

United States Department of Agriculture (USDA)

Food Safety and Inspection Service (FSIS)

and George Mason University

Project Proposal

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1. Background and Problem

1.1 History of the Food Safety and Inspection Service

In 1905, the publication of "The Jungle" by Upton Sinclair caused public outcry with its description of the unsafe and unsanitary conditions present in the meatpacking industry. In response, in 1906 President Theodore Roosevelt signed into law the Pure Food and Drug Act and the Federal Meat Inspection Act (FMIA). These acts were the foundation for the regulations and inspections of today, which safeguard public health through inspection of the quality of meat, poultry, and egg products. It is the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) which provides this mandated oversight.

The department's mission statement is: "The Food Safety and Inspection Service (FSIS) is the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged."¹

Today, the FSIS employs approximately 7600 inspectors, working in over 6500 plants nationwide. Balancing workloads and staffing levels for such a large workforce is a tremendous undertaking, and one which requires careful planning and monitoring.

In 2011 FSIS began implementing the Public Health Information System (PHIS), a web-based application that the Agency uses to perform the following activities:

- Manage profile information for the establishments it regulates
- Task its inspection personnel with verifications to be performed
- Record and report the results of those verification tasks
- Support online coordination of FSIS in-plant resources through the resource information functions of the system

In short, the system uses: (1) the inspection tasks that are to be performed at each establishment based on the establishment's profile, (2) the planned frequencies of those tasks, and (3) the amount of time required to complete those tasks; to determine the amount of work to be done (in hours) for each establishment. Establishments are then grouped together into assignments, targeting a 100% (75%-125%) workload for each assignment based on a 40 hour work week. Inspection assignments are then grouped into circuits and districts, and are then nationalized and annualized to determine the overall national inspection staffing level for the Agency.

Inspection task times are comprised of four parts, direct (comprised of actual observation or hands-on) task time, indirect task time (comprised of data entry, research, and analytical time) internal (in-plant) travel time, and external (plant to plant) time. The four time measures are added to determine the total task time. Many of the direct inspection task times have not been time measured since the 1980s. When FSIS implemented PHIS, it changed the factor to determine indirect task time from 1.6 times the direct task time to an estimated 1.8 times the direct task time. However, this factor was not validated. In addition, new sampling tasks and

techniques, in conjunction with outdated work measurement data have led to the complaint that the workloads assigned by PHIS are in some instances overly burdensome. Meaning that inspection personnel cannot perform all of the verification tasks that the Agency expects them to complete. Agency Program Managers believe that the indirect task time factor may not be adequate to determine the actual data entry, research, and analytical time required for each task resulting in inaccurate determinations of needed staffing.

1.2 Scope of this project

One of the more recent sampling activities performed by FSIS personnel is the N=60 sampling method, used to collect samples of beef trim for the MT60 and MT55 sampling programs. These sampling programs are designed to detect *Escherichia coli* (E. coli) O157:H7 in beef, a toxin which can cause food poisoning. FSIS has performed some work measurement studies to determine the amount of time that should be allocated for the direct activities related to an N=60 sampling task, but there are multiple indirect activities not specifically accounted for in the assignment of an N=60 collection. These indirect activities include such tasks as the use of PHIS to reserve lab time for sample analysis, working with the inspected plant to determine the sample lot and the timing of inspection, and the entry of inspection data into PHIS.

The purpose of this study is to investigate the current multiplier (factor) used for estimating indirect task time. The tasks related to the MT60 sampling program will be used as a case study to assess the ratio of direct and indirect task times and to provide an extensible and defensible methodology for the measurement of direct and indirect inspection tasks.

2. Literature Search

The GMU team will conduct a literature search for information regarding time and motion studies and standards used in other professions (e.g., nursing, law). In addition, the team will conduct a thorough review of following FSIS documentation:

- FSIS Notice 47-13: Verification Testing for Non-0157 Shiga Toxin-Producing *Escherichia Coli* (Non-0157 STEC) Under MT60, MT52, and MT53 Sampling Programs
- FSIS Notice 06-13: Collecting Supplier Information at the Time of Sample Collection for *Escherichia Coli* (E. Coli) O157:H7 in Raw Ground Beef Products and Bench Trim
- FSIS Notice 62-13: Randomly Selecting Beef Trim to be Collected Under the Beef Manufacturing Trimmings (MT60) Sampling Program
- FSIS Notice 69-13: Containers for use when Collecting Raw Beef Samples for Shiga Toxin-Producing *Escherichia Coli* (STEC) and *Salmonella* Testing
- FSIS Directive 10,010.1 Revision 3: Verification Activities for *Escherichia Coli* O157:H7 in Raw Beef Products
- FSIS Directive 13,000 Series: Public Health Information System (PHIS)

The results of the literature search will inform the MT60 task decomposition and data collection plan. Any pertinent information resulting from the literature such that influences the work measurement methodology will be properly cited and included in the final project report.

