

Regulation 61-34

Raw Milk for Human Consumption

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S.C. Department of Health and
Environmental Control

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SECTION I. Definitions and Standards.

A. The following definitions shall apply in the interpretation and the enforcement of this Regulation:

1. ABNORMALITIES OF MILK means

a. Abnormal Milk: Milk that is visibly changed in color, odor and/or texture.

b. Undesirable Milk: Milk that, prior to the milking of the animal, is known to be unsuitable for sale, such as colostrum.

c. Contaminated Milk: Milk that is not sellable or is unfit for human consumption following treatment of the animal with veterinary products, i.e. antibiotics, which have withhold requirements or treatment with medicines or insecticides not approved for use on dairy animals by the United States Food and Drug Administration (FDA) or the United States Environmental Protection Agency (EPA).

2. AUTOMATIC MILKING INSTALLATION (AMI) means the entire installation of one (1) or more automatic milking units, including the hardware and software utilized in the operation of individual automatic milking units, the animal selection system, the automatic milking machine, the milk cooling system, the system for cleaning and sanitizing the automatic milking unit, the teat cleaning system and the alarm systems associated with the process of milking, cooling, cleaning and sanitation.

3. CLEAN means direct product contact surfaces that have had the effective and thorough removal of product and/or contaminants.

4. CODE OF FEDERAL REGULATIONS (CFR) means the current Code of Federal Regulations.

5. COMMON NAME means the generic term commonly used for domestic animals, i.e., cattle, goats, sheep, horses, water buffalo, etc.

6. COOLING POND MEANS a man-made structure designed for the specific purpose of cooling cows.

7. DAIRY FARM means any place or premises where one (1) or more lactating animals (cows, goats, sheep, water buffalo, or other hooved mammals) are kept for milking purposes and from which a part or all of the milk is provided, sold, or offered for sale.

8. DEPARTMENT means the South Carolina Department of Health and Environmental Control and its representatives.

9. DRUG means:

a. articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary or any supplement to any of them;

b. articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

c. articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

d. articles intended for use as a component of any articles specified in clause a, b, or c but does not include devices or their components, parts, or accessories.

10. GOAT MILK means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy goats. Goat milk sold in retail packages shall contain not less than 2.5 percent milkfat and not less than 7.5 percent milk solids not fat. Goat milk shall be produced according to the sanitary standards of this Regulation.

11. MILK means the normal lacteal secretion of hooved mammals, practically free of colostrum, obtained by the complete milking of one (1) or more healthy hooved mammals. This product shall be produced according to the sanitary standards of this Regulation. Hooved mammals milk shall include bovine milk, goat milk, sheep milk, and water buffalo milk.

12. MILK DISTRIBUTOR means any person who offers for sale milk that has been packaged at the same location that it was produced.

13. MILK PRODUCER means any person who operates a dairy farm and provides, sells, or offers milk for sale that was produced at the farm.

14. MISBRANDED MILK means any milk deemed to be misbranded when:

a. the product's container bears or accompanies any false or misleading written, printed, or graphic matter;

b. the milk does not conform to the definitions as contained in this Regulation; and

c. the product is not labeled in accordance with this Regulation.

15. OFFICIALLY DESIGNATED LABORATORY means a commercial laboratory authorized to do official work by the Department or a milk industry laboratory officially designated by the Department for the examination of producer samples of Grade A raw milk for human consumption and commingled milk tank truck samples of raw milk for drug residues and bacterial limits.

16. PERSON means any individual, partnership, corporation, company, firm, trustee, association or institution.

17. SANITIZATION means the application of any effective method or substance to a clean surface for the destruction of pathogens and of other organisms as far as is practical. Such treatment shall not adversely affect the equipment, the milk or milk product or the health of consumers and shall be acceptable to the Department.

18. SHEEP MILK means the normal lacteal secretion practically free of colostrum, obtained by the complete milking of one (1) or more healthy sheep. Sheep milk shall be produced according to the sanitary standards of this Regulation.

19. WATER BUFFALO MILK means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy water buffalo. Water buffalo milk shall be produced according to the sanitary standards of this Regulation.

