Increased Efficiency of Good Manufacturing Practices (GMPs) Through Area Consolidation

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In

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Abstract

Plant operations personnel are responsible for daily food safety paperwork, including a Good Manufacturing Practices (GMP) monitoring form. These practices of along with the standard sanitation operation practices (SSOP) are considered the backbone of safe, quality food. Before the consolidation project, this large United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) inspected meat processing plant was separated into 42 different monitoring areas. Even though many of these areas overlapped with each other, but there were still certain areas of the plant that were not covered, creating an issue for the FSIS and auditors to complete record review. The main objective was to identify if consolidating areas monitored for GMPs would decrease the amount of time dedicated to checking paperwork, while still producing safe, wholesome food. After consolidation of areas monitored on the GMP form, the amount of areas dropped from 42 to 27. Since changing over the GMP monitored areas, more visual checks throughout the production floor were randomly completed throughout the day by the food safety team to ensure a standard of thoroughness since the newly designated areas encompass more square footage. There would be a range of visual checks on the floor from 3-5 times per production day. From my visual monitoring of the production floor, I noticed that the GMP standards have consistently remained the same compared to before the area consolidation. From a reviewing standpoint, food safety staff can check daily paperwork 8.7 minutes faster daily due to the fewer amount of GMP forms to physically review. Food safety staff has also had a much easier time pinpointing which areas are problematic based on the consolidated list. This helps with corrective actions, audits, and overall plant management.

Acknowledgment

Firstly, I would like to thank my family, mostly my husband, and friends for pushing me to complete this program and go outside my comfort zone. This also includes my work family for always supporting my endeavors and allowing me to use real life industry experiences for the academia world. I also must credit an abounding amount of gratitude to Dr. Joseph Eifert for constantly answering my questions and guiding me along the way when I got a little lost. With his help, I was able to successfully complete this program while working in the crazy, time-demanding agricultural industry full-time.

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Introduction

Background and Setting

Good Manufacturing Practices (GMP) are required to ensure safe, unadulterated food is being produced and eventually entering commerce. This includes a comprehensive program that evaluates, identifies, and then controls potential hazards at every step in the process, similar to that of a Hazard Analysis of Critical Control Points (HACCP) analyzation (Moberg, 1989). The first GMPs were published in 1969 as Part 128 of Title 21 of the Code of Federal Regulations (CFR), however, they were recodified in 1977 and then once again revised and updated in 1986 (Cramer, pg. 2 Food Plant Sanitation, 2013). The most recent revision to the GMP requirements was due to the necessary inclusion to control "undesirable microorganisms."

It is portrayed that GMPs cover all aspects of food manufacturing from employee behavior requirements to the engineering of food production machinery. All of the steps in the manufacturing process have to be analyzed to determine potential issues that could create an environment of chemical and physical contamination. New employee orientations at the plant include initial training for GMP, Standard Sanitation Operating Procedures (SSOP), and general food safety practices. After new employee orientation, several training sessions are organized with production supervisors and the food safety department to reiterate the importance of the mandatory practices. GMP are monitored on a formal food safety document in each department and turned into food safety for recordkeeping. These documents are checked for accuracy and completion.

There are minimal time studies focused on checking food safety paperwork and recordkeeping. It is important that the paperwork with checked accurately, but also, that the team

checking it, is set up for success. Successful recordkeeping includes being concise and direct with areas so that the documents serve as resources instead of just busy work. At this specific food manufacturing facility, reviewing food safety paperwork takes the food safety team upwards of almost 2 hours to complete each day. This time could be spent monitoring the food manufacturing process, training improvements, etc. After taking all this time to review paperwork, there are often issues when the paperwork is requested for record review due to the complex list of areas for GMP documents. Through utilizing a consolidated list of monitored areas, the required review time could be decreased and pinpointing the necessary paperwork will be easier and more effective.

Statement of the Problem

The main issues within the GMP paperwork review process were 1) overlapping areas which caused confusion when completing record review and 2) timeliness for record review.