3. Project Approach

3.1 Large Scale Work Measurement Program

After consideration of the challenges facing FSIS in its effort to appropriately scale indirect workloads, the GMU team has developed a recommended approach for an overall work measurement study. The necessary artifacts and activities are detailed below in Figure 1. While a project of this scale is not achievable in the timeframe allowed for this study, it is recorded here to provide context for the case study which will be conducted.

At the top level, the program plan, goals, and stakeholders should be identified and formally documented. This documentation provides bounds and direction for all the activities in the program. Each inspection task should be decomposed into its subtasks, including both the direct tasks involved in the sampling method and the related indirect tasks.

A statistical analysis of the metadata related to each inspected plant should be performed, including information regarding plant size and production levels, as well as plant-specific behavior related to the inspections as they occur. The team should review existing work measurement data to identify data that requires updating, and data that is sufficient for continued use, as-is.

With this understanding in place, the data collection plan and data analysis plan should be created. These two plans should be developed concurrently to ensure that all needed data can be collected, and to prevent rework or unnecessary expenditure of resources during data collection. Data collection and analysis would then proceed according to the established plans.

Results of the analysis would inform the Implementation Plan for proper introduction back into the FSIS workflow. The implementation should include adjustments to PHIS and modifications to the inspector tasking. In addition, implementation would consist of a strategy for defensible workforce planning to cover the FSIS mission and coordinated communication to the current workforce. Finally, a sustainment plan should consist of a method for introduction of new inspection tasks and regular verification of currently utilized work measurements.

