specified in section 381.149 of this subpart, has been terminated in accordance with the provisions of this section, a request for approval of the same or a modified quality control system will be evaluated by the Administrator upon receipt.

(h)(1) *Operating Schedule Under Total Plant Quality Control.* An official establishment with an approved total plant quality control system may request approval for an operating schedule of up to 12 consecutive hours per shift. Permissions will be granted provided that:

(i) The official establishment has satisfactorily operated under a total plant quality control system for at least 1 year.

(ii) All products prepared and packaged, or processed after the end of 8 hours of inspection shall only be a continuation of the processing monitored by the inspector and being conducted during the last hour of inspection.

(iii) All immediate containers of products prepared and packaged shall bear code marks that are unique to any period of production beyond the 8 hours of inspection. The form of such code marks will remain constant from day to day, and a facsimile of the code marks and their meaning shall be provided to the inspector.

(2) *Application.* Applications shall be submitted to the Regional Director and shall specify how the conditions in § 381.145(h)(1) have been or will be met.

(3) *Monitoring by Inspectors.* In order to verify that an establishment is preparing and shipping product in accordance with the approved total plant quality control system and the Act and regulations after the 8 hours of inspection, the official establishment may be provided overtime inspectiom services at the discretion of the circuit supervisor and charged for such services.

(i) To ensure the safe use of preparations used in poultry scald water, the label or labeling on containers of such preparations shall bear adequate directions to ensure use in compliance with any limitations prescribed in 21 CFR Chapter I, Subchapter A or Subchapter B or 9 CFR Chapter III, Subchapter A or Subchapter E.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583–0015)

[37 FR 9706, May 16, 1972, as amended at 45 FR 54323, Aug. 15, 1980; 46 FR 48904, Oct. 5, 1981; 50 FR 6, Jan. 2, 1985; 51 FR 32304, Sept. 11, 1986; 57 FR 43598, Sept. 21, 1992; 62 FR 45026, Aug. 25, 1997; 62 FR 54759, Oct. 22, 1997; 64 FR 72175, Dec. 23, 1999]

EFFECTIVE DATE NOTE: At 64 FR 72175, Dec. 23, 1999, § 381.145, paragraph (i) was revised, effective Jan. 24, 2000. For the convenience of the user, the superseded text is set forth as follows:

§ 381.145 Poultry products and other articles entering or at official establishments; examination and other requirements.

* * * * *

(i) Containers with substances approved for use in the processing of products in § 381.147(f)(3) of this subchapter which enter any official establishment for use in poultry scald water shall, at all times, while they are in such establishment, bear labels showing the chemical names of the substances in such preparations. In the case of preparations containing substances which may be used under § 381.147(f)(3) only in limited amounts, the container labels shall also show the percentage of each such substance in the preparation and shall provide dilution directions which prescribe the maximum allowable use concentration of the preparation.

§ 381.146 Sampling at official establishments.

Inspectors may take, without cost to the Department, such samples as are necessary of any poultry product, or other article for use as an ingredient of any poultry product, at any official establishment to determine whether it complies with the requirements of the regulations.

§ 381.147 Restrictions on the use of substances in poultry products.

(a) All ingredients and other substances used in the processing or handling of poultry products at official establishments shall be such as will not result in adulteration or misbranding of the poultry products.

(b) Poultry products and poultry broth used in the processing of poultry products shall have been processed in the United States only in an official establishment, or imported from a foreign country listed in § 381.196(b), and inspected and passed, in accordance with the regulations. Detached ova and offal shall not be used in the processing of any poultry products, except that poultry feet may be processed for use as human food when handled in a manner approved by the Administrator in specific cases, and detached ova may be used in the processing of poultry products if the processor demonstrates that such ova comply with the requirements under the Federal Food, Drug, and Cosmetic Act.

(c) Liquid, frozen, and dried egg products used in the processing of any poultry product shall have been prepared under inspection and be so marked in accordance with the Egg Products Inspection Act.

(d)(1) Carcasses, parts thereof, meat and meat food products of cattle, sheep, swine, goats, or equines may be used in the processing of poultry products only if they were prepared in the United States only in an official meat packing establishment, or imported, and were inspected and passed, in accordance with the Federal Meat Inspection Act, and the regulations under such Act (subchapter A of this chapter) and are so marked.

(2) Pork from carcasses or carcass parts, used as an ingredient in poultry products, that has been found free of trichinae, as described under § 318.10 (a)(2), (e) and (f) of the Federal meat inspection regulations (9 CFR 318.10 (a)(2), (e) and (f)), is not required to be treated for the destruction of trichinae.

