

Substitution and Standard Yield Instructions

IV. Processing Options

A. Substitution

The Food and Nutrition Service (FNS) in conjunction with the Poultry Programs allows the limited substitution of donated poultry commodities with commercial product of the same quality for use in the state reprocessing program.

1. General Requirements

Interested processors must submit product substitution proposals to FNS and the Grading Branch outlining the handling procedures and control processes they have established to maintain product and program integrity. The proposals must include detailed information for identifying and controlling both the original and substituted products.

Applicable Federal-State supervisors and graders will be notified through their regional office of processor approval. Prior to any substitution, Federal-State supervisors are to review and evaluate the plants established control processes and procedures to assure product integrity.

Plants may substitute commercial product for parts and meat derived from a USDA purchased commodity. However, the commercial product from which the parts or meat originate must comply with all provisions of the applicable USDA commodity specification. Substitution is only allowed when authorization is provided in a written processing agreement between USDA and the processor. No variation in contracted product yields or other contract terms specified by State agencies is allowed. Substitution is not allowed on backhauled product. All other requirements outlined in the current Poultry Graders Handbook, Sections 10 and 12 remain applicable and are to be followed in accordance with that instruction.

2. Graders Responsibilities

Both substituted and original product must be examined by graders and determined to be in compliance with all requirements listed in the current commodity specifications. After destination weights have been determined and reported for original product that will be used for commercial purposes, no further action by the grader is necessary.

Official destination test weights are to be completed on the original product purchased by USDA with results recorded on the PY-210P as outlined in the current specification instructions. Substituted loads will also be test weighed, but the weight certification for substituted product will be documented on a PY-211 Memorandum and filed appropriately. If parts or deboned meat from USDA purchased commodity whole carcasses or parts are substituted, an official test weighing must be completed on the substituted product to ensure it is substituted in equal weights.

After destination weights have been determined for substituted product, all other provisions outlined in the Poultry Graders Handbook, Sections 10 and 12, shall be adhered to.

The costs of the destination test weighing and condition examination for original product shall continue to be charged to the contractor.

3. Certificate and Memorandum Preparation

Graders are to complete and issue destination certificates or prepare PY 211 Memorandums, as applicable, for loads of delivered donated or substituted product. Additionally, graders are to include the

following statements as applicable in the “Remarks” section of the certificate or memorandum representing the product:

Type of Load	Form Issued	Statement in Remarks Section	Exhibit Number
Substituted load before original load is received	PY-211	“Product covered by this memorandum replaces the USDA purchased commodity product to be delivered at a later date”	2
Original load after substituted product is processed	PY-210P	“Product covered by this certificate is original USDA purchased commodity that was substituted with product covered under memorandum numbered _____ dated _____.”	3
Substituted load after original load was received and diverted for commercial use	PY-211	“Product covered by this memorandum replaces the USDA purchased commodity product which was previously delivered under certificate number PPA _____ dated _____.”	4

4. Substitution Tracking

To assist in tracking loads throughout the delivery and substitution process, use the Substitution Tracking Form (Exhibit 5). A separate form shall be maintained for each contract. PY-211 Memorandums will be coded by Julian date and a suffix code if necessary. For example: the first lot test weighed on June 9 will be coded 160A, the second will be coded 160B (Exhibit 6), and so on. The code will be entered on the PY-211 in the block where the certificate number normally resides in a PY-210P.

After completion, PY-210P certificates are to be distributed as follows:

- One copy to grader
- One copy to processor
- Original to applicant

One copy to the recipient agency

Remaining copies distributed according to normal distribution

PY-211 Memoranda shall not be distributed. The starting net weight to be recorded on the PY-209 Reprocessing Certificate will be the official destination test weight as recorded on the PY-210P Grading Certificate, or PY-211 as applicable depending on the load being used for production.

B. Guaranteed Minimum Return

1. By-Products and Buy-Back Parts

The value of by-products sold or used by the processor must be credited to the recipient agency. Additionally, FNS permits the processor to credit or buy-back certain parts resulting from further processing. Credit or buy-back arrangements between the recipient agency and processor must be established prior to any further processing, documented as part of the processing contract, and made available to the grader. Exhibit 7 has been provided to assist graders in the accountability process.

