qualified by education, training, or experience shall conduct a documented review, shall determine whether a failure to meet such a specification could result in an adulterated infant formula, and shall make and document a material disposition decision to reject the ingredient, container, or closure or the affected infant formula; to reprocess or otherwise recondition the ingredient, container, or closure or the affected infant formula; or to approve and release the ingredient, container, or closure or the affected infant formula for use*.[47]

When a PNC or an NC was initiated for a batch, what were referred to as isolation reports, essentially holds, were created for the batch. The holds associated with isolation reports were not to be removed until the PNC or NC was adequately addressed. This meant that there had to be signoffs by management and pertinent specialists as to the various factors that prompted the PNC or NC. In other words, documentation must be in the batch record to establish that the basis for the PNC or NC had been adequately addressed.

However, Complainant consistently encountered situations where he and others were directed by management to prematurely sign off on isolation reports without having the requisite documentation demonstrating that it was acceptable to remove the hold and release the batch. In order to release the batch, all affected product has to be acceptable for release, that is, all release criteria had been met with supporting documentation establishing that all the requisite approvals had been secured.

Quite simply, the representation that Complainant and others were directed to make was false. All of the criteria had not been met. The approval for the release of the hold was premature. The sign off on the holds were premature. All release criteria had not been met. Management was aware of the absence of adequate supporting documentation but nonetheless directed that the hold

[46]Emphasis added.

[47]Emphasis added.

be released. Most of the time when this occurred, the requisite supporting documentation was provided in the evening after the release of the hold.[48]

B. RELEASE OF INFANT FORMULA

The cGMPs and 21 CFR § 106.30, in particular, provides in pertinent part that:

> (a) A manufacturer shall ensure that equipment and utensils used in the manufacture, processing, packing, or holding of an infant formula are of appropriate design and are installed to facilitate their intended function and their cleaning and maintenance.
>
> (b) A manufacturer shall ensure that equipment and utensils used in the manufacture, processing, packing, or holding of an infant formula are constructed so that surfaces that contact ingredients, in-process materials, or infant formula are made of nontoxic materials and are not reactive or absorptive. A manufacturer shall ensure that such equipment and utensils are designed to be easily cleanable and to withstand the environment of their intended use and that all surfaces that contact ingredients, in-process materials, or infant formula *are cleaned and sanitized, as necessary, and are maintained to protect infant formula from being contaminated by any source.*[49]

For several years, some of the equipment associated with the drying process at the Sturgis site was failing and in need of repair.[50] As a result, a number of product flow pipes were pitting and leaving pin holes. This allowed bacteria to enter the system and, at times, led to bacteria not being adequately cleaned out in clean-in-place ("CIP") washes. This, in turn, caused product flowing through the pipes to pick up the bacteria that was trapped in the defective areas of the pipe.

The Micro Batches

Prior to the 2019 FDA audit, management authorized the release of infant formula that tested positive for micros. The batch of infant formula in question was the batch that had triggered

[48]At least two members of management were aware of this practice as they directed the Complainant and, at times, others to direct the premature closure of a hold. In addition to the Complainant, [redacted] Documentary evidence should be available in the form of work orders where the Complainant's signature approving the closing of the hold was crossed out and then signed on a subsequent day. Most often it was on the following day.

[49]Emphasis added.

[50]In terms of the flow pipes, Complainant was advised by an operator that leadership at the Sturgis site was aware of the failing equipment anywhere from five to seven years from the event occurring. *See*, e.g., 21 CFR §§ 106.35(b); 106.55; 117.80(c)(2); 117.80(c)(7).

the internal investigations into the product flow pipes and the investigation into the spray balls. This episode was generally referred as "the micro batches" at the Sturgis site.

Since the micros were discovered during the standard batch testing (10 samples pulled evenly throughout the production of the batch, not including the first and last can produced),[51] 15 additional samples were taken and tested. Of these additional samples, multiple samples tested positive for micros. At that point, the decision was *not* made to destroy the entire batch. Instead, a time code removal was performed.[52]

Management decided to add so many minutes prior to and following each timeframe to "ensure" that they had eliminated all the product with micros. However, once the product was culled out, an additional set of testing was *not* performed to provide evidence that all the micro-positive product was captured and destroyed.[53] The infant formula was released commercially without supporting documentation to suggest it was compliant and safe for consumption.[54]

C. THE 2019 FDA AUDIT

During the 2019 FDA audit, it was generally known that the Sturgis site was worried what the FDA would find about the micro batches. Throughout the audit, QA leadership kept QS staff apprised. One member of management stated that the FDA was on the "right trail." She even volunteered that she was amazed that the FDA was unable to discover what occurred with the micro batches.

