SYST 699
Team USDA
Data Collection Plan

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1. Introduction

1.1 Problem Context

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 (comprises 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 In addition, new sampling tasks and techniques, in conjunction with outdated work measurement data have led to the complaint that the workloads assigned by PHIS are in some instances overly burdensome.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 O157:H7 in beef. 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.

1.1 Data Collection Purpose

This data collection plan describes a methodology for collection of timing data related to the MT60 sampling task. The methodology presented here will allow for collection of time needed for direct inspection tasks, indirect inspection tasks, and internal travel time related to the typical MT60 tasks. The expectation is that data collected under this plan will be sufficient to validate the multiplier currently used to estimate indirect tasking effort required for the MT60 sampling.

In addition, this data collection plan presents a methodology that can be expanded and modified as necessary to accommodate additional inspection tasks, serving as a pilot program that can be expanded to a larger, future workforce measurement program within the FSIS. Therefore, data collection efforts performed under this case study should provide not only raw metric data, but also feedback on the efficacy and usefulness of the methodology defined.

1.2 Data Collection Scope

The plan detailed in this document includes collection of data related exclusively to the MT60 sampling task. Timing activities begin with an inspector's receipt of the assignment of an MT60 task, and conclude with the inspector shipping the collected samples. Between these two events, timing will be collected for a subset of tasks as defined in this plan.

There are some activities that occur only infrequently during the MT60 sampling tasks an inspector is assigned during the year. Activities like rescheduling appointments and ordering sampling supplies are not expected to occur during this case study data collection opportunity. If these kinds of activities occur during any of the MT60 sampling tasks within the study, it is expected that the data collection will include them, along with information about their occurrence. However, the data collection plan does not call them out as required activities for measurement. Data regarding those occurrences will be analyzed as available.

The following activities occur infrequently, and will be excluded from this data collection activity:

- Rescheduling inspections - not called out uniquely in plan, but if they occur, include in measurements
- Ordering supplies - not called out uniquely in plan, but if they occur, include in measurements
- Responding to positive test results - definitely excluded

1.3 Assumptions

The high level assumptions that have influenced the structure of this data collection plan are described below.

- Managers will perform the initial data collection; existing inspectors will be the subjects timed.
- Training needed for inspectors to successfully and efficiently perform the MT60 sampling-related tasks is accounted for separately within staffing estimates. Therefore, no data on training will be collected in this study.
- As part of preparation for performing MT60 sampling in a given plant, the inspector must be familiar with the Hazards Analysis and Critical Control Points plan (HACCP); time to read and become familiar with the HACCP is not specific to the MT60 task, and so is outside the scope of this data collection plan.
- If a sample collected in the MT60 sampling program detects the presence of *E. coli*, the inspector must take further actions. Those actions are not considered as part of this case study.
- The learning curve related to changes in the PHIS workflow and interfaces is not considered a factor in this study
- There is a known issue for some inspectors related to network latency; instructions from FSIS was to ignore that factor in the collection of this data. Timing will not begin until after the inspector's computer is connected to the internet and navigates to the PHIS website.
- Data collection activities for this study are heavily dependent on which inspection opportunities present themselves during the case study collection time frame. For that reason, it is not expected that data collection will be performed for many of the alternative steps that can occur during the course of a normal MT60. These alternative steps would include, for example, responding to positive test results, the need to sharpen the boning knife, freezing the sample, or the need to chill the samples prior to shipping (due to temperature warmer than 40 degrees Fahrenheit).

1.4 Reference Documents

The following documents provided insight into the process of conducting N60 sampling:

- FSIS Directive 10,010.1 Revision 3: Verification Activities for Escherichia Coli O157:H7 in Raw Beef Products
    - Incorporates new changes and a review of the N60 Sampling method.
    - Review the list of supplies needed for a N60 sampling.
    - General sampling instructions to include notifying the establishment, making proper arrangements, ordering lab supplies, restrictions, shipping directions, and checking lab results.

