Guidelines for *Escherichia coli* Testing for Process Control Verification in Poultry Slaughter Establishments

INTRODUCTION

Under the Pathogen Reduction/HACCP Regulation, poultry slaughter establishments are required to test carcasses for generic *E.* coli as a means of verifying process control. This document outlines sampling and microbial testing procedures that would meet this requirement. These guidelines may be helpful to your company microbiologist or testing laboratory. This document is a supplement to the Regulation but not a substitute; in-depth details of microbial sampling and testing may be found in the Regulation.

In this protocol, carcass sampling for broiler and turkey carcasses employs the same nondestructive whole bird rinse used in the FSIS Nationwide Microbiological Baseline Data Collection Programs. Poultry carcasses should be sampled at the end of the chill process, after the drip line, and before packing/cut-up. (Hot-boned poultry, which is boned before chilling, should be sampled at the end of the slaughter line instead of at the end of the drip line.) Samples taken in this manner will have analytic results comparable to National Baseline figures.

E. coli test levels from National Baseline studies, expressed as colony forming units per milliliter (cfu/ml) of rinsate, have been separated into 3 categories for the purpose of process control verification: acceptable, marginal, and unacceptable. In the Pathogen Reduction/HACCP Regulation, the upper limits for the acceptable and marginal ranges were denoted by m and M.

Table 1. Values for Marginal and Unacceptable Results for E. coli performance criteria

Type of poultry	Acceptable Range	Marginal Range	Unacceptable Range
Chicken	100 cfu/ml or less	over 100 cfu/ml but not over 1,000 cfu/ml	above 1,000 cfu/ml
Turkey	NA *	NA *	NA *

* The FSIS Baseline study has not been completed for this type of poultry. Levels will be set upon completion of this baseline.

The *E. coli* test results for a chicken slaughter establishment will be acceptable if not above 100 cfu/ml, marginal if above 100 cfu/ml but not above 1,000 cfu/ml, and unacceptable if above 1,000 cfu/ml. To evaluate overall process performance, the establishment must apply verification criteria to a set of samples; see discussion on pp. 14-16.

If no **m/M** criteria have been established for the type of birds you are required to sample and analyze, you should use a process control approach. The statistical process control approach required by the Agency is based on the principle that every product is produced by a process. All processes are subject to variation, which should be understood and controlled by statistical methods. A process that is in control is stable in terms of average level and degree of variation, i.e., it is predictable within limits and is thus 'doing its best." Processes that have not been subjected to analysis are not likely to be in control. Control is attained, often by degrees, by detecting and eliminating special causes of variation, those not present all the time or not affecting all product output. This involves initially evaluating data to determine process capability (the typical process performance level), and then checking subsequent data to see if they are consistent with this baseline level, i.e., the process is in control and variations are within normal and acceptable limits. This is accomplished by checking for unreasonably high results, trends, etc., and looking for and correcting problems in the process when these signals occur.

It is important to recognize that an in-control process may not necessarily result in product of the desired quality improvements may be needed or the entire process may require reconsideration. Problems in a process may stem from many sources, for example: inadequate knowledge of how a process should work or how a specific process is performing; errors or deficiencies in executing procedures; failure to recognize the need for preventive measures; unnecessary complexity in the process; and uncontrolled variation among inputs.

Specific techniques of statistical process control include the time plot, which charts measurements over time; this is the first technique to use with data collected over time and analyzed for patterns. A further development is the control chart, which plots data over time but also displays an upper control limit for specific measurements, and a centerline, above and below which there is an equal number of sample results (the centerline is in effect a median average). A sample result above the upper control limit would indicate the likely presence of a special cause of variation that should be addressed. Results within control limits indicate simply that the process is in control. Control charts have two essential uses: after-the-fact analysis of process performance and gaining and maintaining control of a process. In most situations more than one type of control chart would be applicable; detailed information can be found in texts on statistical quality control, under the topic “control charts."

In general, statistical process control techniques help to provide experience in "process thinking" (a central tenet of HACCP), develop an historical record of performance, evaluate the long-term stability of a process and determine process capability (i.e., how it is actually working), and evaluate the effectiveness of process improvement actions. With specific reference to *E. coli* test results, statistical process control techniques will not be directly useful for attaining and maintaining control of a process, as

test results will come from the end of the process and in any case would not be timely enough; observations made earlier in the process would be more useful for attaining and maintaining process control. Rather, E. coli testing would serve to verify process control. Process control techniques, applied and verified in this manner, would accomplish the essential intent of the Regulation by integrating process control and microbial testing into slaughter operations.