Once the FDA audit was over, staff and department managers congratulated each other on a successful FDA audit. Complainant came to learn of a meeting where a senior QA official was understood to have admitted the awkwardness of having to avoid providing direct answers to

[51]At the time, this was the standard micro sampling procedure. During the 2019 FDA audit, the FDA cited the Sturgis site for not sampling adequately for micro testing. As a result, the division and the Sturgis site have increased their micro sampling. It is Complainant's recollection that each division site now pulls 30 samples, not including the first and last can produced.

[52]On every can produced, the Julian date and the time the can was produced is printed on the bottom of the can. When a time code removal is performed, every can that contains a time that falls within the affected time frame is culled out and discarded.

[53]Complainant has direct knowledge of this situation as this was a batch for which he was directly involved. He became aware of the situation from records provided to him. [redacted] Excluding members of management, including at the division level who were also aware of what occurred, at least five individuals, including the Complainant were aware of what occurred. The records associated with the batch should reflect the time code removal and the failure to undertake a follow-up test.

[54]At the time, Complainant told his supervisor that he was not comfortable with the decision to release the product. It is the Complainant's understanding that senior management was under significant pressure to meet its "numbers" as the Sturgis site had already had to destroy $8 million in product.

questions asked by the FDA.[55] While Complainant does not know what precisely was withheld from FDA officials, he is aware of a conscious effort to avoid disclosure.[56]

"Preparing" files for Auditors

In addition, in conjunction with FDA and corporate audits, Complainant became aware of what he reasonably believed was a practice of "sanitizing" files before furnishing them to auditors. It involved records being pulled and reviewed by management officials apart from where the auditors were located. He was also led to believe that some records were culled before furnishing a file to the auditors. Complainant does not know what actually took place. But he had and has concerns based upon what he observed in other contexts during his time at the Sturgis site.[57]

D. CLEAN-IN-PLACE (CIP) STAFFING AND PRACTICES

The CIP practices at the Sturgis site were inadequate in countless ways. Aside from being dangerously lax in terms of product safety, they suggest countless violation of cGMPs. Despite concerns raised with management by the Complainant and others, the questionable practices were allowed to proliferate.

1. No Regularized Practice of Verifying that CIP Work Was Performed

The cGMPs and 21 CFR § 106.30(f), in particular, provides that:

> [a] manufacturer shall ensure that equipment and utensils used in the manufacture of infant formula are cleaned, sanitized, and maintained at regular intervals to prevent adulteration of the infant formula.
>
> > (1) An individual qualified by education, training, or experience to conduct such a review shall review all cleaning, sanitizing, and maintenance to ensure that it has been satisfactorily completed.
> >
> > (2) A manufacturer shall make and retain records on equipment cleaning, sanitizing, and maintenance, in accordance with § 106.100(f)(4).

[55]It was generally known that this official is reported to have stated something along the lines of "All I could do was smile. I couldn't answer their questions without incriminating the site."

[56]All of QS was aware of the Sturgis site being worried what the FDA would find. A far greater number of employees were present when a member of management admitted to withholding information from the FDA.

[57]The Sturgis site has a history of misleading Abbott's corporate audit team. After the Sturgis site covered up the 2010 beetle infestation such that within a month or so after the corporate audit, Abbott recalled numerous batches affected by the infestation and shut the plant down temporarily for cleaning.

In addition, 21 CFR 106.100(f)(4) provides that

> [r]ecords, in accordance with § 106.30(f), on equipment cleaning, sanitizing, and maintenance that show the date and time of such cleaning, sanitizing, and maintenance and the production aggregate number of each infant formula processed between equipment startup and shutdown for cleaning, sanitizing, and maintenance. *The person performing and checking the cleaning, sanitizing, and maintenance shall date and sign or initial the record indicating that the work was performed.*[58]

The Sturgis site relies on what is generally referred to as a checklist for its CIP ("CIP checklist") process for equipment. It is essentially a document that directs the operators on how to perform the CIP. It lists all the steps that need to be performed as part of the CIP process such as what needs to be done to prepare the equipment for the CIP; what needs to be done while the CIP is running; and what needs to be done after the CIP is finished.[59] At the Sturgis site, the CIP checklist is not part of the records of a batch and therefore is not subject to review by QS.

The CIP checklists are controlled by the manufacturing departments: processing, drying, and dry blending. Each department creates its own CIP checklist. A committee associated with each department controls all changes to their CIP checklist. The committee decides if a suggested change is needed. For every task in the CIP checklist, there is a provision for an operator to sign and date for completing that task. However, no one reviews the checklists to determine whether the steps were taken, including providing the requisite signature.

At the Sturgis site, there is no requirement for those performing the CIP work to sign and date any document verifying the performance of the work. No review or enforcement takes place by QS or anyone at the Sturgis site. If an operator is not inclined to sign the CIP checklist, no one is held accountable. The checklists are maintained by each department and are not part of the batch records.