B. Standards.

All Grade “A” raw milk for human consumption shall be bottled, packaged and sealed at the same location where it was produced, and it shall conform to the chemical, physical, bacteriological and temperature standards and the sanitation requirements of this Regulation.

SECTION II. Adulterated or Misbranded Milk.

A. No person shall, within the State of South Carolina or its jurisdiction, produce, provide, sell, offer, or expose for sale, or have in possession with intent to sell any milk that is adulterated or misbranded.

B. Any adulterated or misbranded milk or milk product may be impounded by the Department and disposed of in accordance with applicable laws or regulations.

C. Milk shall be examined by the Department as often as necessary to determine that it is not adulterated or misbranded. The Department may, upon written notice to the owner or person in charge, place a hold order on any milk or milk product that it determines, or has probable cause to believe, to be unwholesome or otherwise adulterated or misbranded. Under a hold order, milk shall be permitted to be suitably stored. It shall be unlawful for any person to remove or alter a hold order, notice, or tag placed on milk or milk products by the Department, and neither such milk nor the containers thereof shall be relabeled, repacked, reprocessed, altered, disposed of, or destroyed without permission of the Department except on order by a court of competent jurisdiction.

D. When the freezing point of milk is greater than 31°F. (-0.525°C.), the farm shall be notified that apparently the milk contains added water. If a second violation of this freezing point standard occurs within two (2) years, an observed milking or operation of processing shall be conducted and samples analyzed. The freezing point obtained from milk collected during the observation shall be used to determine a definite freezing point from the individual farm. A violation of the determined freezing point for a specific operation by over three (3) percent within two (2) years of setting the standard shall call for a two (2) day permit suspension or equivalent.

E. A cryoscope shall be used to determine adulteration by water.

F. When milk is found to be adulterated by the presence of drugs, pesticides, herbicides or other poisonous substances, it shall be impounded and additional samples analyzed. Milk found to be adulterated shall be disposed of until analysis shows the product not to be adulterated. If testing reveals milk positive for drug resi-dues, the milk shall be disposed of in a manner that removes it from the human or animal food chain. The Department shall immediately suspend the producer’s Grade “A” permit, or equally effective measures shall be taken, to prevent the sale of milk containing drug residues, and a penalty shall be imposed. Future sales are prohibited until subsequent testing reveals the milk is free of drug residue. The Grade “A” producer’s permit may be reinstated to allow the sale of milk for human food when a representative sample taken from the producer’s milk is no longer positive for drug residue. Whenever a drug residue test is positive, a recall shall be initiated and an investigation shall be made to determine the cause. The farm inspection must be completed by the Department to determine the cause of the residue and actions taken to prevent future violations, including on-farm changes in procedures necessary to prevent future occurrences as recommended by the Department.

SECTION III. Permits.

A. It shall be unlawful for any person who does not possess a permit from the Department to manufacture, bring into, send into, or receive into South Carolina or its jurisdiction, have in storage, sell or offer for sale therein, or offer to give away any milk or milk products defined in this Regulation.

B. Only a person who complies with the requirements of this Regulation shall be entitled to receive and retain such a permit. Permits shall not be transferable to other persons and/or locations.

C. Every milk producer and distributor of raw milk for human consumption shall hold a valid permit issued by the Department prior to beginning operation. No permit shall be issued until all parts of the operation meet the requirements of this Regulation.

D. The Department may deny a permit to produce, distribute or sell raw milk for human consumption when the applicant or facility has a history of difficulty in complying with other standards, regulations or statutes governing milk and milk products.

SECTION IV. Labeling.

A. All bottles, containers, and packages enclosing raw milk for human consumption shall be labeled in accordance with the applicable requirements of the Federal Food, Drug and Cosmetic Act as amended, the Nutrition Labeling and Education Act (NLEA) of 1990 and regulations developed thereunder, the Code of Federal Regulations, and in addition shall comply with the applicable requirements of this section.

B. All bottles, containers, and packages enclosing raw milk for human consumption shall be conspicuously marked with:

1. the words “Grade A Raw” on the exterior surface. Acceptable locations shall include the principal display panel, the secondary or informational panel, or the cap/cover.

2. the identity of the farm where packaged. This identity shall include the name, address, and the Department Permit Number.