GUIDELINES FOR SAMPLE COLLECTORS/MICROBIOLOGISTS Pre-sampling Preparation

Sample collection shall be conducted by the individuals) designated in the establishment's written procedures for microbiological sampling, as required by 9 Code of Federal Regulations (CFR) Part 381. 94 (a) (2) (i). These procedures shall also specify the location of sampling, the random sample selection method chosen by the establishment, and sample handling procedures that will ensure sample integrity.

Before beginning sample collection, assemble sampling supplies, such as sterile gloves, sterile sampling solutions, hand soap, sanitizing solution, etc. Sterile sampling solutions, such as Butterfield's phosphate diluent (BPD) **or** buffered peptone water (BPW), can be stored at room temperature; however, at least the day before sample collection, check such solutions for cloudiness and do not use solutions that are cloudy or turbid or that contain particulate matter.

To obtain the most accurate results, samples should be analyzed as soon after collection as possible. If samples must be transported to an off-site laboratory, they should be refrigerated and then shipped refrigerated, on the same day they were collected, via an overnight delivery service to the laboratory. A sample should arrive at the laboratory and be analyzed no later than the day after it is collected.

If sample collection, pick-up or shipment, and laboratory analysis cannot be carried out within this timeframe, the carcass selected for sampling should be held until the process can be accomplished in the appropriate span of time. The same principle applies for samples that are analyzed in-plant: If a carcass cannot be sampled and the sample analyzed by the day after it is taken, the carcass should be held until this is possible. Rinsate from a collected sample should not be held; it should be either analyzed in-plant by the next day or immediately shipped for overnight delivery to the laboratory that will conduct the analysis.

The **Sample Shipment** section below gives information on shipping containers and transporting samples to off-site facilities.

Sampling frequency

Sampling frequency for *E. coli* testing is determined by production volume. The required minimum testing frequencies for all but very low volume establishments are shown in Table 2 by type of poultry. An establishment need sample only the predominant type when two or more types are slaughtered.

Table 2. ***E.*** coli Testing Frequencies

Chickens	1 test **per** 22,000 **carcasses,** or at **least 1** test **per week**
Turkeys	**1 test per 3,000 carcasses, or at least 1 test per week**

NOTE: These testing frequencies do not apply to very low volume establishments. See Table 3.

Very low volume establishments

Some establishments may be classified as very low volume establishments based on their annual production volume. The maximum yearly slaughter volumes for very low volume establishments are described in Table 3. An establishment need sample only the predominant type when two or more types are slaughtered.

Table 3. Maximum Yearly Poultry Slaughter Volumes for Very Low Volume Establishments

Type of Poultxy	Criteria (Yearly Slaughter Valme)
Chickens	not more than 440,000 birds
Turkeys	not more than 60,000 birds
Mixed Birds	not more than 440,000 total, with not more than 60,000 turkeys

A very low volume establishment will sample the predominant type once per week beginning the first full week of operation after June 1, until at least 13 test results have been obtained or the following June 1, whichever comes first. The establishment will repeat the same sampling regime once per year, beginning the first full week of operation after June 1.

If a very low volume establishment predominantly slaughters a type of poultry for which m/M criteria have been determined, the establishment must sample once per week until results show that it has met the m/M criteria outlined in the Pathogen Reduction/HACCP Regulation and following amendments; see Verification Criteria, pp. 14-16.

Random selection of carcasses

Samples are to be taken randomly at the required frequency. For example, given the frequency of testing for turkeys of one test per 3, 000 turkeys slaughtered, if a plant slaughters 1, 500 turkeys an hour, one sample will be taken every two hours. Note: If more than one shift is operating at the plant, the sample can **be** taken on any shift.

Poultry carcass selection

Different methods of selecting the specific carcass for sampling could be used, but all require the use of random numbers. Examples of methods include random number tables, calculator- or computer-generated random numbers, or drawing cards.

The carcass for sampling must be selected at random from all eligible carcasses. If there are multiple lines or chillers, randomly select the line or chiller for sample collection for that interval. Each line should have an equal chance of being selected at each sampling interval.

The poultry carcasses will be selected at random after chilling and after the drip line, before packing/cut-up. A whole carcass is required, that is, one that has not been trimmed.