(3) Poultry products containing pork muscle tissue which the Administrator determines at the time the labeling for the product is submitted for approval in accordance with part 381 of the regulations in subchapter C, or upon subsequent reevaluation of the product, would be prepared in such a manner that the product might be eaten rare or without thorough cooking because of the appearance of the finished product or otherwise, shall be effectively heated, refrigerated, or cured to destroy any possible live trichinae, as prescribed in § 318.10(c) of the Federal meat inspection regulations (9 CFR 318.10(c)), at the official establishment where such products are prepared. In lieu of such treatment of poultry products containing pork, the pork ingredient may be so treated.

(e) [Reserved]

(f)(1) No substance may be used as an ingredient or otherwise in the processing of any raw or cooked poultry product unless its use is approved as shown in Table 1 of paragraph (f)(4) of this section, or elsewhere in this part, or by the Administrator in specific cases.

(2) Approval of new substances or new uses or new levels of use of approved substances may be granted if:

(i) The substance has been previously approved by the Food and Drug Administration (FDA) for use in poultry or poultry products as a food additive, color additive or as a substance generally recognized as safe and is listed in title 21 of the Code of Federal Regulations, parts 73, 74, 81, 172, 173, 182, or 184.

(ii) Its use is in compliance with applicable FDA requirements; and

(iii) The Administrator has determined that:

(A) The use of the substance will not render the product in which it is used adulterated or misbranded or otherwise not in compliance with the Act; and

(B) Its use is functional and suitable for the product and it is permitted for use at the lowest level necessary to accomplish the desired technical effect as determined in specific cases.

(3) Whenever the Administrator determines that approval of a new substance or a new use or new level of use of an approved substance should be granted in accordance with pararaph (f)(1) of this section, the Administrator shall issue a final rule amending Table 1 of paragraph (f)(4) of this section to include the additional substance or new use of the substance, and any technical effect or change in the level of use of the substance.

(4) No poultry product shall bear or contain any substance which would render it adulterated or misbranded, or which is not approved in part 381 or by the Administrator in specific cases.

TABLE I

[See footnotes at end of this table]

Class of substance	Substance	Purpose	Products	Amount
Acidifiers	Acetic acid	To adjust acidity	Various[3]	Sufficient for purpose.[4]
	Citric acid	...do	...do	Do.
	Glucono delta-lactone	...do	...do	Do.
	Lactic acid	...do	...do	Do.
	Phosphoric acid	...do	...do	Do.
	Tartaric acid	...do	...do	Do.
Antifoaming agent.	Methyl polysilicone	To retard foaming	Soups	10 ppm.
			Rendered fats	10 ppm.
			Curing pickle	50 ppm.
Antimicrobial agents.	Trisodium phosphate	To reduce microbial levels.	Raw, chilled poultry carcasses.	8 to 12 percent; solution to be maintained at 45 °F. to 55 °F. and applied by spraying or dipping carcasses for up to 15 seconds in accordance with 21 CFR 182.1778.
Antioxidants and oxygen interceptors.	BHA (butylated hydroxyanisole).	To retard rancidity	Various	0.01 percent based on fat content. (0.02 percent in combination with any other antioxidant listed in this table based on fat content.)
	BHT (butylated hydroxytoluene).	...do	...do	Do.
	Propyl gallate	...do	...do	0.01 percent based on fat content. (0.02 percent in combination with any other antioxidant listed in this table, except TBHQ, based on fat content.)
	TBHQ (tertiary butylhydroquinone).	...do	...do	0.01 percent based on fat content. (0.02 percent in combination only with BHA and/or BHT based on fat content.)
	Tocopherols	...do	...do	0.03 percent based on fat content. (0.02 percent in combination with any other antioxidant listed in this table, except TBHQ, based on fat content.)
Binders and extenders.	A mixture of sodium alginate, calcium carbonate, lactic acid, and calcium lactate.	To bind poultry pieces	Ground and formed raw or cooked poultry pieces.	Sodium alginate not more than 0.8%, calcium carbonate not more than 0.15%, lactic acid and calcium lactate, in combination, not more than 0.6% of product formulation. Added mixture may not exceed 1.55% of product at formulation. The mixture must be added in dry form.
	Algin	To extend and stabilize product.	Various	Sufficient for purpose.
	Carrageenan	...do	...do	Do.
	Carboxymethyl cellulose (cellulose gum).	...do	...do	Do.
	Enzyme (rennet) treated calcium reduced dried skim milk and calcium lactate.	To bind and extend product.	Various	Sufficient for purpose. (Calcium lactate required at rate of 10 percent of binder.)
	Enzyme (rennet) treated sodium caseinate and calcium lactate.	...do	...do	Sufficient for purpose. (calcium lactate required at rate of 25 percent of binder.)
	Gelatin	...do	...do	Sufficient for purpose in accordance with 21 CFR 172.5.
	Gums, vegetable	...do	...do	Do.
	Methyl cellulose	To extend and to stabilize product (also carrier).	...do	0.15 percent.
	Isolated soy protein	To bind and extend product.	...do	Sufficient for purpose.