Purpose of the Research

The purpose of this research study was to identify if consolidating areas monitored for GMPs would increase efficiency of recordkeeping, but still uphold a robust food safety program. The questions guiding the research were the following:

1. Does the number of areas monitored for GMP effect the standard of cleanliness?
2. How will consolidating areas monitored for GMP actually help with effective recordkeeping to create a resource of information?

Objectives of the Research

The amount of time for reviewing GMP documents each day was evaluated for 30 days (of full production, not calendar days) before and after the monitored area consolidation is completed. Alongside this data will be the comparison of necessary corrective actions for mistakes completely on the paperwork. FSIS inspectors and food safety personnel will be interviewed with the progress and attainment levels for record review procedure. Through the evaluation of this material, it will become evident if there is value in consolidating the monitoring list or not. The hypothesis of this research project was that a well-designed consolidated area monitoring list for GMP would result in the same sanitary conditions, whilst increasing the efficiency of formally reviewing documents and documenting issues for each department.

Definition of Terms

1. *Recordkeeping*- the act of keeping track of the history of a person's or organization's activities, generally by creating and storing consistent, formal records (Dictionary.com) Records promote traceability and provide documentation that the food business has followed appropriate practices (North Dakota State University, 2017).
2. *Code of Federal Regulations*- a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government (Center for Devices and Radiological Health, 2018)
3. *Food Safety Audit*- a systematic, independent and documented process for obtaining audit evidence, and evaluating it objectively to determine the extent to which the audit criteria are fulfilled (Food Safety Auditing, n.d.).

4. *Good Manufacturing Practices*- generally address matters including appropriate personal hygienic practices, design and construction of a food plant and maintenance of plant grounds, plant equipment, sanitary operations, facility sanitation, and production and process controls during the production of food (Center for Food Safety and Applied Nutrition, 2020).

Review of Literature

The purpose of this literature review was to gain insight on the current good manufacturing practice requirements of food manufacturing plants. This includes but is not limited to the additional programs food manufacturing plants are also required to establish in order to be fully credited and recognized as providing safe, wholesome product (Diaz, 2009).

Current Legal Requirements

Currently, the GMP program follows the same assessment as HACCP which determines whether a requirement is necessary or appropriate after conducting a risk assessment. These risk assessments are utilized to determine if a requirement is appropriate given the associated risks within the process. The GMP regulations are promulgated by the US Food and Drug Administration under the authority of the Federal Food, Drug, and Cosmetic Act. Under this act, there are mandates for proactive steps to ensure only wholesome products enter commerce. This requires a quality approach to manufacturing, assisting companies to minimize contamination and other erroneous errors. GMP regulations can also be referred to as cGMP, with the “c” standing for current. This is to remind manufacturers to employ technologies and operational processes that are up-to-date in order to ensure compliance with the legal requirement. First rate technologies and processes utilized 20 years ago may not be close to adequate in current

manufacturing practices. As time goes on, the knowledge must evolve for how to keep consumers safe through different food safety practices and prevention measures. As the understanding between science and food continues to grow, so does the ability to safeguard society. Consequences of failing to comply with GMP regulations include recalled product, lost sales, government seizure of product, fines, and jail time (ISPE, n.d.).

Prerequisite Programs for Food Safety

In addition to mandatory GMP programs, sanitation standard operating procedures (SSOP) and a HACCP system are the basis of the food-safety system that is often adopted by food manufacturers. Both GMPs and SSOP are the foundational programs for HACCP implementation. All three of these programs require formal documentation. SSOP are procedures developed and implemented to prevent adulteration of products. These procedures breakdown ways to keep equipment free of pathogenic microorganisms (de Oliveira, da Cruz, Tavolaro, & Corassin, 2016). Once pre-operational monitoring has been completed after sanitary protocols have been finalized, it is of the utmost important that employees and visitors follow basic GMPs to prevent any adulteration of clean surfaces or product from entering commerce (Cramer, 2013, pg. 78).