Aseptic techniques/sampling

Extraneous organisms from the environment, hands, clothing, sample containers, sampling devices, etc., may contaminate samples and lead to non-representative analytical results. It is necessary to use aseptic sampling techniques and clean, sanitized equipment and supplies.

An area should be designated for preparing sampling supplies. A stainless steel, wheeled cart or table would be useful during sampling. A small tote or caddy could be moved to the location of sampling and used for carrying supplies; sample bags could be placed on the tote or caddy when sterile solutions are added to the bags.

Sterile gloves should be used for collecting samples. Nothing should contact the external surface of the glove except the exposed sample being collected. Keep in mind that the outside surfaces of the sample container are not sterile. The following procedure for putting on sterile gloves can be followed when collecting samples:

a) Peel open the package of sterile gloves from the top without contaminating (touching, breathing on, contacting) the exterior of the gloves.

b) Remove a glove by holding it by the inner . surface of the wrist-side opening. Avoid any contact with the outer surface of the glove. Insert the washed and sanitized hand into the glove, taking care not to puncture the glove.

c) Next, taking care not to contaminate the outer surface of the glove, repeat the step above for the hand you will use to physically handle the sample.

d) If at any time you are concerned that a glove may be contaminated, discard it and begin again with Step a) above.

Preparation for Sample Collection

On the day of sampling, gather all sample collection bags, sterile gloves, sanitizer, hand soap, sterile solutions for sampling, and any other materials needed. Ensure that all sampling supplies are on hand and readily available before beginning sample collection.

Label the sample bags before starting the sampling procedure. Use permanent ink. If you are using paper labels, it is important that the label be applied to the bag at normal room temperature; it will not stick to the sample bag if applied in the cooler.

Outer clothing such as frocks, gloves, or head gear worn in other areas of the plant should be removed before entering the sampling area or preparing to collect samples. Replace outer clothing with clean garments, such as a laboratory coat, that have not been directly exposed to areas of the plant outside of the sampling area.

Sanitize the sample work area surfaces by wiping with a clean disposable cloth or paper towel dipped in a freshly prepared 500 ppm sodium hypochlorite solution (0.05% sodium hypochlorite) or other approved sanitizer that provides an equivalent concentration of available chlorine. The sample work area surfaces must be free of standing liquid before sample supplies or product containers are placed on them.

Before sampling, thoroughly wash and scrub hands to the midforearm. Use antibacterial hand soap. This procedure should include a sanitizer with 50 ppm equivalence available chlorine. Dry the hands using disposable paper towels.

Chicken Carcass Rinse Sampling Procedure

Material :

1. 2 Sterile 3500 milliliter (ml) stomacher-type or ziplock-type bags or equivalent. The bag must be sterile and should be large enough to hold the carcass while rinsing.

2. 400 ml sterile Butterfield's phosphate diluent (BPD) or sterile buffered peptone water (BPW)

3. Plastic tie wraps or equivalent (to secure the bag)

4. Sterile gloves

5. Sterile leak-proof container (optional)

Collection

1. Ensure all sampling supplies are present and have been properly labeled. An assistant may be helpful during sampling.

2. Open a large stomacher-type bag without touching the sterile interior of the bag. (Rubbing the top edges of the bag between the thumb and forefinger will cause the opening to gap for easy opening.)

3. Put on sterile gloves.

4. With one hand, push up through the bottom of the sampling bag to form a 'glove' over one hand with which to grab the bird, while using your other hand to pull the bag back over the hand that

will grab the bird. This should be done aseptically without touching the exposed interior of the bag.

5. Using the hand with the bag reversed over it, pick up the bird by the legs (hocks) through the stomacher bag. (The bag functions as a 'glove' for grabbing the bird's legs.) Take care not to contaminate the exposed interior of the bag. Allow any excess fluid to drain before reversing the bag back over the bird.

6. Rest the bottom of the bag on a flat surface. While still holding the top of the bag slightly open, add the sterile BPD or BPW (400 ml) to the bag containing the carcass, pouring the solution into the carcass cavity and over the exterior of the carcass.

7. Expel most of the air from the bag, then close the top of the bag. While securely holding the bag, rinse the bird inside and out using a rocking motion for 30 shakes (approximately one minute). This is done by holding the bird through the bottom of the bag with one hand and the closed top of the bag with the other hand. Hold the bird securely and rock it in an arcing motion, alternating the weight of the bird from one hand to the other (motion like drawing an invisible rainbow or arch), ensuring that all surfaces (interior and exterior of the carcass) are rinsed.