Management was well aware of the inadequacy of the monitoring of the CIP checklists.[60] On numerous occasions, Complainant, as well as others, specifically requested that the CIP

[58]Emphasis added. Again, it should be noted and emphasized that the Sturgis site *did not and does not* require "the person performing and checking the cleaning, sanitizing, and maintenance" to "date and sign or initial the record indicating that the work was performed."

[59]Some examples would include spraying down the inside of the equipment; ensuring the chemical hoses are properly connected to the equipment; and verifying the absence of any remaining product or water in the equipment after the completion of the CIP.

[60]This was common knowledge throughout these production departments (processing and dry blending). Complainant became directly aware of this failure when he was a dry blending operator. In addition to management, at least seven in QS knew that the CIP checklists exist and the absence of any meaningful monitoring. Over 20 people in the two production departments are aware of the CIP checklists and the inadequate monitoring of the checklists.

checklists be converted to a work order, be subject to Abbott's change control processes, and be audited to ensure compliance with FDA protocols. Their requests were repeatedly rejected.

2. Lack of Adequate Education, Training, or Experience

The cGMPs for infant formula and 21 CFR § 106.10(a), in particular, provides that:

> [a] manufacturer *shall* employ sufficient personnel, *qualified by education, training, or experience, to perform all operations*, including all required recordkeeping, in the manufacture, processing, packing, and holding of each infant formula and to supervise such operations to ensure that the operations are correctly and fully performed.[61]

The cGMPs for infant formula and 21 CFR § 106.30(f), in particular, also provides that:

> [a] manufacturer shall ensure that equipment and utensils used in the manufacture of infant formula are cleaned, sanitized, and maintained at regular intervals to prevent adulteration of the infant formula.
>
> > (1) An individual *qualified by education, training, or experience* to conduct such a review shall review all cleaning, sanitizing, and maintenance to ensure that it has been satisfactorily completed.[62]

What is often referred to as a "CIP chart" is a chart that records the mechanical testing as part of the CIP process and the chemical concentrations used in the CIP process. For example, the CIP Chart also shows when one piece of equipment turns on and off. The chart shows at the cleaning stage and at the sanitization stage how much of each chemical is being used for cleaning.

In 2019, management at the Sturgis site decided to no longer have the CIP engineer or a quality engineer review CIP charts after a cleaning was performed on stationary equipment. The recommendation was made to create a position and hire an individual who would undergo the proper training to be able to understand and review these charts. However, the two ranking members of the committee, the QS manager and the site compliance manager, rejected the recommendation and chose to have a contingent employee "review" the charts instead.

On a number of occasions, Complainant raised concerns with management as to the inadequacy of the training and experience of those individuals conducting the CIP review process.[63] Since the contingent worker did not have the experience, knowledge base, or training,

[61]Emphasis added.

[62]Emphasis added.

[63]All of which was consistent with the mandate of the cGMPs and 21 CFR §§ 106.30(f)(1); 117.4(b) in particular. Two of Complainant's colleagues brought the situation to Complainant's attention. In addition to

he or she could only audit the chemical concentration information in the CIP chart.[64] It was and remains the Complainant's view, which was shared by others, that the Sturgis site did not,[65] and still does not, have someone of sufficient experience or training conducting the review process of the CIP charts.[66]

3. Inadequate Review of CIP Charts

The cGMPs for infant formula and 21 CFR § 106.35(b), in particular, provides in pertinent part that:

> [a]ll systems shall be designed, installed, tested, and maintained in a manner that will ensure that they are capable of performing their intended function and of producing or analyzing infant formula in accordance with this subpart and subpart C of this part.
>
> > (1) A manufacturer shall ensure, at any point, step, or stage where control is necessary to prevent adulteration of the infant formula, that all hardware is routinely inspected and checked according to written procedures and that hardware that is capable of being calibrated is routinely calibrated according to written procedures.
> >
> > * * * * *
> >
> > *(3) A manufacturer shall ensure that each system is validated prior to the release for distribution of any infant formula manufactured using the system.*
>
> (c) A manufacturer shall make and retain records, in accordance with § 106.100(f)(5), concerning mechanical or electronic equipment.

management, the leadership of the three departments were well aware of the decision to hire an untrained individual lacking in relevant experience and education.

[64]At the time of Complainant's termination, no one in QS had the appropriate training or knowledge base needed to review the CIP charts. The knowledge base for this task would require substantial training and experience.

[65]During one of the 2019 micro events, one of the root causes was an electrical shortage that caused some of the spray balls (cleaning chemicals are shot through the system via the spray balls) inside the processing equipment to malfunction. As a result, the spray balls were covered in caked-on moldy product. This malfunction could have been caught simply by a review of the CIP chart by experienced and properly trained CIP staff. Indeed, this issue was discovered on a CIP chart several weeks later once QA leadership asked a CIP engineer, who had the requisite training, to take a look at the chart pertaining to this CIP.