TABLE I—Continued

[See footnotes at end of this table]

Class of substance	Substance	Purpose	Products	Amount
	Sodium caseinate	...do	...do	3 percent in cooked product, 2 percent in raw product; in accordance with 21 CFR 172.5 and 182.1748.
	Tapioca dextrin	...do	...do	Sufficient for purpose in accordance with 21 CFR 184.1277.
	Wheat gluten	...do	...do	Sufficient for purpose in accordance with 21 CFR 184.1322.
	Whey (dried)	...do	...do	Do.
	Xanthan gum	To maintain: Uniform viscosity; suspension of particulate matter; emulsion stability; freeze-thaw stability.	Various, except uncooked products or sausages or other products with a moisture limitation established by subpart P of this part.	Do.
Chilling media	Salt (NaCl)	To aid in chilling	Raw poultry products	700 lbs. to 10,000 gals. of water.[1]
Coloring agents (natural).	Annatto, Carotene	To color products	Various	Sufficient for purpose.
Coloring agents (artificial).	Coal tar dyes (FD&C certified), Titanium dioxide.	To color products; to whiten products.	...do Salads and spreads	Do. 0.05 percent.
Curing accelerators; must be used only in combination with curing agents.	Ascorbic acid	To accelerate color fixing.	Cured poultry; cured, comminuted poultry products.	75 oz to 100 gal pickle at 10 percent pump level; ¾ oz to 100 lb of poultry product; 10 percent solution to surfaces of the product prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product.)
	Erythorbic acid	...do	...do	Do.
	Fumaric acid	...do	Cured, comminuted poultry or poultry products.	0.065 percent (or 1 oz to 100 lb) of the weight of the poultry or poultry byproducts, before processing.
	Sodium ascorbate	...do	...do	87.5 oz to 100 gal pickle at 10 percent pump level; ⅞ oz to 100 lb of poultry product; 10 percent solution to surfaces of product prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product.)
	Sodium erythorbate	...do	...do	Do.
	Citric acid or sodium citrate.	...do	...do	May be used in cured products to replace up to 50 percent of the ascorbic acid or sodium ascorbate that is used.
Curing agents	Sodium or potassium nitrate.	Source of nitrite	...do	7 lb to 100 gal pickle; 3½ oz. to 100 lb or poultry product (dry cure); 2¾ oz to 100 lb of chopped poultry meat.

TABLE I—Continued

[See footnotes at end of this table]