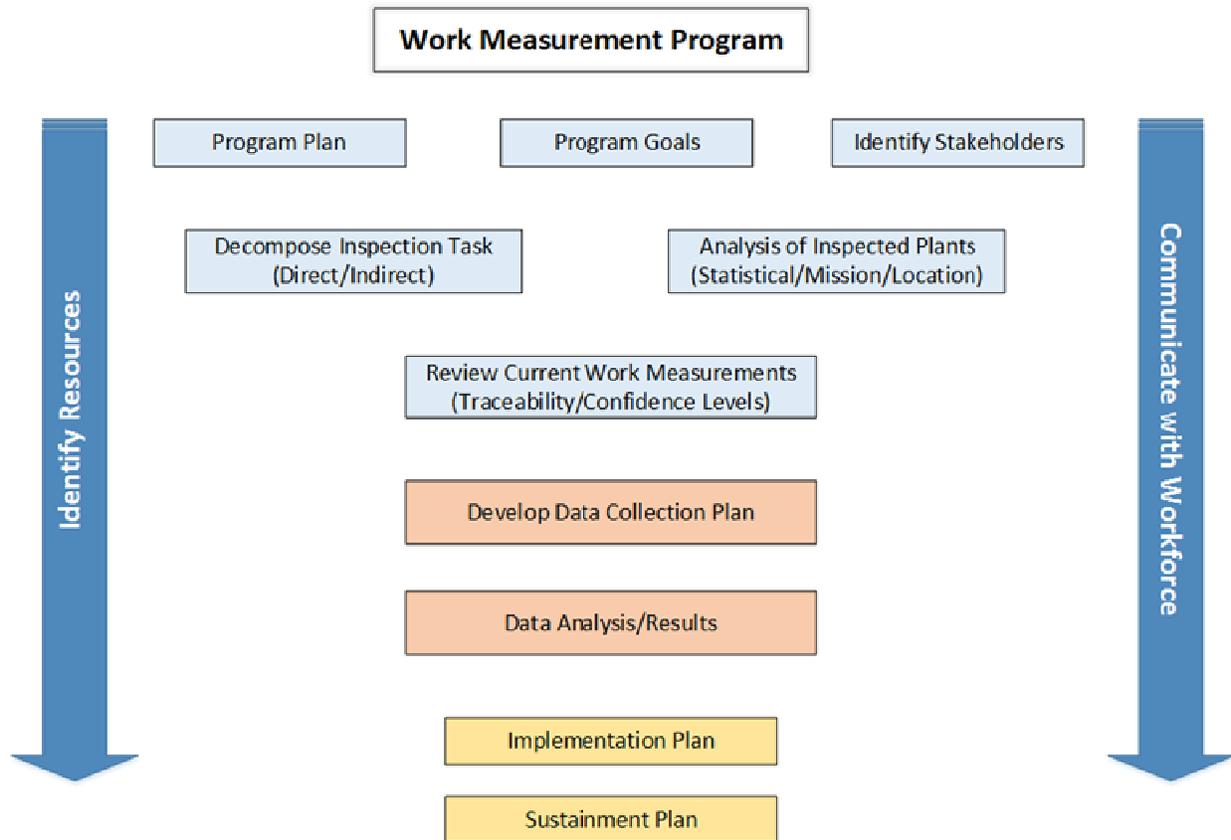


Figure 1. Large Scale Work Measurement Program Framework

3.2 Case Study

The large scale work measurement program described in Figure 1 above is well beyond what can be accomplished within a semester of work. Therefore, the GMU team worked with FSIS to limit the study to a useful effort that is achievable within the established time and effort limits.

The goal of this project is to perform a subset of the work measurement program tasks described above, limited to a single inspection task. That task, as selected by the FSIS, is the MT60 sampling program. The MT60 sampling program is an inspection activity wherein the N=60 sampling method is used to collect samples of beef trim to be tested for E. coli. This case study will focus on the task decomposition, data collection, and data analysis of the direct and indirect tasks related to the MT60 sampling program, as illustrated in Figure 2 below. Tasks to be examined will include the N=60 sampling method and the interaction of inspectors with PHIS in support of the task.

The case study will incorporate a decomposition of the MT60 inspection task as well as a statistical analysis of plants where samples are collected for this sampling program. The plant analysis will support an assessment of whether the MT60 work measurement data is dependent on the type of plant in which it is performed (e.g., large vs. small plant). A review of existing work measurement data for the MT60 inspection task will be performed to assess its completeness and to inform the planned data collection. The GMU team will develop a Data

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Collection Plan which will identify both the specific steps within the MT60 for which timing data must be collected and the instructions to be used in that collection. The GMU Team will provide FSIS with a “Confidence vs. # of Samples” curve and work with FSIS to determine a sample size for this case study that balances confidence and the available data collection time. The GMU team will provide a data collection form, for use in capturing work measurement data in the field. Based on this plan and form, FSIS will coordinate the collection of a limited set of data from the field, to be used by the GMU team for analysis. This data collection will be performed by FSIS staff.

The GMU team will develop and deliver a Final Report. The Final Report will include a data analysis plan for the collected work measurement data. This plan will support an assessment of the current indirect labor multiplier and an evaluation of the data collection methodology.

From a data verification perspective, the GMU Team will analyze the collected work measurement data to assess time variances. The team will identify process steps with high time variances and recommend ways for FSIS to understand and/or avoid those variances going forward.

The GMU team will develop and provide actionable work measurement process, data collection, and data analysis recommendations to FSIS. These recommendations will serve as input to a future, larger scale FSIS work measurement program. The Final Report will be developed in close coordination with FSIS experts. The final report with all associated data, computer code, analysis, and recommendations will be delivered to FSIS, along with a final presentation.