[66]Prior to August of 2020, the absence of sufficiently trained and experienced personnel had been ongoing for well over a year. This was not an oversight on the part of management. Management fully understood the importance of having someone with adequate experience and training.

It is the Complainant's understanding that the Sturgis site has been reporting to the FDA that CIP charts were reviewed prior to the release of each batch.[67] Such an assertion was false and, importantly, materially false. The only time someone would review the CIP charts was when problems arose. The contingent worker was basically gathering and filing the charts. Given their lack of experience and inadequate training, they were unable to undertake a credible review of the CIP charts.

But aside from a lack of training and experience, the audit of the CIP charts was inadequate. No audit or review of the CIP checklists takes place to ensure that the requisite steps were taken. The CIP checklists tell operators what to do or how to perform the CIPs. The CIP chart only shows whether everything mechanically worked correctly and whether or not the correct chemical concentration was used.

The CIP chart does not state whether or not the equipment is actually clean or whether a CIP is performed properly. For example, unlike the CIP chart, the CIP checklists literally direct an operator, after the CIP is complete, to open the equipment and visually inspect for any missed product. If there is still product in the equipment after the CIP, the check list directs the CIP to be redone.

4. Spot Cleaning Instead of Entire Area Cleaning

The cGMPs for infant formula and 21 CFR § 106.20(a), in particular, provides that:

> [b]uildings used in the manufacture, processing, packing, or holding of infant formula shall be maintained in a clean and sanitary condition and shall have space for the separation of incompatible operations, such as the handling of raw materials, the manufacture of the product, and packaging and labeling operations.

Spot cleaning is usually done after a protein-free CIP takes place. In order to provide data stating an environment is truly protein free, the lab takes environmental swabs. If one of the swabs comes back positive for protein, that specific spot is re-cleaned and re-tested. If an environmental swab tests positive for protein, Abbott policy requires that the entire environment be re-cleaned and re-swabbed. But again, meeting metrics took precedence. The practice at the Sturgis site was to re-clean the localized area and then re-test. The policy was repeatedly disregarded during Complainant's time at the Sturgis site.[68]

[67]Indeed, a member of management stated to others on several occasions that this is what was being told to FDA officials.

[68]Complainant first experienced this ongoing practice as a dry blending operator. It was a common practice in the processing, drying, and dry blending departments. Several people from QS previously worked in production, and they too were aware of these practices as it was discussed with Complainant from time to time. In addition to management, the lab performing the swabs was also aware of the practice.

E. FAILURE TO TAKE CORRECTIVE MEASURES

The mandate of the cGMPs and 21 CFR § 117.110(a), in particular, require that

> [t]he manufacturer, processor, packer, and holder of food must *at all times* utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.[69]

a. Failure to Correct a Notoriously Deficient Testing Procedure

Complainant was responsible for a testing procedure relating to the export of product that was widely known to be prone to lead to mistakes by highly competent employees. This was common knowledge within the division and the Sturgis site.[70] Complainant was even told by division headquarters that some sites were not using the testing procedure because of the extreme difficulties it posed in leading to errors.

The Sturgis site produces more products affected by this procedure than any other site in the division. In February of 2020, Complainant was explicit in raising concerns as to the efficacy of the testing procedure. He suggested that steps be taken to address the problems with the procedure so as to avoid a recurrence of what had happened to him as well as countless others within Abbott's operations.

Despite the widely acknowledged deficiencies of the testing procedure, Complainant's suggestion for taking remedial action was rejected by management at the Sturgis site.[71] No remedial action of any kind was suggested or even encouraged. Despite its widely-recognized deficiencies, the testing procedure continues to be used.[72]

b. Inadequate Training and Experience to Interact with Third-Party Labs

Aside from failing to comply with the mandate of 21 CFR § 117.110(a) to reduce natural or unavoidable defects, the Sturgis site failed to comply with the requirements of the cGMPs of

[69]Emphasis added.

[70]It was even acknowledged at a 2019 Abbott Nutrition conference attended by the Complainant with other QA representatives.

[71]As further evidence of the nature of the retaliation against those who raised concerns, Complainant's isolated mistake associated with the procedure was used against him. It was his first and only mistake associated with the procedure. The irony was that the Complainant became the "go to" expert within the division as to the testing procedure.