Implementation of GMP

There are many barriers and difficulties that both small and large food companies alike will face when implementing GMP and other food safety programs. Employees come from many different backgrounds in which food safety practices vary greatly. Large companies have more resources at their disposal, making training more feasible and somewhat easier to implement. The difficulty in implementing the food safety programs comes from different backgrounds, constant employee turnover, and maintaining the standard required for safe food production.

There are often weak incentives for voluntary adoption and no tangible benefits of said programs by employees, thus decreasing ability to implement. Employees are not directly affected by not washing their hands when touching food or picking up trash with the correct gloves, so the importance is sometimes mistranslated. The biggest burden of implementing food safety programs is record keeping. Record keeping requires a great deal of verbal communication and a record-keeping culture is necessary. However, if employees come from a background with minimal food safety practices, they will often ignore obvious food safety violations based on what they were taught growing up. The idea of lacking food safety practices during developmental years can widen the gap between food plant requirements and employee comfort. If the company is mandating certain food safe behaviors and procedures, but the employee does not understand the benefit, they will question their employer's motive. Through the explanation and inclusion of employees during the development of food safety programs (such as GMP), a certain investment attitude is invoked, allowing the record keeping aspect to improve and ultimately align with the plant's standards (de Oliveira, da Cruz, Tavolaro, & Corassin, 2016).

Conceptual Framework

Conceptual framework highlights what one will expect to find through specific research. This project's conceptual framework highlights the theory of planned behavior. The efficiency of recordkeeping was improved due to the consolidation of areas monitored; however, individuals could have decreased monitoring intensity due to the change, but this did not happen. This did not happen because employees saw the potential improvement to their time spent at work. The amount of effort had to increase to create an output that was on par with the previous amount of areas monitored. This framework is depicted in the diagram below.

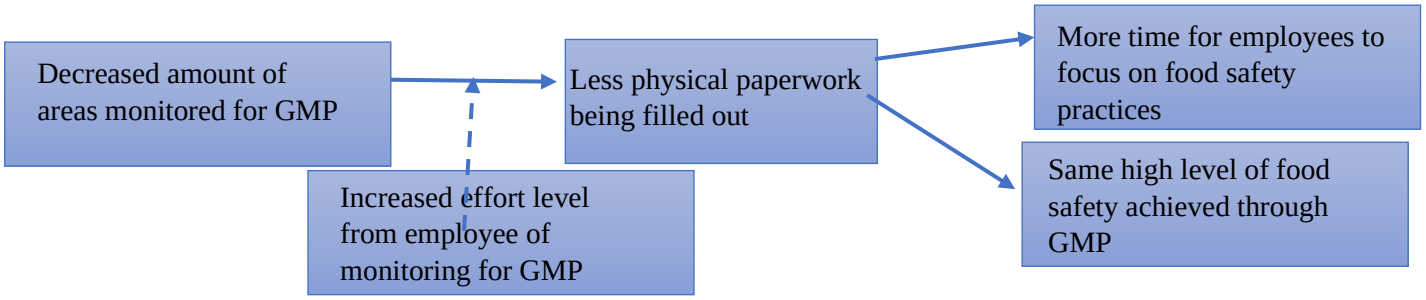


Fig. 1 Conceptual framework of research project

Project Overview

Study Timeline and Participating Audience

The timeline for this study was from January – May 2019. The main participants for this study were the employees from a large, FSIS inspected meat processing plant located in Virginia. Participants involved in the study volunteered at their normal departmental location.