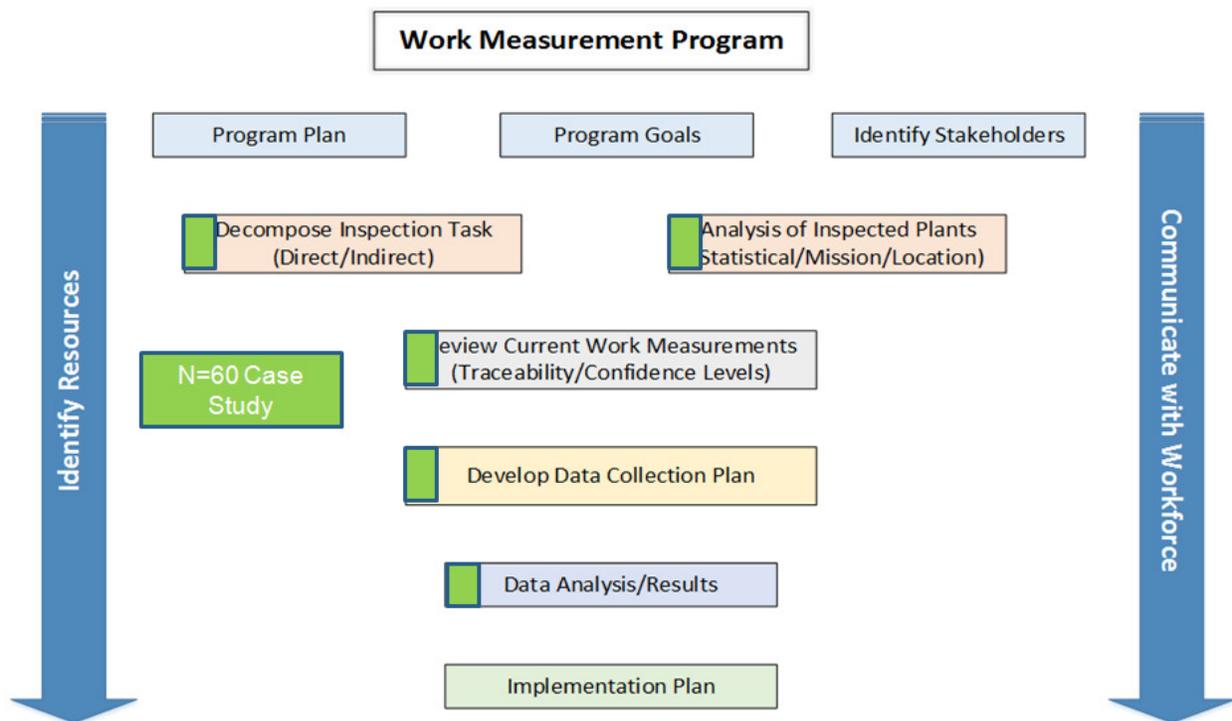


Figure 2. Large Scale Work Measurement Program Framework - Case Study

4. Management

4.1 Resource Allocation

The GMU team consists of four graduate students. Three out of the four have full-time jobs and the fourth member is a full-time student. In addition to the graduate students, the GMU team is advised by Dr. Karla Hoffman, the GMU Professor teaching the Master's Project class; and Dr. Phil Barry, a GMU adjunct professor and Technical Director, Center for Enterprise Modernization at Mitre Corporation.

The GMU team will leverage the expertise of the FSIS staff, treating them as colleagues as well as clients. Regina Tan, Lynvel Johnson, Robert Cooke, Carl Mayes, Charles Gioglio, and Susan Knower all offer expertise in specific areas of FSIS management, operations, and workflow. The GMU team will work with FSIS subject matter experts to ensure analysis and deliverables are properly constructed and vetted. Below is a list of key FSIS staff members along with their positions:

- Regina Tan - Office of Field Ops, Recall Management Staff (Director)
- Robert Cooke – Office of Field Ops, Resource Management & Planning Staff (Director)
- Charles Gioglio – Program Manager, OFO
- Lynvel Johnson – Program Manager, OFO
- Carl Mayes – Deputy CIO
- Susan Knower – CIO Staff (Business Analyst)

4.2 Deliverables

The GMU team will develop the following items and provide them to FSIS at the conclusion of this effort:

- Decomposition of MT60 Inspection Task. This will be a breakdown of the MT60 task into its component steps, with each level of decomposition having between 3 and 7 steps. The decomposition will include direct and indirect tasks.
- Data Collection Plan. The plan will identify the measurements to be taken and how they should be taken. The plan will be developed with consideration of how the data will be analyzed to ensure that the data collection will be in the form and level of detail needed to assess the indirect multiplier. The plan will include a data collection form to be used by FSIS in collecting work measurement data over the next few months.
- Final Report. The report will provide an overview of the task, discussion of the work measurement methodology, the results of the plant analysis, an analysis of the data, recommendations for adjustments to the data collection methodology, and an assessment of the indirect labor multiplier.