Graders will certify the weight of buy-back parts or edible by-products remaining after processing on the reprocessing production certificate. Credit for buy-back parts can only be given for carcass parts such as drumsticks, wings, tails, skin, necks, comminuted meat, and frames. It may not be given for primal cuts

such as breast and thighs. When a recipient agency utilizes credit or buy-back procedures, graders will maintain control and accountability of the parts to be credited or bought back by listing each credited or buy-back item on the production certificate. Product remaining after a production run and not included as part of a credit or buy-back agreement will be recorded on the reprocessing production certificate as "Other." (Exhibit 8)

If processors are observed using the frames to produce an edible product for commercial purposes, graders shall report the weight of the frames or resultant MSM on the reprocessing production certificate. Frames that are not used for edible product will not be accounted for or reported on the production certificate. In instances where product is deboned at one location and shipped to another location for manufacturing of end products, the grader at the origin plant shall list the weight of the frames used for edible purposes on the certificate accompanying the shipment. The grader preparing the production certificate will then incorporate the weight of the frames on the production certificate.

2. Batching

If a processor wishes to combine lots of donated poultry from more than one state, the processor must obtain written concurrence from the affected recipient agencies verifying that batching is acceptable to them. Additionally, the same end products must be produced and processed using same option coverage. Any change in option coverage must be approved by each affected agency. Return of end products will be based on the recipient agency's prorated share of the raw product in the lot. Distribution of end products on this basis is the responsibility of the processor. Graders will issue one reprocessing production certificate covering the consolidated lot and, in the remarks section, list names and addresses of the states for whom the product is being processed.

3. Handling Rework

Further processing poultry commodities quite often results in the generation of rework product. Products such as broken or misshapen patties, nuggets, franks, hams, or other defects such as crumbles, missing breading, and lumps and ridges are classified as rework and must be accounted for. Procedures for the handling of rework must be clearly established prior to reprocessing. Upon concurrence from the recipient agency, processors may use any of the options listed below to dispose of, account for, or reuse rework product:

- a. Product may be blended into raw formulated batches in accordance with FSIS procedures provided that the finished product is in compliance with labeling requirements established by FSIS. Following production of each shipment, graders shall record the pounds of rework remaining on the reprocessing production certificate as "pounds of rework." (Exhibit 8) During processing, graders shall inventory pounds of rework remaining on each day's production worksheet.
- b. Rework product may be packaged and returned to the recipient agency. Graders will inventory amount produced each day and will record totals on the reprocessing production certificate as "pounds of rework."
- c. Rework product may be accumulated for use in subsequent production runs when weighed, inventoried, and stored under proper conditions. Graders will list amount of rework saved on each day's production worksheet. Product handled in this manner will be recorded on the reprocessing production certificate as "pounds of rework" and on subsequent production certificates as "Product Received for Reprocessing." A condition examination shall be performed on all rework prior to blending or use.
- d. Rework product may be disposed of as normal processing loss provided the amount does not exceed 2 percent of the raw deboned weight. When this option is used, the grader will certify the weight of rework disposed of on the

reprocessing production certificate. Rework exceeding 2 percent must be handled according to one of the other approved methods described in this section.

- e. Processors may buy back the rework by crediting the recipient agency for the value of poultry contained in the rework. Graders will certify the weight of rework produced and bought back on the reprocessing production certificate.
- f. Processors may replace rework product with commercial product provided the product is produced from poultry equivalent to the original commodity specified. The commercial product must meet all formulation and processing requirements listed on the EPDS and/or attachments to the EPDS. After replacement, the processor may use or dispose of the rework at their discretion. Show in the remarks section of the Reprocessing Production certificate the amount of product replaced by the vendor.

Rework product may be commingled for recipient agencies within a state but may not be commingled with product from another state unless batching has been approved. Rework must be properly identified and labeled throughout all phases of blending, storing, and shipping regardless of the option used.

4. Condemnations and Processing Losses

Unusual losses of product, such as condemnations resulting from product becoming unwholesome during processing or processing losses (other than rework) exceeding 1 percent of the raw bone-in or deboned weight, as applicable, shall be reported on the reprocessing production certificate. When losses exceed the 1 percent level, report the entire amount including the 1 percent. Graders shall not report incidental condemnations or normal processing losses. Additionally, graders shall list causes for product condemnations or other unusual losses on the reprocessing production certificate under "Other". (Exhibit 8)

Replacement of end products for condemnations or unusual losses will be permitted provided the end product has been formulated and processed in accordance with the EPDS and attachments. Further, the product must be produced from raw product (whole carcasses, parts, or boneless meat) that is equal to or better quality than the original product as determined by the grader. Quality determination can be made online, by stationary lot grading, or as evidenced by product labeling. Additionally, acceptance of commercial type products may be utilized when approved by the recipient agency. Condemned product may be replaced with commercial product provided the grader determines and is assured that the replacement product is substantially equivalent to the original product.