Class of substance	Substance	Purpose	Products	Amount
	Sodium or potassium nitrite. (Supplies of sodium nitrite and potassium nitrite and mixtures containing them must be kept securely under the care of a responsible employee of the establishment. The specific nitrite content of such supplies must be known and clearly marked accordingly.).	To fix color	Cured products	2 lb to 100 gal pickle at 10 percent pump level; 1 oz to 100 lb of poultry product (dry cure); ¼ oz to 100 lb chopped poultry meat. The use of nitrites, nitrates, or combination shall not result in more than 200 ppm of nitrite, calculated as sodium nitrite, in finished product.
Emulsifying agents.	Acetylated monoglycerides.	To emulsify product	Various	Sufficient for purpose.
	Diacetyl tartaric acid esters of mono- and diglycerides.	do	Rendered poultry fat or a combination of such fat with vegetable fat.	Do.
	Glycerol-lacto stearate, oleate or palmitate.	do	do	Do.
	Lecithin	To emulsify product (also as antioxidant).	Various	Do.
	Mono- and diglycerides (glycerol palmitate, etc.).	To emulsify product	do	Do.
	Polysorbate 80 (polyoxyethylene (20) sorbitan monooleate).	To emulsify product	Various	1 percent when used alone. If used with polysorbate 60, the combined total shall not exceed 1 percent.
	Propylene glycol mono- and diesters of fats and fatty acids.	do	Rendered poultry fat or a combination of such fat with vegetable fat.	Sufficient for purpose.
	Polysorbate 60 (polyoxyethylene (20) sorbitan monostearate).	do	do	1 percent when used alone. If used with polysorbate 80, the combined total shall not exceed 1 percent.
Flavoring agents; protectors and developers.	Artificial smoke flavoring..	To flavor product	Various	Sufficient for purpose.
	Smoke flavoring	do	do	Do.
	Autolyzed yeast extract.	do	do	Do.
	Citric acid	To protect flavor	do	Do.
	Corn syrup solids; corn syrup; glucose syrup.	To flavor product	do	Do.
	Disodium inosinate	do	do	Do.
	Disodium guanylate	do	do	Do.
	Hydrolyzed plant protein.	do	do	Do.
	Malt syrup	do	do	Do.
	Milk protein hydrolysate.	do	do	Do.
	Monosodium glutamate.	do	do	Do.
	Monoammonium glutamate.	do	do	Do.
	Sodium sulfoacetate derivative of mono and diglycerides.	do	do	0.5 percent.
	Sugars approved (surcose and dextrose).	do	do	Sufficient for purpose.

TABLE I—Continued

[See footnotes at end of this table]

Class of substance	Substance	Purpose	Products	Amount
	Potassium lactate	To flavor product	Various poultry and poultry food products, except infant formula and infant food.[3]	Not to exceed 2 percent of formulation; in accordance with 21 CFR 184.1639.
	Sodium lactate	...do...	...do...	Not to exceed 2 percent of formulation; in accordance with 21 CFR 184.1768.
	Sodium Acetate	To flavor product	Various	Not to exceed 0.12 percent of formulate in accordance with 21 CFR 184.1721.
	Sodium Diacetate	To flavor product	Various	Not to exceed 0.1 percent of formulate in accordance with 21 CFR 184.1754.
Gases	Carbon dioxide solid (dry ice).	To cool product or facilitate chopping or packaging.	Various	Do.
	Carbon dioxide liquid	Contact freezing	...do	Do.
	Nitrogen	To exclude oxygen from sealed containers.	...do	Do.
	Nitrogen liquid	Contact freezing	...do	Do.
Miscellaneous	Sodium bicarbonate	To neutralize excess acidity; cleaning vegetables.	Rendered fat, soups, curing pickle.	Do.
	Calcium propionate	To retard mold growth	Fresh pie dough	0.3 percent of calcium propionate or sodium propionate alone, or in combination, based on weight of the flour used.
	Sodium hydroxide	To decrease the amount of cooked out juices.	Poultry food products containing phosphates.	May be used only in combination with phosphate in a ratio not to exceed one part sodium hydroxide to four parts phosphate.
	Sodium propionate	To retard mold growth	Fresh pie dough	0.3 percent of calcium propionate or sodium propionate alone, or in combination, based on weight of the flour used.
	Disodium phosphate	To decrease the amount of cooked out juices.	Poultry food products except where otherwise prohibited by the poultry products inspection regulations.	0.5 percent of total product.
	Monosodium phosphate.	...do	...do	Do.
	Sodium metaphosphate, insoluble.	...do	...do	Do.
	Sodium polyphosphate, glassy.	...do	...do	Do.
	Sodium tripolyphosphate.	...do	...do	Do.
	Sodium pyrophosphate.	...do	...do	Do.
	Sodium acid pyrophosphate.	...do	...do	Do.
	Dipotassium phosphate.	...do	...do	Do.
	Monopotassium phosphate.	...do	...do	Do.
	Potassium tripolyphosphate.	...do	...do	Do.
	Potassium pyrophosphate.	...do	...do	Do.
	Tricalcium phosphate	To preserve product color during dehydration process.	Mechanically deboned chicken to be dehydrated.	Not to exceed 2 percent of the weight of the mechanically deboned chicken prior to dehydration, in accordance with 21 CFR 182.1217.