8. Rest the bag with the bird on a flat surface and, while still supporting the bird, open the bag.

9. With a gloved hand, remove the carcass from the bag, first letting any excess fluid drain back into the bag. Since the carcass was rinsed with a sterile solution, the bird can be returned to the chill tank. Be sure not to touch the interior of the bag with your gloved hand.

10. Secure the top of the bag so that the rinse fluid will not spill out or become contaminated.

11. Place the sample bag (or leak-proof container) into another bag and secure the opening of the outer bag.

12. a) If samples are to be analyzed at an on-site laboratory, begin sample preparation for the selected method of analysis.

b) If samples are to be analyzed at an off-site laboratory, follow the **Sample Shipment** procedures.

Turkey Carcass Rinse Sampling Procedure
Materials:

1. 2 Sterile 3500 ml stomacher-type or ziplock-type bags or equivalent. The bag must be sterile and should be large enough to hold the carcass while rinsing; the bags FSIS will be using for the *Salmonella* sampling program measure approximately 18" x 24". Large turkeys should be placed in a plain, clear polypropylene autoclave bag, about 2411 x 30" to 36".

2. 600 ml sterile Butterfield's phosphate diluent (BPD) or sterile buffered peptone water (BPW)

3. Plastic tie wraps or thick rubber bands or equivalent, if needed to secure sample bag

4. Sterile gloves

5. Optional - sterile, leak-proof container

Collection

1. Ensure that all supplies are on hand and readily available. An assistant will be needed to hold the bag for collecting the bird.

2. Have an assistant open the large sterile stomacher-type bag (designated for rinsing the carcass) and be ready to receive the turkey carcass. (Rubbing the top edges of the bag between the thumb and index finger will cause the opening to gap open.)

3. Put on sterile gloves.

4. Remove the selected turkey from the drip line by grasping it by the legs and allowing any fluid to drain from the cavity.

5. Place the turkey carcass, vent side up, into a sterile sampling bag. Only the carcass should come in contact with the inside of the bag.

6. Manipulate the loose neck skin on the carcass through the bag and position it over the neck bone area to act as a cushion and prevent puncturing of the bag. The assistant will need to support the carcass with one hand on the bottom of the bag.

7. While still supporting the bottom of the bag, have the assistant open the bag with the other hand. Alternatively, rest the bottom of the bag on a pre-sanitized surface (i.e. a table), and while still supporting the carcass in the bag, open the bag with the other hand.

8. Add the sterile BPD or BPW (600 ml) to the bag containing the carcass, pouring the diluent into the carcass cavity and over the exterior of the carcass.

9. Take the bag from the assistant and expel excess air from the bag and close the top. While securely holding the bag, rinse the bird inside and out using a rocking motion for 30 shakes (approximately one minute). This is done by holding the carcass through the bag with one hand and the closed top of the bag with the other hand. Holding the bird securely with both hands, rock in an arcing motion alternating the weight of the bird from one hand to the other (motion like drawing an invisible rainbow or arch), ensuring that all surfaces (interior and exterior of the carcass) are rinsed.

10. Hand the bag back to the assistant.

11. With a gloved hand, remove the carcass from the bag letting excess fluid drain back into the bag. Since the carcass was rinsed with a sterile solution, the bird can be returned to the chill tank. Be sure not to touch the interior of the bag with your gloved hand.

12. Expel excess air, taking care not to expel any rinse fluid. Secure the top of the bag so that the rinse fluid will not spill out or become contaminated.

13. Place the sample bag (or container) into another bag and secure the opening of the outer bag.

14. a) If samples are to be analyzed at an on-site laboratory, begin sample preparation for the selected method of analysis. (See **Analytical Methods** section.)

b) If samples are to be analyzed at an off-site laboratory, follow **Sample Shipment** procedures.

Sample Shipment

Samples analyzed on-site must be analyzed as soon after collection as possible. If no on-site facilities are available, samples must be shipped to an off-site laboratory the same day they were collected. Samples must be analyzed no later than the day after collection.