[72]Complainant repeatedly raised his concerns with management at the Sturgis site as well as others at the division level. The deficiencies were widely known despite risk to product safety and quality assurance in the export of product.

having "an individual qualified by education, training, or experience" in a position to make such determinations in interacting with the TPLs. Indeed, 21 CFR § 106.40(d) provides:

> A manufacturer shall develop written specifications for ingredients, containers, and closures used in manufacturing infant formula and shall develop and follow written procedures to determine whether all ingredients, containers, and closures meet these specifications. When any specification is not met, *an individual qualified by education, training, or experience* shall conduct a documented review, shall determine whether a failure to meet such a specification could result in an adulterated infant formula, and shall make and document a material disposition decision to reject the ingredient, container, or closure or the affected infant formula; to reprocess or otherwise recondition the ingredient, container, or closure or the affected infant formula; or to approve and release the ingredient, container, or closure or the affected infant formula for use.[73]

Every division site in the United States utilizes TPLs to test items they are not capable of testing. Sometimes TPLs are also used where it may be more efficient. Except for the Sturgis site, the analytical labs at each site work directly with the TPLs. This can involve highly technical issues requiring significant training and expertise.

The Sturgis site moved the responsibility for interacting with the TPLs to QS. No one within QS had the same level of expertise as the staff of the analytical lab at the Sturgis site. Nor did the Complainant who was made responsible for interacting with the TPLs. He was repeatedly put in situations where he lacked adequate training and experience.

While Complainant tried to compensate for his lack of expertise by seeking input from the analytical lab, he was not qualified to address many of the complexities associated with the TPL. He repeatedly raised concerns with management as to his lack of training and experience. He suggested that, like the other division sites, it should be more competently handled by properly trained staff of the analytical labs.[74]

F. LACK OF TRACEABILITY

The cGMPs for infant formula and 21 CFR § 106.80, in particular, provides that:

> [e]ach production aggregate of infant formula shall be coded with a sequential number that identifies the product and the establishment where the product was packed and that permits tracing of all stages of manufacture of that production

[73] Emphasis added.

[74] In addition to management and members of the analytical lab, [redacted]

> aggregate, including the year, the days of the year, and the period during those days that the product was packed, and the receipt and handling of raw materials used.

The Sturgis site has had significant issues regarding the traceability of its products.[75] QS Sturgis frequently received notification from its warehouse that pallets were found to be either mislabeled or not labeled.[76] Often the batch to which the pallet belonged had already been released and shipped.

The Sturgis site uses an automated pallet labeler. The labeler is supposed to be able to read the pallet, print a label with the correct batch specific information, and apply the label to the pallet. However, the labeler did not always work properly. This was more apt to occur when multiple batches of different products were running. Management at the Sturgis site was well aware of this recurring problem.

Whenever an issue arises during production and a rework is required, every pallet in the affected time frame gets pulled back to the production floor and inspected. To ensure the correct pallets are being selected, lists of pallet identification numbers associated with that batch are reviewed and the pallets pulled. Due to the mislabeled or unlabeled pallets in the warehouse, QS staff never knew with certainty if every affected pallet was retrieved.[77]

III. INADEQUATE INTERNAL CONTROLS

In countless ways, Abbott has failed to implement and actively enforce adequate internal controls with respect to the Sturgis site. This failure does not appear to be limited to the Sturgis site. Officials at the division level were aware of many of the problems and failed to take corrective measures. Corporate policies and practices were and are clearly inadequate. Indeed, there is evidence that some officials at the division and corporate levels may also be complicit.

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[75] In addition, 21 CFR § 106.60 provides that

> (a) A manufacturer shall examine packaged and labeled infant formula during finishing operations to ensure that all containers and packages in the production aggregate have the correct label, the correct use-by date, and the correct code established under § 106.80.
>
> (b) Labels shall be designed, printed, and applied so that the labels remain legible and attached during the conditions of processing, storage, handling, distribution, and use.

[76] Abbott was under a legal duty to ensure that the equipment "be designed, installed, tested, and maintained" so that it will perform as intended. *See*, e.g., 21 CFR § 106.35(b). This includes being routinely inspected and calibrated. *See*, e.g., 21 CFR §106.35(b)(1).

[77] It could also extend to situations where the wrong product could be shipped. [redacted]

A. CONTINUED RELIANCE ON PAPER RECORDS

It is generally recognized that electronic records enhance an entity's ability to monitor activities at more remote locations. The integrity of record-keeping is enhanced as is the ability to track and audit entries and modifications. The continued reliance on paper records at the Sturgis site raises questions, especially with the conversion to electronic records being budgeted.

For reasons not entirely transparent, the proposed conversion has been repeatedly deferred. One reason volunteered by one member of management to the Complainant is that electronic records would make the Sturgis site more accountable to others at the division and corporate level. This same member of management has made the same comment to others, including well after the Complainant's departure.