TABLE I—Continued

[See footnotes at end of this table]

Class of substance	Substance	Purpose	Products	Amount
	Sodium citrate buffered with citric acid to a pH of 5.6.	To inhibit the growth of micro-organisms and retain product flavor during storage.	Cured and uncured, processed whole-muscle poultry food products, e.g., chicken breasts.	Not to exceed 1.3 percent of the formulation weight of the product in accordance with 21 CFR 184.1751.
Poultry scald agents; must be removed by subsequent cleaning operations.	Alpha-hydro-omega-hydroxy-poly (oxyethylene) poly (oxypropylene) (minimum 15 moles) poly (oxyethylene) block copolymer (polyoxamer).	To remove feathers ...	Poultry carcasses	Not to exceed 0.05% by weight in scald water.
	Dimethylpolysiloxane	.....do	.....do	Sufficient for purpose.
	Dioctyl sodium sulfosuccinate.	.....do	.....do	Do.
	Dipotassium phosphate.	.....do	.....do	Do.
	Ethylenediaminetetraacetic acid (sodium salts).	.....do	.....do	Do.
	Lime (calcium oxide, calcium hydroxide).	.....do	.....do	Do.
	Polyoxyethylene (20) sorbitan monooleate.	.....do	.....do	Not to exceed 0.0175% in scald water.
	Potassium hydroxide	.....do	.....do	Sufficient for purposes.
	Propylene glycol	.....do	.....do	Do.
	Sodium acid phosphate.	.....do	.....do	Do.
	Sodium bicarbonate ..	.....do	.....do	Do.
	Sodium carbonate	.....do	.....do	Do.
	Sodium dodecylbenzenesulfonate.	.....do	.....do	Do.
	Sodium-2-ethylhexyl sulfate.	.....do	.....do	Do.
	Sodium hexametaphosphate.	.....do	.....do	Do.
	Sodium hydroxide	.....do	.....do	Do.
	Sodium lauryl sulfate	.....do	.....do	Do.
	Sodium phosphate (mono-, di-, tribasic).	.....do	.....do	Do.
	Sodium pyrophosphate.	.....do	.....do	Do.
	Sodium sesquicarbonate.	.....do	.....do	Do.
	Sodium sulfate	.....do	.....do	Do.
	Sodium tripolyphosphate.	.....do	.....do	Do.
	Tetrasodium pyrophosphate.	.....do	.....do	Do.
	Sodium tripolyphosphate.	.....do	.....do	Do.
	Sodium pyrophosphate.	.....do	.....do	Do.
	Sodium acid pyrophosphate.	.....do	.....do	Do.
Proteolytic enzymes.	Aspergillus oryzae	To soften tissue	Raw poultry muscle tissue of hen, cock, mature turkey, mature duck, mature goose, and mature guinea.	Solutions consisting of water and approved proteolytic enzyme applied or injected into raw poultry tissue shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Aspergillus flavus oryzze group.	.....do	.....do	Do.
	Bromelin	.....do	.....di	Do.
	Ficin	.....do	.....do	Do.
	Papain	.....do	.....do	Do.

TABLE I—Continued

[See footnotes at end of this table]

Class of substance	Substance	Purpose	Products	Amount
Radiation Sources.	Ionizing radiation sources as approved in 21 CFR 179.26(a)	For control of foodborne pathogens	Fresh or frozen, uncooked, packaged poultry products that are: (1) Whole carcasses or disjointed portions of such carcasses that are ''ready-to-cook,'' which includes such poultry products as fresh or frozen, uncooked ground, hand-boned, and skinless poultry, (2) mechanically separated poultry—a finely comminuted ingredient produced by the mechanical deboning of poultry carcasses or parts of carcasses	Minimum absorbed dose of 1.5 kiloGray (150 kilorads) to a maximum absorbed dose of 3.0 kiloGray (300 kilorads).
Synergists (used in combination with antioxidants).	Citric acid	To increase effectiveness of antioxidants.	Poultry fats	0.01 percent alone or in combination with antioxidants in poultry fats.
	Malic acid	.....do	.....do	Do.
	Monoisopropyl citrate	.....do	.....do	0.01 percent poultry fats.
	Phosphoric acid	.....do	.....do	0.01 percent.
	Monoglyceride citrate	.....do	.....do	0.02 percent.
Tenderizing agents.	Aspergillus oryzae	To soften tissue	Raw poultry muscle tissue of hen, cock, mature turkey, mature duck, mature goose, and mature guinea.	Solutions consisting of water and approved proteolytic enzymes applied or injected into raw poultry tissue shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Aspergillus flavusoryzae group.	.....do	.....do	Do.
	Bromelin	.....do	.....do	Do.
	Ficin	.....do	.....do	Do.
	Papain	.....do	.....do	Do.
	Potassium chloride	.....do	.....do	Not more than 3 percent of a 2.0 molar solution.
	Magnesium chloride	.....do	.....do	Not more than 3 percent of a 0.8 molar solution.
	Calcium chloride	.....do	.....do	Not more than 3 percent of a 0.8 molar solution.
	Potassium, magnesium or calcium chloride.	.....do	.....do	A solution of approved inorganic chlorides alone or in combination, applied or injected into raw poultry muscle tissue shall not result in a gain of more than 3 percent above the weight of the untreated product.