Shipping containers and-coolant packs

It is important that samples fit easily into the shipping containers so that the sample bags do not break. Correct use of the coolant gel-ice packs and proper packing of the shipping container are necessary so that samples arrive at the laboratory at an acceptable temperature (0-10'C). Maintaining samples at improper temperatures may cause inaccurate results.

The sample should be kept refrigerated, not frozen, in the shipping container before pickup by the courier service. The shipping container itself should not be used as a refrigerator; however, multiple samples (if needed) for that day may be stored in the open shipping container in the cooler or refrigerator.

Recommended procedure

1. Prechill shipping container by placing the open shipping container in the refrigerator at least the day before sampling.

2. Place the appropriately-labeled, double-bagged sample in the prechilled shipping container in an upright position to prevent spillage. Newspaper may be used for cushioning the sample and holding it in the upright position. Ensure that samples are maintained at refrigeration temperature. Refrigeration temperatures limit multiplication of any microorganisms present.

3. Place a corrugated cardboard pad on top of samples. The corrugated pad prevents direct contact of frozen gel packs with the samples. Next, place the frozen gel pack(s) on top of the corrugated pad. Use sufficient frozen coolant to keep the sample refrigerated (0-10'C) during shipment to the designated laboratory. Insert foam plug and press it down to minimize shipper head space.

4. Ship samples via overnight delivery or courier to the laboratory.

Suggested Criteria for Microbiological Laboratories

These suggestions are not meant to be exhaustive. Specific needs will vary from one processor to another.

Personnel

Both laboratory analysts and supervisors must have education, training, and experience in food microbiology. Specific familiarity with poultry operations would be desirable. Personnel should be well versed in methods of analysis for poultry samples and the organisms associated with poultry products.

Facilities

Laboratory facilities should be suitable for conducting routine and specialized microbiological. analyses and should provide adequate bio-safety precautions. It is crucial that the laboratory maintain separate, defined areas for sample receipt, preparation, and analytic work.

Equipment

The laboratory should have suitable equipment, appropriate preventive maintenance programs, readily available equipment manuals, and log books for documentation. Specialized equipment may be necessary for some applications.

Operations

The laboratory should have in place a written quality assurance (QA) program that is available to all employees. The QA program should include bio-safety equipment, media preparation,

microbiological methods and procedures, control programs, equipment control, culture maintenance, sample receipt, handling, result reporting, and record keeping.

Records

Records should contain a complete sample description, including condition, source, lot code, date, quantity, etc. Results should be reported promptly and all data and summaries permanently recorded with the results.

Analytical Methods

All sample analyses must begin no later than the day after collection. Samples must be analyzed using one of the *E.* coli (Biotype I) quantitation methods found in the Official Methods of AOAC International, 16 Ih edition, 3 Id revision, 1997, or by any method that is validated by a scientific body in collaborative trials against the 3-tube Most Probable Number (MPN) method and that agrees with the 5% upper and lower confidence limits of the appropriate MPN index.

The following methods for generic *E. coli* quantitation in foods have been AOAC-approved:

1) 3-tube MPN method - AOAC 17.2.01-17.2.02

2) Modified 3-tube MPN method - AOAC 17.3.07 - Substrate Supporting Disc Method (ColiComplete®). ColiComplete® Substrate Supporting Discs are available from BioControl Systems, Inc., 19805 North Creek Parkway, Bothell WA 98011.

3) Modified 3-tube MPN method - AOAC 17.4-01 - Fluorogenic Assay for Glucuronidase. Lauryl sulfate tryptose broth with added 4-methylumbelliferyl-O-D-glucuronide (MUG) is used in a 3-tube MPN method.

4) Plating Method - AOAC 17.3.04 - Dry Rehydratable Film (Petrifilm *E. coli* Count Plate) Method. Medical-Surgical Division/3M, 275-5W 3M Center, St. Paul MN 55144.

5) Filtration/Plating Method - AOAC 17.3.09 - Hydrophobic Grid Membrane Filter/MUG (ISO-GRID) Method. QA Life Sciences, Inc., 6645 Nancy Ridge Dr., San Diego CA 92121.

Note: For most quantitative assays, week-end laboratory work can be kept to a minimum by refrigeration of incubated plates/tubes until Monday. A programmable refrigerated incubator is useful in such cases. For commercially available methods follow manufacturer's recommendations.