The following documents provided insight into the process of conducting an MT60 inspection:

- FSIS Directive 10,010.1 Revision 3: Verification Activities for Escherichia Coli O157:H7 in Raw Beef Products
    - A general description is given on different FSIS sampling project numbers for E. Coli O157:H7 testing including MT60 formerly known as MT50.
    - MT60 Sample Collection Procedures for Beef Manufacturing Trimmings
- FSIS Notice 47-13: Verification Testing for Non-0157 Shiga Toxin-Producing Escherichia Coli (Non-0157 STEC) Under MT60, MT52, and MT53 Sampling Programs

    - Inspection program personnel's (IPP) testing of beef manufacturing trimmings for six non-O157 STEC serogroups under the MT60 sampling code.
- FSIS Notice 62-13: Randomly Selecting Beef Trim to be Collected Under the Beef Manufacturing Trimmings (MT60) Sampling Program
    - Sampling code changed from MT50 to MT60 to include a more risk-based design.
    - Inspection program personnel's (IPP) responsibilities to accept, schedule and complete a MT60 when the task popped up in the Public Health Information System (PHIS).
- FSIS Notice 69-13: Containers for use when Collecting Raw Beef Samples for Shiga Toxin-Producing Escherichia Coli (STEC) and Salmonella Testing
    - Details of sample collection for MT60

The following documents provided insight into the PHIS:

- FSIS Directive 13,000.1 Revision 1: Scheduling In-Plant Tasks in the Public Health Information System (PHIS)
    - Provide a list of PHIS's terminology with their definitions.
    - Provides instructions to IPP on how to schedule and accept tasks in the PHIS.
    - Explain the different task's priority determined by the potential public health impact.
    - Explain the three different paths IPP can take in regards to questions on PHIS.
    - Describe IPP's responsibilities associated with PHIS.
- FSIS Directive 13,000.2 : Performing Sampling Tasks in Official Establishments using the Public Health Information System
    - Provides general instructions to the Inspection Program Personnel (IPP) and Enforcement Investigation and Analysis Officers (EIAOs) on conducting sampling tasks using PHIS.
- FSIS Directive 13,000.3 : Responding in PHIS to Industry Appeal of a Noncompliance Record (NR)
    - Provides guidance on how to respond to Industry Appeal of a NR submitted through PHIS and appeals not submitted through PHIS (submitted by means of a written or oral method).
    - Explain IPP and Supervisory Personnel's responsibilities in regards to an appeal.
    - Provide instructions on possible outcomes of an appeal, chain-of-command for appeal decisions, and time frame for different individuals to respond to an appeal.
    - Provide step by step PHIS instructions to IPP on how to delete and modify a NR.
- FSIS Directive 13,000.4 : PHIS Disconnected State and Offline Synchronization Application
    - Provides instruction to IPP on how to install the PHIS Disconnected State Application.
    - Discuss what activities are available in the PHIS Disconnected State.
    - Explain the importance on the synchronization of inspection data and the minimum synchronization frequency.
    - Provides two guidance documents as attachments for IPP.

PHIS subject matter experts at FSIS headquarters provided two walk-throughs of the PHIS activities associated with an MT60 inspection. They also provided a recording of a third walk-though.

Finally, FSIS provided an introductory N60 Sampling video and an additional training video on how to perform a N60 sampling.

2. MT60 Process

2.1 General Description

The MT60 sampling program is designed to detect *E. coli* in beef manufacturing trimmings produced via on-site slaughter of cattle. According to FSIS Notice 62-13, "Randomly Selecting Beef Trim to be Collected under the Beef Manufacturing Trimmings (MT60) Sampling Program", the intent of the MT60 sampling program is to "assess the effectiveness of slaughter and dressing operations and to verify that establishments are effectively addressing STEC [Shiga toxin-producing *Escherichia coli*]". This program was redesigned in 2012; that redesign triggered the renumbering of the sampling program from MT50 to MT60.

The MT60 sampling program begins with assignment of an MT60 task to an inspector via PHIS. The inspector accepts and schedules the assignment at the specified plant, coordinating a time for sampling with the specified plant and an FSIS laboratory. Onsite at the plant, the inspector collects information about a randomly chosen lot of trimmings and also collects a sample of trimmings in accordance with the N=60 collection method. These samples are sent to the pre-determined lab for testing; results are sent back to the inspector and plant.