[1] Special labeling requirements are prescribed in § 381.120 for raw poultry products chilled in a medium with more than 70 lbs. of salt to 10,000 gals. of water.

[2] [Reserved]

[3] Information as to the specific products for which use of this substance is approved may be obtained upon inquiry addressed to the Standards and Labeling Division, Meat and Poultry Inspection Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, South Building, 14th Street and Independence Avenue SW., Washington, DC 20250.

[4] Provided, that its use is functional and suitable for the product and it is permitted for use at the lowest level necessary to accomplish the desired technical effect as determined in specific cases prior to label approval under § 381.32.

[37 FR 9706, May 16, 1972]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 381.147, see the List of CFR Sections Affected in the Finding Aids section of this volume.

EFFECTIVE DATE NOTE: At 64 FR 72175, Dec. 23, 1999, § 381.147 was removed, effective Jan. 24, 2000.

§ 381.148 Processing and handling requirements for frozen poultry products.

Procedures with respect to processing of frozen ready-to-heat-and-eat poultry products or stuffed ready-to-roast poultry shall be in accordance with sound operating practices and carried out in a manner which will assure freedom from adulteration of the products. Products to be frozen shall be moved into the freezer promptly under such supervision by an inspector as is necessary to assure preservation of the products by prompt and efficient freezing. Adequate freezing facilities shall be provided within the official establishment where products to be frozen are prepared, except that, upon written request, and under such conditions as may be prescribed by the Administrator in specific cases, such products may be moved from the official establishment prior to freezing: *Provided,* That the official establishment and freezer are so located and the necessary arrangements are made so that the Inspection Service will have access to the freezing room and adequate opportunity to determine that the products are being properly handled and frozen.

§ 381.149 Irradiation of poultry product to control foodborne pathogens.

(a) Definitions of food irradiation terms:

(1) *Absorbed dose* is the amount of energy imparted by ionizing radiation to a quantity of product.

(2) *Bulk density* is the mass (weight) of a product unit divided by its total volume.

(3) *Dose mapping* is the identification of the regions of minimum and maximum absorbed dose in a product unit.

(4) A *dosimeter* is the device for measuring absorbed dose.

(5) *Dosimetry* is the process of measuring absorbed dose.

(6) *Ionizing radiation* is radiation with sufficient energy to cause the removal of electrons from atoms or molecules, thereby creating ions.

(7) *Irradiate* means to expose a material to ionizing radiation.

(8) A *product unit* is the volume of product, made up of one or more packages of product, which is collectively transported past the radiation source (e.g., in boxes or totes or on pallets or carriers).

(9) A *production lot* is the quantity of like product units designated as such by the operator of the irradiation facility or their agent to be processed in no more than one continuous shift of up to 8 hours.

(10) *Radiation source* is the radioactive material (e.g., cobalt-60) or machine that emits ionizing radiation.

(11) *Source activity decay* is the decrease in the radioactivity of radionuclide source material (e.g., cobalt-60) with the passing of time.

(12) *Traceability* is the capacity, through documentation, to relate an end-point measurement to recognized standards.

(b) Poultry product may be treated to reduce foodborne pathogens by the use of ionizing radiation as identified in § 381.147(f)(4) of this subpart. Only irradiation facilities operating under a FSIS-approved quality control system, in accordance with paragraph (c) of this section, may irradiate poultry product for food uses.

(c) A description of the quality control system must be sent to the Administrator identifying the responsible official for quality control and stating that all data and information generated by the system will be maintained to enable the Department to monitor compliance. The quality control system will be evaluated and approved in accordance with § 381.145(e) of this subpart. A copy of the description will be placed on file in the irradiation facility and be available to any duly authorized representative of the Secretary. At a minimum, the operator of the irradiation facility must establish and comply with a quality control system which provides for the following:

(1) Licensing, Sanitation, and Facility. (i) Documentation showing that the irradiation facility is licensed and/or possesses gamma radiation sources registered with the Nuclear Regulatory Commission (NRC) or the appropriate