Research Design & Procedure

Before completing the GMP area consolidation, emails were sent out to all production supervisors, superintendents, and operations managers (Appendix A) providing a general outline of how the changeover would occur. Supervisors who had their areas greatly consolidated on the GMP paperwork physically met with the food safety team to review the changes and ensure success when changing to the new practice. USDA supervisors and inspectors were provided a new list of numbers for specific departments when reviewing daily paperwork. This list (Appendix C) was posted near where the GMP paperwork is stored post- record review. The food safety team was heavily involved with the before and after of the consolidation and

volunteered to provide interviews after the project completion (Appendix B). After the switchover, paperwork designated hourly employees, food safety personnel, and USDA team members were asked to fill out an anonymous short survey. The results would assist in confirming success or failure of the consolidation.

The study was both quantitative and qualitative in method and pre-experimental. The quantitative methods included measuring the time recorded to review food safety paperwork, specifically formal GMP forms. The individual measuring the review time would start the clock when one of the five food safety employees flipped the first GMP form for the different areas monitored. When the last area's paper was reviewed, the timer was stopped, and the allotted time was inputted into a Google spreadsheet. This process of measuring the time required to review unconsolidated and consolidated GMP paperwork was recorded daily for 30 days (of full production) each. Once the information was collected, the average was taken from each of the 30 days for comparison. The qualitative methods included visual inspections of the consolidated areas for acceptableness for comparison to the previous smaller inspected areas. The success of consolidating areas can also be measured by the number of corrective actions required before and after the change. These corrective actions are cataloged by date and paperwork specificity. After reviewing the corrective action list for strictly GMP paperwork, the average before and after the consolidation was easily obtained. The average of 30 days before the consolidation and 30 days after the consolidation was used for comparison.

Summary of Outcomes, Discussion, and Recommendations

Research Outcomes

After the consolidation of the areas monitored for daily GMP, the amount of time required for record review was cut down by an average of 8.7 mins or 42%. The food safety team was able to review paperwork quicker and provide it timelier for USDA review. In addition to decreasing amount of time required for record review, efficiency in locating records for audits also increased. As depicted in Table 1.1, the average time for reviewing paperwork before the consolidation was 20.7 minutes compared to the 11.9 minutes average required post monitored area consolidation. The average number of corrective actions on paperwork decreased from an average of 12 to an average of 7 after the consolidation. However, many of these corrective actions continued to be minor clerical errors and not detrimental to food safety standards. This increased efficiency did not come at a cost for quality of inspection or cleanliness of area monitored. The plant floor's cleanliness was measured based on visual checks completed by the food safety team and the FSIS team. During the day, the food safety team would also monitor the camera footage of different areas of the plant, ensuring that areas were maintained even when an employee was not being directly watched in-person. The same standards were upheld and maintained throughout the production day compared to before the consolidation project.

Also, the general emotional reaction to having less paperwork to review was positive in nature and provided a boost in morale within the food safety team. There was also a positive emotional reaction within others while record reviewing for audits and daily FSIS checks.

The project evaluation survey completed by the food safety team after completing the area consolidation indicated that 100% felt the project benefited the plant's food safety standard

and their relationship with production employees. Out of the 37 completed surveys, 37 indicated that consolidating the monitored areas did not decrease the facility's overall facility. One hundred percent indicated that they would like to consolidate the areas monitored for other documentation such as SSOP.

Table 1.1- Average time required to review paperwork 30 days before the area consolidation and 30 days after the area consolidation

GMP Day	Pre-Area Consolidation Time Required (mins)	GMP Day	Post- Area Consolidation Time Required (mins)
1	20.2	1	11.4
2	19.1	2	12.3
3	22.5	3	12.1
4	17.4	4	12.9
5	23.0	5	13.2
6	20.5	6	13.7
7	20.1	7	14.1
8	19.6	8	12.8
9	21.7	9	13.4
10	20.6	10	11.0
11	19.9	11	12.3
12	20.3	12	12.2
13	18.6	13	11.9
14	22.4	14	12.5
15	21.9	15	11.6
16	17.5	16	11.7
17	19.1	17	12.1
18	20.2	18	11.9
19	19.9	19	12.5
20	21.4	20	13.1
21	20.1	21	10.5
22	23.4	22	12.7
23	19.9	23	11.7
24	18.2	24	11.2
25	22.9	25	10.9
26	20.7	26	9.9
27	24.1	27	9.6
28	21.6	28	10.4
29	22.9	29	10.8
30	19.9	30	10.0
Average	**20.7**	**Average**	**11.9**