2.3 Process Decomposition

Based on this input, the GMU team developed a structured decomposition of the MT60 process ("MT60 decomposition"), including direct, indirect and internal / external travel process steps.

The MT60 decomposition is provided in the related "MT60 Decomposition" document. Direct activities are color-coded with black, indirect activities are color-coded gray, internal travel activities are color-coded with blue. The possibility of external travel was briefly mentioned in the MT60 decomposition but was not given its own associated color instead external travel was lumped in with internal travel color-coded blue.

3. Data Collection Philosophy

The goal of this study is to determine the amount of time that should be allocated for the MT60 sampling program in staffing plans. With approximately 6500 plants within the FSIS purview, it is infeasible to have a measurement plan that records and maintains data on every plant individually. Instead, a representative subset of plants will be measured and those measurements will be statistically analyzed to determine global averages. Many factors will influence the validity of this data collection program. The following sections discuss these factors, describing the number of samples to be taken, the locations where those samples should be collected, who should collect the data, and the level of detail needed within the data collection program.

3.1 Collection Locations

It is the hypothesis of the study's creators that the time for the MT60 sampling is dependent on plant size. Therefore, the study will analyze the ratio of time to perform indirect and direct tasks

at three different classes of plant - large, mid-sized, and small. The sampling program must take this into consideration in creation of the study. Sufficient plants in each category should be sampled in order to evaluate validity of the hypothesis and, if valid, to provide statistical significance for the determined average for each category.

Additionally, the study will examine other potential factors that might influence the time for the MT60 sampling.

3.2 Data Collectors

A full-fledged data collection program should include trained data collectors who have no stake in the results of the study. Using the same collectors to perform all measurements at all sites removes some variability from the process. For this case study, it is not possible to develop such a team of collectors, so experienced managers from within the workforce will be used. These managers have the advantage of deep familiarity with the workforce in the field and the inspection sites. They bring an understanding of the processes involved in the MT60, and will be able to not only perform quantitative measurements in the field, but also will provide a qualitative assessment of both the process documented for measurement and the relative speed at which the measured inspector is working.

3.3 Level of Data Collection

We could measure each leaf-level step in the decomposition, but that would make for difficult data collection. With such short steps, the Data Collector may have a difficult time keeping up, which could result in inaccurate data.

We could just measure the largest block of direct, indirect, and internal travel time as possible. This might be ok for the purpose of validating the indirect multiplier. But, the other goal of this task is to develop a data collection methodology that would be applicable to the larger, future work measurement program. To that end, it is desirable to collect measurements that apply to multiple inspection programs.

For example, most inspection programs would likely include logging into PHIS, navigating to the assigned tasks, and adding a task to the calendar. Measuring to this level of detail would allow FSIS to reuse this work measurement for multiple tasks, thereby reducing the number of required measurements.

3.4 Sample Size

The goal of this case study is to collect an initial set of data that will provide a basis for future more in depth studies. This data will be analyzed to discover patterns in the ratio between direct and indirect task time. Ideally, data from 10 or more different plants will be collected for this pilot project. A larger sample size will provide a great level of confidence in the data, but even a small set can be analyzed to provide useful results.

3.5 Data Collection Methodology

3.5.2 Pre-Collection Planning

Data Collectors should familiarize themselves with:

- The MT60 process. Data Collectors must be able to identify the process steps and any activities that are not typically part of that process.
- The stopwatch functionality. Data Collectors must be familiar with the start, stop, lap, and reset capabilities of the stopwatch. There will only be once chance to measure the process - equipment challenges could result in missed or inaccurate data.
- The data collection methodology as described in this document. Data Collectors must be very familiar with the data collection methodology to ensure that the methodology is followed properly. Inconsistent methodology across plants could result in inconsistent and incorrect data.
- The data collection form. Data Collectors must be very familiar with the data collection form to ensure that the required measurements are properly collected and documented on the form.