5. Option 1

Option 1 provides certification to the recipient agency that end products have been processed from the specified donated poultry. Graders are to monitor the processing activities to maintain product accountability and assure nonsubstitution and nondiversion. All of the general requirements outlined in Section 12, IV, A Substitution apply to Option 1 reprocessing.

a. Non-substitution and Non-diversion - Required

Verification provides certification to the recipient agency that end products have been processed from the specified donated poultry. Graders shall monitor the processing activities to maintain product accountability and assure non-substitution and non-diversion. Any deviations or additions to the items listed in this section must be specified on the EPDS, or attachments, and authorized by the applicable recipient agency representative. Notation of any specific waivers, deviations, or additions, and the person granting them, shall be shown on the grading certificate issued covering final certification at time of

shipment. Requirements that cannot be checked and verified by graders shall be brought to the attention of the Federal-State supervisor. Unless otherwise noted, all verification checks for these items will be completed according to policies, procedures, and frequencies outlined in this Handbook. Consolidation of samples for temperature and condition examinations at time of shipment is permissible when the processor has established and is at a Level II freezing history. In addition, items listed on the EPDS or its contractual attachments may cover the verifications listed below. These items may be altered, expanded, or eliminated as deemed necessary by the recipient agency.

6. Option 2

Option 2 coverage incorporates all of the requirements of Option 1 and, in addition, will cover the items listed in Section 12.V Certification Procedures. These items may be altered, expanded, or eliminated as deemed necessary by the recipient agency. Any deviations or additions to the Option 2 items listed in this section must be specified on the EPDS, or attachments, and authorized by the applicable recipient agency representative. Notation of any specific waivers, deviations, or additions, and the person granting them, is to be shown on the grading certificate issued covering final certification at time of shipment.

Requirements that cannot be checked and verified by graders shall be brought to the attention of the Federal-State supervisor. Unless otherwise noted, all verification checks for these items will be completed according to policies, procedures, and frequencies outlined in this Handbook. Consolidation of samples for temperature and condition examinations at time of shipment is permissible when the processor has established and is at a Level II freezing history.

7. Standard Yield Option

Under the Standard Yield Option, a fixed or standard de-boning yield has been established for bulk pack chicken (small or large) and turkeys using current industry practices and available data.

a. **Established Yields for Poultry**

If processors and recipient agencies include bone-in products, the following standard yields shall be used for a standard 8-piece cut utilizing the entire carcass.

Bone-In Chicken

Breasts	38 %	13,680 pounds
Thighs	29 %	10,440 pounds
Drums	17 %	6,120 pounds
Wings	12 %	4,320 pounds
	96 %	34,560 pounds

Under Standard Yield, each purchase unit delivery to a processor for conversion under the State Processing Program must yield a total of 26,640 pounds of boneless chicken or 30,960 pounds of boneless turkey. Unless adjustments are made, the following component parts and standard yields must be present in the finished products offered on the End Product Data Schedule (EPDS):

Boneless Chicken (Large or Small)

Boneless Breasts W/Tenderloins	-	Minimum	24 %	-	8,640 pounds
White Trim Meat	-	Maximum	2 %	-	720 pounds
Boneless Thighs	-	Minimum	12 %	-	4,320 pounds
Boneless Drums	-	Minimum	9 %	-	3,240 pounds
Dark Trim Meat	-	Maximum	1 %	-	360 pounds
Boneless Wings	-	Maximum	5 %	-	1,800 pounds

Mechanically Separated Meat (MSM)	-	Maximum	11 %	-	3,960 pounds
Skin	-	Maximum	<u>10 %</u>	-	<u>3,600 pounds</u>
			74 %	-	26,640 pounds