The ongoing reliance on paper records is suggestive of inadequate internal controls. This is especially so when management at the Sturgis site has repeatedly admitted a desire to keep division and corporate officials from being able to monitor its compliance with regulatory requirements.[78] This need is ever-present with there being multiple episodes where management has consciously misled division officials as to PNCs or NCs or the seriousness of a situation.[79]

B. LACK OF CONFIDENTIAL MEANS OF REPORTING CONCERNS

As the Justice Department has deemed in its guidance for evaluating a company's compliance program, a "hallmark of a well-designed compliance program is the existence of an efficient and trusted mechanism by which employees can anonymously or confidentially report allegations of a breach of the company's code of conduct, company policies, or suspected or actual misconduct."[80]

Proactive measures should be instituted "to create a workplace atmosphere without fear of retaliation, appropriate processes for the submission of complaints, and processes to protect whistleblowers."[81] As exemplified by the Sturgis site, Abbott's practices fail to meet one of the

[78]Every year Complainant was in QS he was told of there being the availability of funding to transition from paper to electronic work orders. Yet the transition never occurred. On several occasions, a member of management told Complainant and [redacted] that the Sturgis site not wanting division officials "to see everything we do at Sturgis." [redacted]

[79]As previously noted, *see* page 10, PNCs and NCs were re-characterized as a quality assessment to avoid the need for approval by division. A quality assessment allowed the Sturgis site to proceed without input and approval from division officials.

[80]U.S. Dep't of Justice, *Evaluation of Corporate Compliance Programs* ("Compliance Program Guidance"), at 6 (June 2020)("Confidential reporting mechanisms are highly probative of whether a company has 'established corporate governance mechanisms that can effectively detect and prevent misconduct.'")(citing U.S. DEP'T OF JUSTICE, U.S. ATTORNEYS' MANUAL, § 9-28.800; U.S.S.G. § 8B2.1(b)(5)(C)).

[81]*Compliance Program Guidance, supra* note 80, at 6.

basic hallmarks of an effective compliance program. It is a workplace where fear of retaliation is palpable. The basis for that fear is well founded.

1. A Palpable Fear of Retaliation Pervades the Sturgis Site

The Complainant can attest to a number of instances in which his identity as the source of elevating concern was disclosed by management at the Sturgis site. Employees are not free to raise concerns without fear of retaliation. In a recent whistleblower investigation conducted by MIOSHA, the Michigan equivalent of OSHA, management identified in the presence of other staff the names of the individuals being questioned. Even at the corporate level, no meaningful steps were taken to protect the identity of witnesses or to protect against retaliation.[82]

As a further example, the Complainant brought an incident involving a stun gun to the attention of Abbott's office of Employee Relations ("ER"). As a matter of corporate policy, complaints to ER are to be considered protected activity. Employees are led to believe that disclosures to ER will be treated as confidential. At the time he made the complaint to ER, he and his colleague actually discussed the likelihood of retaliation. Despite Abbott's ostensible policy, his identity was disclosed to others at that Sturgis site and retaliation soon followed.[83]

2. No Independent Investigations

In addition, the "independent" investigation conducted by ER that led to Complainant's termination was fabricated. It was, in part, drafted by the supervisor seeking his termination. No follow-up inquiry took place despite an explicit assurance that his side of the allegations made against him would be sought. Instead, the investigator allowed the supervisor to literally draft or re-draft portions of the so-called investigative report.

The investigation was neither "properly scoped" nor "independent, objective, appropriately conducted, and properly documented" as prescribed by the Department of Justice's guidance for corporate compliance programs.[84] Aside from not fully investigating what occurred, the investigator demonstrated a remarkable lack of knowledge of the relevant issues. She was in no position to make a determination.

[83]It should be further noted that Abbott refused to place a litigation hold on all records relating to the Complainant when notified in writing that a complaint had been filed with federal and state authorities. The refusal was made in writing and a copy will be provided on request. Counsel has ongoing concerns as to whether records have been altered or destroyed.

[84]*Compliance Program Guidance, supra* note 80, at 16.

C. LACK OF ACCOUNTABILITY

As Complainant grew in experience and understanding of the operations at the Sturgis site, he became increasingly concerned as to the absence of accountability in terms of regulatory compliance. He spoke out. He believed the breadth of the lax practices put in jeopardy the safety of the product being produced. Consistent with 21 CFR § 117.110(a) and other regulatory provisions, he and others reasonably believed that Abbott was under a duty to minimize the likelihood of adulterated product.

1. Overlooking the Failure to Follow cGMPs

Discipline for failing to follow Abbott policies and cGMPs was selective.[85] It was selectively employed to chill outspoken employees. It was almost always overlooked when favored employees were involved.[86] Certainly, employees who were part of management's social network were largely if not entirely exempt from discipline. More than any other site, the Sturgis site was reputed to have the largest number of certificates of analysis ("COA") returned for incompleteness or false information. Yet no one was held accountable for this ongoing practice.