Suggested quantitation schemes

For poultry rinse fluid samples, if a generic 1 milliliter (ml) plating technique is used for *E. coli* quantitation, the plate count would not have to be divided to get the count per ml of rinse fluid. **Record this value even if it is less than I cfu/ml.** To cover the marginal and unacceptable range for *E. coli* levels, the undiluted extract (optional), a 1:10 and a 1:100 dilution should be plated, preferably in duplicate. Higher or lower dilutions may need to be plated based on the specific product.

If a hydrophobic grid membrane filtration method is used, the only difference would be filtration of 1 ml of the undiluted extract (optional), 1:10 and 1:100 dilutions.

Additional dilutions of the original extract may need to be used if a 3-tube MPN protocol is used.The 3 highest dilutions positive for *E. coli* are used to calculate the MPN.

Recordkeeping

Results of each test must be recorded in terms Of colony forming units per milliliter rinse fluid (cfu/mi) for chicken and turkeys. **Record this value even if it is less than I cfu/ml.** A process control table or chart can be used to record the results and facilitate evaluation. Results should be recorded in the order of sample collection and include information useful for determining appropriate corrective actions when problems occur. The information needed for each sample includes date and time of sample collection and, if there is more than one slaughter line, the slaughter line from which the sample was collected. These records are to be maintained at the establishment for twelve months and must be made available to Inspection Program employees on request.

For *E. coli* testing to be most useful for verifying process control, timeliness is important and the record should be updated with the receipt of each new result. Records should also be kept of any corrective

actions taken if process control deviations are detected through microbiological testing. Note: Occasionally, samples shipped to off-site laboratories may be lost during shipping or may arrive at the laboratory late or outside the acceptable temperature parameters for sample analysis (0-10^{o}C). Any reasons for missing data should be documented.

APPLYING PERFORMANCE CRITERIA TO TEST RESULTS

As was stated above on pp. 1-2, *E.* coli test levels for chickens have been separated into three categories for the purpose of process control verification: acceptable, marginal, and unacceptable. *E. coli* test results for a chicken slaughter establishment will be acceptable if not above 100 cfu/ml **(#@m),** marginal if above 100 cfu/ml but not above 1,000 cfu/ml **(>m** but ≤**M**), and unacceptable if above 1,000 cfu/ml (>**M**).

Verification Criteria

Verification criteria are applied to test results in the order that samples are collected. The criteria consist of limits on occurrences of marginal and unacceptable results.

As each new test result is obtained, the verification criteria are applied anew to evaluate the status of process control with respect to fecal contamination. This way of looking at the number of marginal and unacceptable results is described in the regulation as a "moving window" approach. With this approach, results are accumulated until 13 have been accrued. After this, only the most recent 13 results - those in the "moving window" are considered.

1. An unacceptable result should trigger action to review process controls, discover the cause, and prevent recurrence.

2. A total of more than 3 marginal or unacceptable results in the last 13 consecutive results also signals a need to review process controls.

An example of a table of results for Chicken testing is shown below for an establishment performing 2 tests per day.

Test	Date	Time Collected	Test Result (cfu/ml)	Result Unacceptable?	Result Marginal?	Number Marginal or Unacceptable in last 13	Pass/ Fail?
1	10-07	08:50	120	No	Yes	1	Pass
2		**14:00**	**10**	No	No	1	Pass
3	10-08	07:10	150	No	Yes	2	Pass
4		13:00	50	No	No	2	Pass
5	10 - 09	10:00	negative	No	No	2	Pass-
6		12:20.	10	No	No	2	Pass
7	10-10	09:20	800	No	Yes	3	Pass
8		13:30	10	No	No	3	Pass
9	10-11	10:50	10	No	No	3	Pass
10		14:50	10	No	No	3	Pass
11	**10-14**	08:40	500	No	Yes	4	**Fail**
12		12:00	30	No	No	4	**Fail**
13	10-15	09:30	10	No	No	4	**Fail**
14		15:20	10	No	No	3	Pass
15	10-16	07:30	10	No	No	3	Pass
16		**11:40**	**10**	No	No	2	Pass
17	10-17	10:20	**1200**	**Yes**	No	3	**Fail**
118	1	14:40	10	No	**No**	3	Pass

The following observations can be made regarding this example:

1. As of 10-14 at 08:40 (sample 11), there are 4 marginal or unacceptable results in the last 11 results, which exceeds the limit of 3 in 13 consecutive tests.