Boneless Turkey

Boneless Breasts W/Tenderloins	-	Minimum	28 %	-	10,080 pounds
White Trim Meat	-	Maximum	3 %	-	1,080 pounds
Boneless Thighs	-	Minimum	13 %	-	4,680 pounds
Boneless Drums	-	Minimum	11 %	-	3,960 pounds
Dark Trim Meat	-	Maximum	2 %	-	720 pounds
Mechanically Separated Wings	-	Maximum	7 %	-	2,520 pounds
Mechanically Separated Meat (MSM)	-	Maximum	13 %	-	4,680 pounds
Skin	-	Maximum	<u>9 %</u>	-	<u>3,240 pounds</u>
			86 %	-	30,960 pounds

The carcass frames used to produce MSM will be considered a by-product and therefore not required in the formulation. If the frames are not used in the finished products and are destroyed, the total standard yield will be reduced to 63 percent for chicken and 73 percent for turkey. To ensure accountability, AMS graders will monitor frame disposal. All other yields representing each component part are required in the formulation to provide the total standard yield.

If the frames are used to produce finished products for recipients, used for commercial products, or sold, the standard yield of 74 percent for chicken and 86 percent for turkey must be used.

b. Substitution of Meat or Parts

Similar to the guaranteed minimum return program, the primal parts (breasts and thighs) cannot be substituted during processing. However, the remaining components may be adjusted provided the standard yield representing that part is replaced with additional breast, thigh, drum, or trim meat. If adjustments are made to the component yields for parts such as wings, trim, etc., the amount and type meat used for replacement must be shown. Since all the component parts must be accounted for, the buy-back or credit options do not apply to the Standard Yield Option. All parts must be replaced as follows:

<u>Adjusted Part</u>		<u>Replacement Part</u>
Drums	-	Breast or Thigh Meat
White Trim Meat	-	Breast Meat
Dark Trim Meat	-	Breast, Thigh or Drum Meat, White trim
Wing Meat	-	Breast Meat
MSM	-	Breast, Thigh, Drum, or Trim Meat
Skin	-	Breast, Thigh, Drum, Trim Meat or MSM

c. USDA Contract (Procurement and Delivery)

Purchase units processed under the Standard Yield Option will be identified on the contract abstract that no weight variation is allowed. In this case, USDA will only pay for 36,000 pounds of chicken or turkey. Any purchase unit weighing less than 36,000 pounds will be rejected.

d. End Product Data Schedules (EPDS)

All EPDS's used under the Standard Yield Option must be approved by AMS Poultry Programs, Grading Branch prior to submission to the state agency for approval. The current Standard Yield EPDS and associated instructions (Exhibit 9) distributed by the American Commodities Distribution Association shall be used.

Instead of using a Guaranteed Minimum Return, the Standard Yield EPDS will show a guaranteed number of finished cases or pounds that represent the total meat block plus ingredients. Formulations will be verified by National Staff to determine the guaranteed number of finished cases or pounds are accurate. Since a guaranteed number of cases are required to be delivered for each purchase unit, rework products no longer need to be tracked during production and storage.

Each EPDS must clearly demonstrate that the total meat block representing a 36,000-pound purchase unit(s) is accounted for. Specifically, the type and amount of meat used for each formulation must be listed. When decimal numbers result from formula calculations, each value must be rounded up to the next pound or case to ensure that each recipient receives their entitlement. Once completed, the total meat block used to produce a company's product mix should equate to the standard yield for a purchase unit or multiples thereof. Additionally, the EPDS must show how each component part is used in the formulation to achieve the total yield.

Any changes made to product formulations will require preparation and approval of a new EPDS.

e. Boneless Meat Processing

The processor must notify the AMS grader prior to beginning of any standard yield processing. If the original product is substituted with a boneless meat block, the replacement load used to derive the Standard Yield meat block will not be checked for grade, net weight, or weight range in the whole carcass form. Instead, equivalency will be determined by examining the meat block for quality defects as listed and assuring the standard yield meat block has been satisfied. A statement indicating that boneless meat complying with the Standard Yield Option criteria shall be entered in the remarks section of the PY 210P certificate covering delivery of the load. If the original product is not substituted, it is not necessary to regrade the boneless meat derived from the previously graded carcasses provided adequate controls are in place (e.g. a production line dedicated to only reprocessed products) to assure that boneless meat product added to the formulas meets the defect requirements in the table below. The following quality factors have been developed for assessing meat quality:

Organoleptic and Defect Requirements for Chicken and Turkey Meat and Skin

General Requirements	Defects	
	Chicken Meat and Skin	Turkey Meat and Skin
Organoleptic:	The meat is rancid; has fruity, sulfide-like, cardboardy, tallowy, oily, metallic, chlorine, other foreign or off odors; contains foreign materials (e.g., glass, paper, rubber, metal); shows evidence of mishandling or deterioration; does not have a bright color or and shows evidence of dehydration or freezing and thawing. Meat or skin that does not meet the definition of ready-to-cook.	
Meat: (Excluding trim, wings, and MSM)	<p>Fatty blubber and spongy fat from the crop cavity on breast meat, or areas of discoloration as described below.</p> <p>The meat contains blood clots. Bruises, which exceed an area equivalent to a circle with a diameter of 0.50 inch.</p> <p>Any discoloration, which exceeds an area equivalent to a circle with a diameter of 1.00 inch. Slight discoloration is permitted, regardless of the area, provided the discoloration does not detract from the overall appearance of the meat.</p>	<p>Fatty blubber and spongy fat from the crop cavity on breast meat, or areas of discoloration as described below.</p> <p>The meat contains blood clots. Bruises, which exceed an area equivalent to a circle with a diameter of 0.625 (5/8") inch.</p> <p>Any discoloration, which exceeds an area equivalent to a circle with a diameter of 1.25 (1¼) inch. Slight discoloration is permitted, regardless of the area, provided the discoloration does not detract from the overall appearance of the meat.</p>
Specific Requirements	Defects	
Skin:	<p>More than 3 Feathers exceeding 0.50 inches.</p> <p>Any discoloration, which exceeds an area equivalent to a circle with a diameter of 1.50 (1½) inches. Slight discoloration is permitted, regardless of the area, provided the discoloration does not detract from the overall appearance.</p>	<p>More than 3 Feathers exceeding 0.75 inch.</p> <p>Any discoloration, which exceeds an area equivalent to a circle with a diameter of 1.75 (1¾) inches. Slight discoloration is permitted, regardless of the area, provided the discoloration does not detract from the overall appearance.</p>
Trim, MSM:	<p>Cartilage (gristle) and tendons that are soft-like in texture that extends more than 0.50" in length beyond the meat tissue.</p> <p>Bruises or blood clots, darkened colored veins or arteries that exceed 0.25" in diameter or exceed 0.30" in length.</p> <p>Moderate discoloration that exceeds 0.50" in diameter.</p>	
Wings	<p>Cartilage (gristle) and tendons that are soft-like in texture that extends more than 0.50" in length beyond the meat tissue.</p> <p>Bruises or blood clots, darkened colored veins or arteries that exceed 0.25" in diameter or exceed 0.30" in length.</p> <p>Moderate discoloration that exceeds 0.50" in diameter.</p>	
Breasts:	A whole Breast with more than ¾ of the meat missing (½ of a half breast).	
Tenderloins	A tenderloin with more than ½ of the meat missing.	
Thighs and Drums	Thighs or Drums with more than ½ of the meat missing.	

Except for domestic origin, AMS graders will not monitor the slaughter and carcass deboning since certified boneless meat is being used. The processor must notify the AMS grader prior to beginning of formulation. Once the meat is ready for batching, the grader will examine the meat for the above referenced quality defects using Poultry Programs' Sample Plan Level 2. Alternatively, the meat may be

examined during deboning using on-line procedures.

Product that fails to meet the quality requirements will not be eligible for the State Processing Program. The firm must simply continue to process until the guaranteed number of finished cases or pounds as stated on the EPDS have been satisfied. As a result, all rework, condemnation, and processing loss will be eliminated. Once the meat has been examined and accepted, the product will be monitored through packing. As provided under FNS regulations, this requirement will continue to prevent economic fraud through diversion or replacement with product of lower economic value.