2. Calling Regulatory Concerns "Petty"

Most often, Complainant directed his concerns as to a lack of accountability to his supervisor. But other members of management were involved, including officials at the division level. His concerns were summarily dismissed as "petty." This extended to situations where unaddressed PIRs were intentionally placed in batch files after the release of a batch, thereby suggesting a regulatory violation.[87]

In these instances, the batch files were effectively falsified to suggest a regulatory violation when none existed. It was largely due to lax practices that PIRs were allowed to be submitted late

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[85]A classic example is one of the bases for the Complainant's termination. He is alleged to have made a mistake on one of nine batches of product. However, he spotted the oversight, disclosed it, and then had the incomplete projection pages corrected for each batch. Four employees had verified or certified the projection pages on nine batches. Yet none of the latter were terminated. Moreover, whether the Complainant was responsible for the sole oversight is highly questionable as he was following his training when the alleged oversight occurred.

[86]When a favored employee brought a stun gun into the facility at the Sturgis site and shot it twice, management disregarded Abbott policy in failing to bring the incident to the attention of ER. Previously, employees were terminated when employees had guns in their car in the parking lot. In this particular situation, the supervisor admitted that the employee was given a "free pass."

[87]This was in part retaliation directed toward the Complainant for being outspoken in terms of compliance issues. In these situations, Complainant was able to catch the unaddressed PIR and take the necessary measures to ensure that the issue had been adequately addressed. Yet management was aware of the practice and took no action despite putting the Sturgis site at risk for regulatory violations. This practice was limited to the Complainant and suggestive of management's complicity in the retaliation for his efforts in having raised regulatory concerns.

by management. Complainant suspects that some of what occurred was intended as retaliation for his efforts to insist upon timely submission of PIRs. Management looked the other way, including officials at the division level.

3. Inconsistent and Disparate Treatment

Disciplinary actions and incentives have not been consistently applied as prescribed by the Department of Justice's guidance for evaluating compliance programs.[88] At the Sturgis site, discipline is not applied consistently. Favored employees are not disciplined in the same manner as those viewed as being outspoken as to compliance issues. Enforcement is selective and inconsistent thereby signaling retaliation to those who raise concerns.

More serious is the fact that members of management who are intimately involved with circumventing what exist in terms of internal controls are not subject to any discipline other than for failures to meet their metrics. These are individuals who also repeatedly misled officials at the division and corporate level. These are individuals who knowingly direct and approve of actions in direct violation of FDA regulations. A culture of compliance does not exist at the Sturgis site as mandated by the FDA and the Department of Justice's guidance.[89]

D. HIGHLY QUESTIONABLE INCENTIVE STRUCTURE

It is Complainant's understanding that management at the Sturgis site is rewarded in terms of bonuses of some sort for meeting metrics vis-à-vis other production sites. Productivity is tracked based upon meeting certain data points. Each site provides the information. It was well known to the Complainant and others at the Sturgis site that the information provided to evaluate productivity is frequently and, at times, blatantly false.

Electronic reports were completed where boxes were checked. Despite the reality of what occurred, the Sturgis site would routinely check the boxes saying in effect "yes" to questions addressing, among others: "no discrepancy in work order"; "everything correct in work order"; "did correctly test every time"; and "perfect batch." To all of the questions, the Sturgis site would answer "yes" every time.[90] It was generally recognized among employees at the Sturgis site that management simply "lied" on these reports.

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[88] *Compliance Program Guidance, supra* note 80, at 13.

[89] *Id*., at 4.

[90] To be more specific, this information was tracked through a "perfect batch" form. On this form were tracked, among others, discrepancies (missing signatures/dates or data entries), quality assessment/PNC/NC information, and destruct information. A member of the QS staff tracked the information. For certain periods, this included the Complainant. Despite the information being tracked, the QS manager disregarded the tracked information and dictated what to report so that the Sturgis site would have a perfect batch metric each month. Rarely would the underlying data support a perfect batch metric.

Complainant firmly believes that the unrelenting pressure to meet metrics was a factor in overriding product safety concerns. The failure to meet metrics was weaponized against employees. When product safety concerns were raised, employees were told that they would be singled out and held personally responsible for failing to meet certain metrics in terms of production.[91] Meeting metrics was an all-consuming consideration in almost every decision.

As the Justice Department has also deemed in its guidance for evaluating a company's compliance program that "[a]nother hallmark of effective implementation of a compliance program is the establishment of incentives for compliance and disincentives for non-compliance."[92] The incentives relative to compliance are insignificant if not nonexistent at the Sturgis site. Despite the incredible risks associated with failing to meet FDA regulations, meeting quantitative metrics was and is the governing consideration at the Sturgis site.

E. MATERIAL CONTINGENT LIABILITY

Certifications of compliance with FDA regulations, including cGMPs, are required to secure rebates under the Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC Program"). The WIC Program provides federal grants to states for supplemental foods, health care referrals, and nutrition education for low-income pregnant, breastfeeding, and non-breastfeeding postpartum women, and to infants and children up to age five who are found to be at nutritional risk. Abbott is a major participant in the WIC Program.