2. The limit of 3 in 13 also is exceeded for the next 2 tests, but since no new marginal or unacceptable result has occurred, these failures should not be treated as evidence of a new problem. The log or documentation of corrective action taken for the first failure should be adequate to verify that the deviation or problem, if any, was addressed.

3. On 10-15 at 15:20 (sample 14) the number of marginal or unacceptable results in the last 13 tests goes down to 3 because the marginal result for 10-07 at 08:50 is dropped and replaced by the next, acceptable result as the 13-test window moves ahead 1 test.

4. The result for 10-17 at 10:20 (sample 17) exceeds 1,000 **(>M)** and is unacceptable. Such a result should trigger immediate establishment review of process controls to discover the cause of the failure, prevent recurrence, and if product has been affected, consider the status and proper disposition of the product.

Note, however, that this specific result **>M** only counts as one result that exceeds **m.** With the next sample (18) - 10-17 at 14:40 - the establishment is again defined by having no more than 3 samples **>m** in the last 13. At this point, a negative result would mean that the current set of 13 samples was passing, a marginal result would mean that the set would fail for having 4 results **>m** in its 13 samples (samples 6-18), and a result >**M** would mean that sample would fail by exceeding **M** *and* the sample set would fail for having 4 results **>m** in its 13 samples.

5. The result for 10-17 at 14:40 is negative. The set is now passing by virtue of having had no more than 3 results **>m** in its 13 samples (samples 6-18).

This information could also be displayed in chart form, with test numbers, times, dates, and results.

Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety an4 Inspection Service (Docket No. 97-041N]
Notice of Request for Extension and Revision of a Currently Approved Information Collection

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and the office of Management and Budget (OMB) regulations, this notice announces the Food Safety and Inspection Service's (FSIS) intention to request an extension for and revision of a currently approved information collection regarding processing procedures and quality control systems.

DATES: Comments on this notice must be received on or before (insert date 60 days after publication of this notice]. ADDITIONAL INFORMATION OR COMMENTS: Contact Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, 300 12th Street SW, Washington, DC 20250-3700, (202) 720-0346.

SUPPLEMENTARY INFORMATION:

Title: Processing Procedures and Quality Control Systems

OMB Number: 0583-0089

E2Miration Date of Approval: October 31, 1997.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: FSIS has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. **451,** et seq.). These statutes mandate that FSIS protects the public by ensuring that meat and poultry products are safe, wholesome, unadulterated, and properly labeled and packaged.

To carry out its responsibility, FSIS has promulgated specific regulations containing requirements for the processing of certain meat and poultry products. FSIS requires that establishments producing cooked beef, roast beef, and corned beef document the time, temperature, and humidity at which the product is cooked and cooled. FSIS program employees review these records no less than three times a week to ensure regulatory compliance.

Establishments canning meat and poultry products must document the date of production; type of product canned; canning process used; size and type of container used; and any time/temperature processing requirements. FSIS program employees review these records no less that three times a week to verify regulatory compliance.

Additionally, FSIS permits establishments to develop total quality control (TQC) systems or partial quality control (PQC) programs which provide establishments with flexibility in meeting FSIS's regulations. TQC systems encompass all aspects of product processing; PQC programs cover only a specific processing operation. Quality control systems/programs incorporate inspection activities contained in FSIS's regulations.

TQC systems and PQC programs must contain detailed information concerning the manner in which the system will function. Such information must include procedures for raw material control; the nature and frequency of tests to be made; the critical check or control points to be addressed; the nature of charts and other records that will be used; the length of time such charts and records will be maintained; the nature of deficiencies the system is designed to identify and control; the parameters or limits that will be used; and the points at which corrective action will occur and the nature of such corrective action -- ranging from the least to the most severe. FSIS program employees review TQC and PQC system charts and records. FSIS program employees review these records no less than three times a week to ensure regulatory compliance. Because of the continued need for these information collection activities, FSIS is requesting OMB extension for and revision of the Information Collection Request covering information collection activities related to these requirements.

Estimate of Burden: The public reporting burden for this collection of information is estimated to average 120 hours per response.

Respondents: Meat and poultry establishments

Estimated Number of Respondents: 6,186

Estimated Number of Responses per Respondent: 2,292

Estimated Total Annual Burden on Respondents: 743,750 hours

Copies of this information collection assessment and comments can be obtained from Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, 300 12th Street SW, Room 109, Washington, DC 20250-3700, (202) 720-0346.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS' estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Thomas J. Billy
Administrator