Graph 1.1 Average time required to review paperwork 30 days before the area consolidation and 30 days after the area consolidation

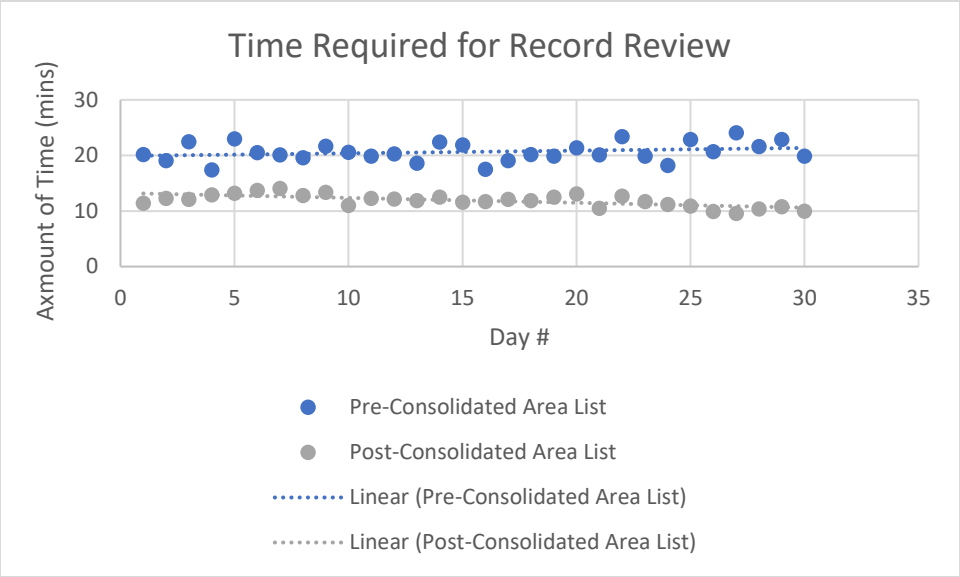
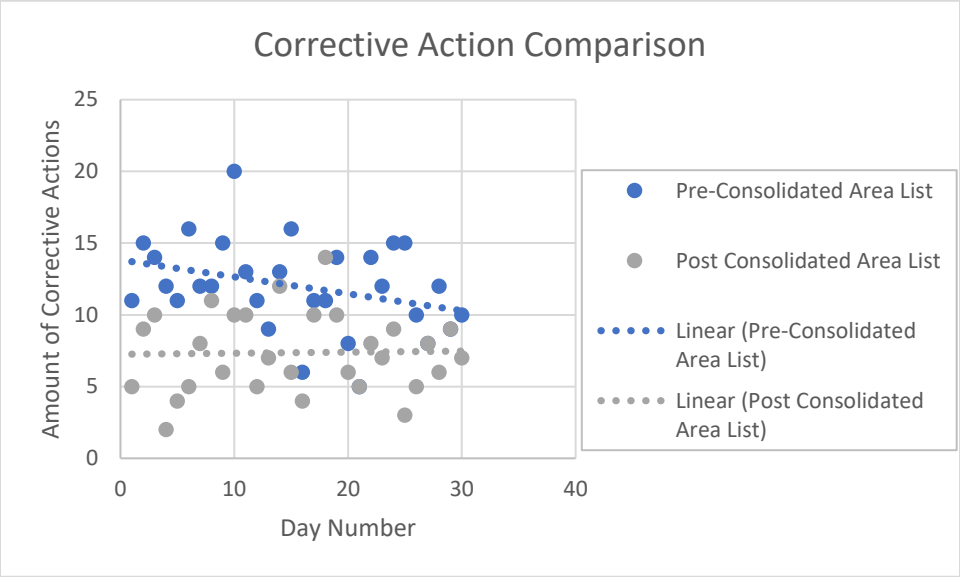