Rebates are provided to manufacturers who supply infant formula for the program and are otherwise eligible. Eligibility for the WIC program is governed by 42 U.S.C. § 1786(f)(15):

> To be eligible to participate in the program authorized by this section, a manufacturer of infant formula that supplies formula for the program shall—
>
> > (A) register with the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.); and
> >
> > (B) before bidding for a State contract to supply infant formula for the program, *certify with the State health department that the formula complies with such Act and regulations issued pursuant to such Act*.[93]

[91] Indeed, for a period of time, an employee who caused the site to miss a metric had a one-on-one performance review with the site Director.

[92] *Compliance Program Guidance, supra* note 80, at 13.

[93] Emphasis added.

The regulations for the WIC Program and 7 CFR § 246.2, in particular, states that "[i]nfant formula means a food that meets the definition of an infant formula in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)) and that meets the requirements for an infant formula under section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) and the regulations at 21 CFR parts 106 and 107." As has been laid out in some detail in the foregoing, credible evidence exists to suggest that Abbott has for some time not fully complied with FDA regulations and 21 CFR part 106 in particular.

The regulations relating to the cGMPs appear to directly apply to many of the violations observed and reported by the Complainant and others at the Sturgis site. Abbott is a major beneficiary of rebates under the WIC program. To what extent it benefits from the five-to-six-billion-dollar a year program is unclear. Yet the prospect of being terminated from the WIC program poses a material contingent liability. Given what the Complainant has reported, the veracity of certifications provided to federal and state officials are suspect.

F. ***Fraud Against Shareholders.***

Fundamental to federal law relative to fraud against shareholders is the issue of materiality. However, materiality is not limited to quantitative materiality. "The omission or misstatement of an item in a financial report is material if, in the light of surrounding circumstances, the magnitude of the item is such that it is probable that the judgment of a reasonable person relying upon the report would have been changed or influenced by the inclusion or correction of the item. This formulation in the accounting literature is in substance identical to the formulation used by the courts in interpreting the federal securities laws. The Supreme Court has held that a fact is material if there is –

> a substantial likelihood that the . . . fact would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available."[94]

"[A]n intentional misstatement of immaterial items in a registrant's financial statements may violate Section 13(b)(2) of the Exchange Act and thus be an illegal act."[95] Among the considerations that may well render material a quantitatively small misstatement of a financial statement item are –

[94] 17 CFR Part 211, Staff Accounting Bulletin No. 99 – Materiality ("SAB No. 99") (citing *TSC Industries v. Northway, Inc.*, 426 U.S. 438, 449 (1976). *See also Basic, Inc. v. Levinson*, 485 U.S. 224 (1988). "As the Supreme Court has noted, determinations of materiality require "delicate assessments of the inferences a 'reasonable shareholder' would draw from a given set of facts and the significance of those inferences to him . . . ." *TSC Industries*, 426 U.S. at 4) (internal citation omitted).

[95] *Id.*

- whether the misstatement affects the registrant's compliance with regulatory requirements

It is unknown whether and, if so, to what degree, the situation with respect to the suspected regulatory violations outlined above may bear on Abbott's financial statements. But from the standpoint of investors, the implications of the violations are apt to be material in ways that may not be fully appreciated at this point in time. Certainly, the degree to which Abbott has falsely certified its compliance with the cGMPs is apt to heighten the materiality to shareholders.

IV. CONCLUSION

Even though Abbott's senior management is now aware of many of the alleged regulatory violations referenced in the foregoing, no serious effort to remedy the violations have been reported to date. Instead, the emphasis appears to be more focused on identifying current employees at the Sturgis site who may have reported concerns to the Complainant. Aside from the mandate of FDA regulations, Abbott's inaction is directly at odds with the mandate of Sarbanes-Oxley mandating adequate internal controls and the Department of Justice's policy mandating effective compliance programs.

Abbott's inaction is also inconsistent with the Corporate Integrity Agreement that it entered into with the Office of Inspector General of the Department of Health and Human Services in May of 2012 as part of a plea agreement. *United States v. Abbott Laboratories*, No. 12-cr-00026 (W.D. Va., filed May 7, 2012). At the same time, Abbott also entered into settlement agreements with various states. Though not directly applicable to Abbott Nutrition, the core concepts apply in terms of the ongoing obligations on the part of Abbott's management and board of directors.

It is further submitted that what is being reported is based upon the Complainant's direct knowledge and, in a few instances, highly credible sources. Throughout his time at Abbott, and even since his departure, others have reported additional concerns that he was unable to verify. In countless situations, he was told by employees that the Sturgis site was like a "house of cards" if employees could speak freely. But the consensus remains that only with the intervention and protections of responsible enforcement officials would employees be inclined to speak freely.