3.5.3 Pre-Collection Meeting

- Meet with plant manager
    - The plant manager should be informed in advance of the data collection activity.
    - Explain data collection purpose and scope
- Meet with inspector
    - Explain data collection purpose and scope
    - Confirm schedule for sampling
    - Review the process steps, as we have defined them, with the inspector. If the inspector plans to follow a different set or sequence of steps, document the steps that they plan to take.
    - If this is the first time the inspector is using the new version of PHIS, they should run through the interface prior to timing it.

3.5.4 Inspection Scheduling

- Clear the stopwatch and then start it once the inspector submits the PHIS URL in Internet Explorer (or other browser).
- Log the elapsed time on the stopwatch when the inspector completes each of the following tasks:
    - Log in, navigate to their Task Calendar, and the Task Calendar is fully loaded
    - Find the MT60 task in the Task List, add it to the inspector's schedule, the task calendar reloads and the inspector confirms that the task appears correctly in the schedule
    - Open the task Document and complete the "Generate a Sample" tab
    - Complete the "Sample Collection Data" tab (if the inspector needs to leave the computer to find the lot number, note the departure time and the return time), click the "Save and Continue" button, and the "Additional Info" tab is fully loaded
    - At this point, the inspector might open the questionnaire and partially complete it. Or, they could leave the entire questionnaire until after the sample collection is complete.
    - Stop the stopwatch

3.5.5. MT60 Task using the N60 Sample Procedure

- Clear the stopwatch and then start it. Log the elapsed time on the stopwatch when the inspector completes each of the following tasks:
    - Walk from the office or wherever the inspectors' last task was completed to sampling supplies storage area.
    - Collect the following sampling supplies:
        - FEDEX Billable Stamps with Sample Seal and ID Labels
        - Plastic Caddy
        - Sterile Gloves
        - Cut Resistant Mesh Gloves
        - Sharp Boning Knife
        - Hook
        - Steel
        - Sampling Template
        - 2 Sterile Whirlpak Sampling Bags
        - Large Non-Sterile Plastic Bag
        - Clip
        - Sanitizing Solution or Hot Water (If the establishment in question uses hot water only.)
        - Sterile Towel Drape
    - Locate a suitable area in the plant to station your sampling equipment. Clean and sanitize the area as necessary or place the sterile towel drape if sanitizing the area is not possible. Prepare for the MT60 Task by washing hands, sanitizing all relevant sampling equipment including boots and helmet, putting on a white coat/frock, boots, helmet and cut resistant mesh gloves follow by sterile gloves.
    - Choose the appropriate number of containers (one to five) in the lot to collect the sampling pieces. Collect the 60 - 1 x 3 inches x ⅛ inch sampling pieces for the first Whirlpak bag and random size sampling pieces for the second Whirlpak bag.
    - Obtain and sanitize a thermometer to take the temperature of the top pieces of beef trimmings of each sampled container. Record the warmest temperature.
    - Clean up sampling equipment as necessary.
    - Walk to the sampling supplies storage area to return the sanitized sampling equipment.
    - Walk from the sampling supplies storage area to the office.
    - Stop the Stopwatch

3.5.6. Post-Sample Collection PHIS Data Entry and Task Completion

- Log the elapsed time on the stopwatch when the inspector completes each of the following tasks:
    - Log in, navigate to and fully load the "Additional Info Tab" for the inspection that was just completed
    - Open the questionnaire and complete the first page of questions
    - Complete the second page of questions
    - Complete the third page of questions

- Complete the fourth page of questions, click the button to submit the questionnaire, and the "My Questionnaires" page fully loads
- Return to the Document for the MT60 task, navigate to the "Additional Information" tab, populate all of the required data.
- Navigate to the "Sample Collection Data" tab and click the "Submit to Lab" button
- Print the Form
- Walk with printed form to the packing location
- Obtain the appropriate shipping materials. Complete the needed forms. Label the samples and form accordingly with the ID labels. Pack the box and label.
- Internal travel to ship the samples. Note: if travel is external, estimate distance and duration.
- Stop the stopwatch

3.5.7. Post-Measurement Closeout

- Once the data collection is complete, the Data Collector will scan the form and mail it to GMU.

Appendix A. Workforce Measurement Data Collection Form