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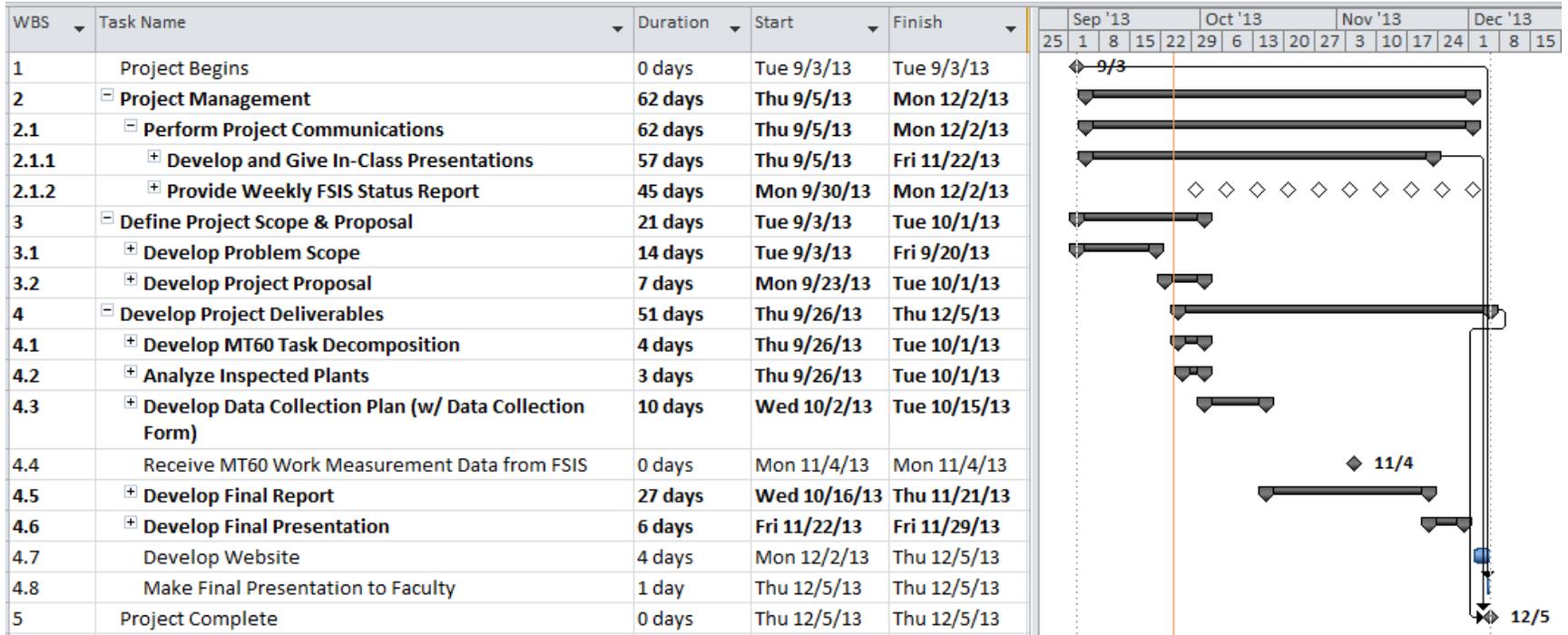
4.3 Schedule

4.3.1 Key Milestones

The key project milestones are listed, below:

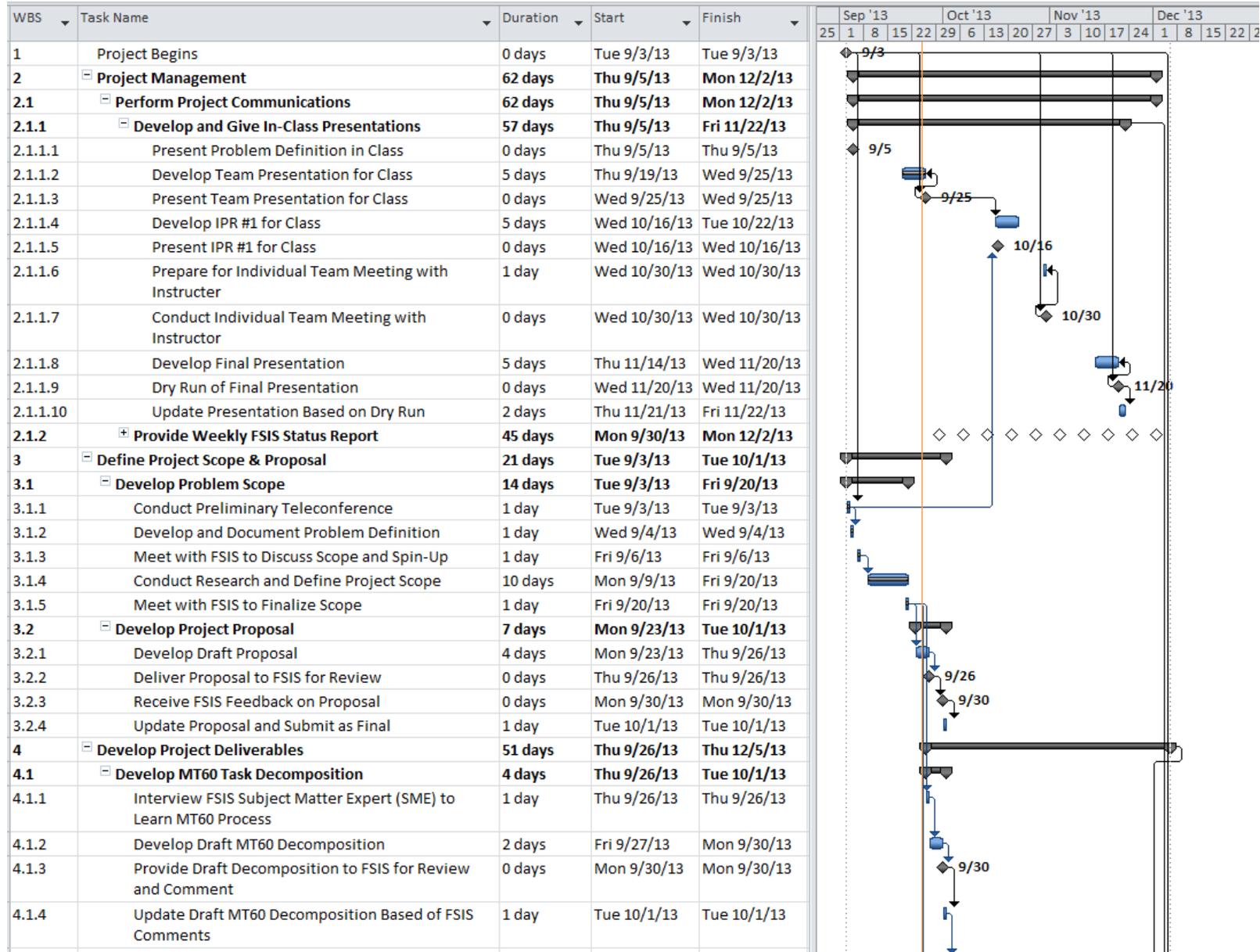
- 26 Sep – Proposal
- 15 Oct – Final Data Collection Plan
- 25 Oct – Data Collection Complete
- 21 Nov – Final Report
- 6 Dec – Final Presentation

4.3.2 Summary Schedule



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4.3.3 Detailed schedule



4.4 Risks

4.4.1 Risk #1 – Lack of Industrial Engineering Expertise

4.4.1.1 Risk Statement

Given that the GMU team does not include any Industrial Engineers, there is a possibility that the proposed work measurement methodology will not include the most current industrial engineering techniques, resulting in resistance from stakeholders to accepting the conclusions and recommendations.

4.4.1.2 Risk Score

- Likelihood = 3 (Moderate)
- Schedule Impact = NIL
- Project Success Impact = 3 (Moderate)

Project stakeholders, such as the inspectors and the union may challenge the results due to the lack of GMU team member industrial engineering (IE) credentials, and there is a moderate likelihood that they would do so.

4.4.1.3 Handling Strategy / Mitigation Plan

The GMU team will mitigate this risk by:

- Researching IE work measurement techniques and applying them in a clear and direct way
- Avoiding techniques that are not widely accepted or that would not be intuitively reasonable from the CIS and union perspective
- Explicitly stating all assumptions, to support future refinement of the approach.