Additionally, AMS will verify the criteria listed in Section 12 V. Certification Procedures.

f. Bone-in Parts Processing

If product is substituted, the replacement product will not be checked for grade, net weight, or weight range in the whole carcass form. Instead, equivalency will be determined by examining the parts for quality defects and assuring the standard yield has been satisfied. Parts produced as replacement for **small** bulk pack chicken must meet U.S. Grade A criteria for all factors, except breasts may be U.S. Grade B quality for exposed flesh. Parts produced as replacement for **large** bulk pack chicken must meet quality criteria for U.S. Grade B or higher. Weights for individual bone-in parts must meet the following:

	<u>Small Bulk Pack</u>	<u>Large Bulk Pack</u>
		<u>Minimum</u>
Breasts	7.6 – 11.4 ounces	11.4 ounces
Thighs	5.8 – 8.7 ounces	8.7 ounces
Drums	3.4 – 5.1 ounces	5.1 ounces
Wings	2.4 - 3.6 ounces	3.6 ounces

Except for domestic origin, AMS graders will not monitor the slaughter and cutting phases of processing for the replacement product since certified parts are being used. The processor must notify the AMS grader prior to beginning of processing. The grader will examine the parts using the applicable Poultry Grading procedures. The parts may be examined using on-line procedures. Product that fails to meet the quality requirements will not be eligible for the State Processing Program. The firm must simply continue to process until the guaranteed number of finished cases or pounds as stated on the EPDS has been satisfied. With this option, accountability of rework, condemnation, and processing loss will not be necessary. Once the parts have been examined and passed, the product will be tracked through packing. As provided under FNS regulations, this requirement will continue to prevent economic fraud through diversion or replacement with product of lower economic value.

Additionally, AMS will verify the criteria listed in Section 12 V. Certification Procedures.

g. Labeling, Shipping, and Certification

Finished product that complies with program requirements shall be identified with the Contract Compliance stamp and certificate number during production. Alternatively, upon approval by the Federal-State Supervisor, the Delivery Order number may be used in the stamp. When the DO is used, the certificate shall indicate that the containers were stamped with the “Contract Compliance Stamp with Delivery Order Number ____.” No additional stamping is necessary at time of shipment. Section VI. Lot Identification, Stamping and Labeling contains additional instructions for stamping of finished cases.

V. CERTIFICATION PROCEDURES

A. General Requirements

1. Starting Weight

Graders shall be provided a copy of the EPDS containing the product formulation, which will be used as a guide in assuring non-substitution and non-diversion. For all commodities, except bulk pack, the starting product weight will be the total marked weight (as stated by the applicant). The applicant will also provide the grader with the total box count. For bulk pack reprocessing, the starting product weight will be the total net weight shown on the official destination weight certificate (Exhibit 10). When net weights for bulk pack exceed the permitted tolerance, the starting weight will be the actual weight listed in the remarks section of the destination weight certificate. These processing guidelines will be the same for all commodities after initial weight and box counts are determined.

2. Product Control

Under Options 1 & 2, plants are required to identify and isolate all donated product such as whole birds, meat, parts, etc. Donated food items will be labeled at all times during processing, storage, and transfer between plants. Vessels used to hold product, such as tanks, vats, etc., shall be identified with a permanent-type number or conspicuously marked. For example, an adhesive label bearing the USDA lot stamp may be used provided the label cannot be removed without being torn or destroyed. Plants are required to maintain identity of product throughout all phases of further processing by identification and separation from commercial product. Control and identity of donated products may be accomplished by separate lines, rooms, or other procedures approved by the Federal-State supervisor to assure control. Products transferred from one plant to another for further processing must be accounted for and accompanied by a Poultry Products Grading Certificate (PY-210P). The certificate shall list the type of product, pounds, and any additional information required by the grader at the receiving plant. These shipments must be sealed and the seal numbers listed on the certificate.

3. Inventory and Documentation

Graders will maintain daily inventories of all donated product processed under options 1 & 2 regardless of the stage of further processing. This can be done by listing the number of racks, containers, pounds, or by whatever means necessary to maintain proper accountability. Exhibit 11 has been provided as an example of inventory accountability.

Plants are required to maintain a log of meat used during formulation. This log shall be posted at the mixer, stuffer, or wherever containers of meat lose identity. Graders will make periodic random checks of meat and ingredients at these points and initial the logs. Graders shall note on worksheets when these checks are made. All processing checks, evaluations, and observations conducted by the grader will be documented on worksheets approved by the Federal-State supervisor. Any reference to plant records, plant logs, or other plant-kept data will be checked and documented by the grader on their daily worksheets. Deviations shall be documented, product disposition shown (rejected, retained, etc.), and the deviation brought to the attention of a designated plant representative.