Table 1.2 Average number of corrective actions during record review 30 days before the area consolidation and 30 days after the area consolidation

Paperwork Corrective Actions Pre-Area-Consolidation		**Paperwork Corrective Actions Post-Area-Consolidation**	
Day	**Amount**	**Day**	**Amount**
1	11	1	5
2	15	2	9
3	14	3	10
4	12	4	2
5	11	5	4
6	16	6	5
7	12	7	8
8	12	8	11
9	15	9	6
10	20	10	10
11	13	11	10
12	11	12	5
13	9	13	7
14	13	14	12
15	16	15	6
16	6	16	4
17	11	17	10
18	11	18	14
19	14	19	10
20	8	20	6
21	5	21	5
22	14	22	8
23	12	23	7
24	15	24	9
25	15	25	3
26	10	26	5
27	8	27	8
28	12	28	6
29	9	29	9
30	10	30	7
Average	12	**Average**	7

Graph 1.2 Average number of corrective actions during record review 30 days before the area consolidation and 30 days after the area consolidation



Research Discussion and Recommendations

The response from plant and outside auditors was positive and gracious that the documented areas were specific and concise to help guide them where the problems would be properly documented. All surveys completed by the hourly employees, food safety team, and the FSIS personnel, indicated that the plant benefited from consolidating the areas.The consolidated list provided a sense of clarity, allowing individuals to know exactly where to document issues in specific department compared to the overanalytical list of areas previously. Additional surveys should be developed to determine if other forms of food safety paperwork can benefit from an area consolidation without losing the required standard of monitoring.

The average time required for record reviewing paperwork was affected by factors such as: employee completing the record review, the skill level of employee physically completing the paperwork, and issues that were documented on the paperwork itself. Firstly, new food safety employees may take a little longer to review paperwork simply because they are not used to the layout or looking for key details or mistakes. Within this project, it was the same five food safety technologists reviewing GMP paperwork every day. These five employees ranged from well-seasoned (10 years in the department) to new (1 month). Next, the skill level of hourly plant employees filling out the paperwork can directly impact how many mistakes are on the GMP paperwork, thus slowing down the food safety employees when reviewing and flagging corrective actions. Corrective actions would be necessary for clerical mistakes or any details not given on the paperwork itself by the hourly production monitor. Lastly, if there were GMP issues within departments, they must be documented to a certain detail. If these issues are not completely documented, it will once again slow the food safety employees down from reviewing

the paperwork. All these factors can directly affect how quickly and efficiently the GMP paperwork is able to be reviewed.

The reason this project came about was two-fold: 1. the food safety team was experiencing increased pressure to complete record review quicker and more accurately; 2. Individuals looking back at food safety paperwork were getting frustrated because they did not know which department's paperwork to review for certain areas. Allowing employees to feel that they had their voices heard provided a sense of partnership, pushing for the implementation of successful GMP record keeping.

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Appendices

Appendix A- Email Sent to Plant Management

Good Morning,

Hope everyone is having a great day! The food safety team is excited to initiate a new change to the GMP paperwork practice.

Below you will find a new list of areas. These are consolidated areas- for example, the kill floor used to be responsible for areas 1-9, but are now responsible for 1a-1c only. The monitoring/documenting process and area monitored is the exact same, but now each department will have less physical paperwork to turn in.

This will help pinpoint which paper to write issues down—no more guessing which one to write condensation on! Please review with your designated food safety paperwork employees. The most current GMP form with the accurate consolidated areas is to be used starting tomorrow. Please discard any old copies you may have. As always, this can be found on Qualtrax or in the food safety office.

For departments that had a drastic consolidation for paperwork (cut floor, kill floor, case ready), supervisors and superintendents will be receiving a calendar invitation for a formal training.