4.4.2 Risk #2 – Lack of Data Collection Time

4.4.2.1 Risk Statement

Given that FSIS will have less than three weeks to provide the GMU team with work measurement data after receiving the final Data Collection Plan, there is a possibility that the work measurement data will be delivered late, resulting in insufficient time to properly analyze the data and meet the project deadlines.

4.4.2.2 Risk Score

- Likelihood = 2 (Low)
- Schedule Impact = NIL
- Project Success Impact = 4 (High)

Based on discussions between the FSIS and GMU teams, FSIS fully intends to provide the work measurement data by the scheduled due date. However, unknown challenges in the data collection process could cause delays. There are multiple parties involved (FSIS management, District Managers, plant managers, CIS's) who are not all co-located and have other full-time job responsibilities.

If the data is not provided by the scheduled due date, the time for analysis may not be sufficient and the quality of the conclusions and recommendations would be negatively impacted.

4.4.2.3 Handling Strategy / Mitigation Plan

The GMU team will mitigate this risk by:

- Requesting that FSIS notify the individuals who will be collecting the work measurements as soon as the plants have been selected, to allow them to include that work in their schedule
- Working closely with FSIS during the development of the Data Collection Plan to ensure a common understanding of the approach and to minimize rework
- Delivering the Data Collection Plan as early as possible and no later than the due date
- Drafting as much of the Final Report and other deliverables as possible prior to receiving the data, so that the GMU team can spend as much time as possible on the data analysis.

4.4.3 Risk #3 – Delays in Obtaining Plant and/or MT60 Information

4.4.3.1 Risk Statement

Given that the MT60 task decomposition and an analysis of plant data are needed to develop the Data Collection Plan and FSIS team members are busy, there is a possibility that plan development will be delayed due to delays in obtaining that data from FSIS.

4.4.3.2 Risk Score

- Likelihood = 1 (Very Low)
- Schedule Impact = 2 (Low)
- Project Success Impact = 2 (Low)

Given the responsiveness and high level of participation by FSIS, this risk is very unlikely to occur. If delays do occur, the expectation is that the delays would be less than 5 days. A delay of this magnitude could reduce the time available for data collection or analysis and have a low impact on project success.

4.4.3.3 Handling Strategy / Mitigation Plan

The GMU team will mitigate this risk by:

- Communicating the urgency of the need for this data to FSIS
- Providing weekly project status, planned activities, and issues

4.4.4 Risk #4 – Lack of Access to SMEs

4.4.4.1 Risk Statement

Given the tight schedule and the need for participation by FSIS SMEs, there is a possibility that the FSIS team will not be sufficiently available to contribute to the project, resulting in schedule delays and lower quality deliverables.

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4.4.4.2 Risk Score

- Likelihood = 1 (Very Low)
- Schedule Impact = 2 (Low)
- Project Success Impact = 2 (Low)

Given the responsiveness and high level of participation by FSIS, this risk is very unlikely to occur. If delays do occur, the expectation is that the delays would be less than 5 days, largely driven by more substantial rework being required following the submission of draft deliverables. A delay of this magnitude could reduce the time available for data collection or analysis and have a low impact on project success.

4.4.4.3 Handling Strategy / Mitigation Plan

The GMU team will mitigate this risk by:

- Scheduling working session as far in advance as possible
- Communicating issues in the weekly status reports

4.4.5 Risk #5 – Low Statistics Depth of Knowledge and Experience

4.4.5.1 Risk Statement

Given the need for statistical analysis and the moderate statistics depth of knowledge and experience held by the GMU Team, there is a possibility that the analysis will be insufficient or sub-optimal, resulting in a negative impact to project success.

4.4.5.2 Risk Score

- Likelihood = 1 (Low)
- Schedule Impact = NIL
- Project Success Impact = 3 (Moderate)

4.4.5.3 Handling Strategy / Mitigation Plan

The GMU team will mitigate this risk by obtaining confirmation of statistical analysis accuracy and sufficiency from GMU professors and/or other statistics subject matter experts. Also, the current expectation is that the required statistical analysis will be fairly straight-forward, so the statistics classroom experience held by the GMU Team will be sufficient.

5. References

- 1) United States Department of Agriculture - Food Safety and Inspection Service.
www.fsis.usda.gov
- 2) Tan, Regina PHD, The Food Safety and Inspection Service Office of Field Operations
Work Measurements Proposal to George Mason University, June 24, 2013