Please don't hesitate to ask any questions or send any comments/concerns.

Thanks,

Lauren

Appendix B- Post Project Evaluation Survey

Project Evaluation Survey

Please answer the following statements by circling "agree" or "disagree"

1. Consolidating the GMP monitoring areas decreased the facility's overall food safety.

   Agree or Disagree Comments:

2. After the GMP monitoring areas were consolidated, record review was simpler and easier to pinpoint issues.

   Agree or Disagree Comments:

3. USDA is now able to locate specific issues within departments easier than before the area consolidation.

   Agree or Disagree Comments:

4. The plant has benefited from consolidating the GMP monitoring areas.

   Agree or Disagree Comments:

Please circle Yes or No: Would you support areas being consolidated for other food safety paperwork, such as SSOP?

Yes or No Comments:

Additional Comments:

Appendix C- List of Areas Prior Consolidation vs After Consolidation

1. List of Areas Prior to Consolidation

1. Stick Pen
2. Kill Floor
3a. Carcass Coolers (Upstairs)
3b. Carcass Coolers (Downstairs)
4a. Cut Main Break (Upstairs)
4b. Cut Cold Offal (Upstairs)
5a. Cut Dry Storage, Cut Catwalks, Stairwells
5b. Cut Grading
6. Carcass Pack
7. Case Ready Cooler
8. L-Shape cooler
9. Ham Boning
10. LB
11. Center Cut Line
12. Tender & Easy
13a. Case Ready Room 1 Wet Side
13b. Case Ready Room 1 Dry Side
14a. Case Ready Room 2 Wet Side
14b. Case Ready Room 2 Dry Side
14c. Case Ready Dock & Office
15. Pickle Room
16. Belly Curing
17. Smokehouse
18. Brine Chillers
19. Country Ham
20. Thaw Cooler
21. Sausage Dock
22. Trash Dock
23. Trim Blend
24. Coolers 68 & 69
25. Coolers 15 & 16
26. Coolers 17 & 18
27. Coolers 19 & 20
28. Press Room
29. Layout Bacon)
30. Stack Pack Bacon
31. Retail Bacon Room #1
32. Retail Bacon Room #2
33. Smoked Meats
34. RTC Palletizing
35. Microwave Raw
36. Microwave Catwalk
37. Microwave Upstairs Cooler
38. Microwave RTE
39. Knife Room
40. Shipping Cooler
41. Shipping Warehouse
42. Dry Warehouse

2. List of Areas After Consolidation

1a. Stick Pen
1b. Scald
1c. Kill
1d. Head Room
1e. Variety Meats
2a. Carcass Coolers (Upstairs)
2b. Carcass Coolers (Downstairs)
3a. Cut Main Break (Upstairs)
3b. Cut Cold Offal (Upstairs)
3c. Cut Dry Storage, Cut Catwalks, Stairwells
3d. Cut Grading
3e. Cryovac Room
3f. Carcass Pack
4. Case Ready
5. L-Shape cooler
6. Ham Boning
7. LB, Center Cut, T&E
8a. Case Ready Room 1 Wet Side
8b. Case Ready Room 1 Dry Side
9a. Case Ready Room 2 Wet Side
9b. Case Ready Room 2 Dry Side
9c. Case Ready Dock & Office
10. Pickle Room
11. Belly Curing
12. Smokehouse and Brine Chillers
13. Country Ham
14. Thaw Cooler & Sausage Dock
15. Trash Dock
16. Trim Blend
17. Coolers 68 & 69
18. Coolers 15, 16, 17, 18
19. Coolers 19 & 20
20. Press Room, Room #1 (Layout/Retail)
21. Room #2 (Stack Pack/Retail/Smoked Meats)
22. RTC Palletizing
23. Microwave Raw, Catwalk, Upstairs Cooler
24. Microwave RTE
25. Knife Room
26. Shipping Cooler/Warehouse
27. Dry Warehouse