3. the following information statement, in print no smaller than six (6) point font, shall be included on the package: “This is a raw milk product that is not pasteurized.”

4. the common name of the hooved mammal producing the milk shall precede the name of the milk when the product is made from other than cattle’s milk. As an example, “Goat,” “Sheep,” “Water Buffalo,” or “Other Hooved Mammal” milk respectively.

C. The Department shall not permit the use of any misleading marks, words, or endorsements upon the label. The Department may permit the use of registered trade designs or similar terms on the bottle cap or label, when, in its opinion, they are not misleading and are not used to obscure the labeling required by the Regulation. Descriptive labeling terms must not be used in conjunction with the Grade “A” designation or name of the raw milk and must not be false or misleading.

SECTION V. Inspection of Dairy Farms Bottling Raw Milk for Human Consumption.

A. Each dairy farm manufacturing raw milk for human consumption shall be inspected by the Department prior to the issuance of a permit. Following the issuance of a permit, the Department shall inspect each dairy farm at least once every three (3) months. For the purposes of determining the inspection frequency

for dairy farms producing raw milk for human consumption, the interval shall include the designated three (3)-month period in addition to the remaining days of the month in which the inspection is due. Inspections of dairy farms shall be made at milking time as often as possible.

B. Should a violation of any requirement set forth in Section VII be found to exist on an inspection, a second inspection shall be required after the time deemed necessary to remedy the violation, but not before three (3) days. This second inspection shall be used to determine compliance with the requirements of Section VII. Any violation of the same requirement of Section VII on such second inspection shall call for enforcement action pursuant to Section XI of this Regulation provided that when the Department finds that a critical processing element violation involving conditions whereby direct contamination of raw milk is occurring, the Department shall take immediate action to prevent further movement of such milk until such violations of critical processing element(s) have been corrected.

C. One copy of the inspection report shall be handed to the producer, or other responsible person, or be posted in a conspicuous place on an inside wall of the establishment. Said inspection report shall not be defaced and shall be made available to the Department upon request. An identical copy of the inspection report shall be filed with the records of the Department.

D. The Department shall also make such other inspections and investigations as are necessary for the enforcement of this Regulation.

E. Inspection Notification - The inspector should advise the owner or other responsible person of the intent to inspect upon arrival at the premises.

F. Every permit holder shall, upon request of the Department, allow access of officially designated persons to all parts of the permitted establishment or facilities to determine compliance with the provisions of this Regulation.

G. It shall be unlawful for any person who, in an official capacity, under the provisions of this Regulation obtains any information of disposition of milk, or results of inspections or tests thereof to use such information to his/her own advantage or to reveal it to any unauthorized person.

SECTION VI. The Examination of Raw Milk for Human Consumption.

A. Samples of raw milk for human consumption may be taken for scientific examination for public health purposes, at any reasonable time or place, and examined bacteriologically or for any other public health reason by agents of the Department.

B. Samples of raw milk for human consumption shall be collected and tested prior to a permit being issued. No permit shall be issued until the milk meets the requirements of Section VII.A.

C. The producer shall provide to the Department satisfactory pathogenic testing results prior to:

1. receiving a permit and beginning production and/or distribution; or
2. reinstatement of a permit that has been suspended because of positive results of testing for pathogenic organisms in association with a suspected outbreak of disease. In testing associated with a suspected outbreak of disease, the Department shall provide up to two (2) tests at no cost to the producer; pathogen testing required beyond these two (2) tests shall be the responsibility of the producer.

D. During any consecutive six (6) months, at least four (4) samples of raw milk for human consumption shall be collected from each producer in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained under the direction of the Department or shall be taken from each producer under the direction of the Department and delivered in accordance with this section.

E. Required bacterial counts, somatic cell counts, and cooling temperature checks shall be performed on raw milk for human consumption. In addition, drug tests on each producer's milk shall be conducted at least four (4) times during any consecutive six (6) months.

F. When multiple samples of the same milk are collected from the same producer from multiple tanks on the same day, the laboratory results shall be averaged arithmetically by the Department and recorded as the official results for that day. This is applicable for bacterial (standard plate count and coliform), somatic cell count and temperature determinations only.

G. Whenever two (2) of the last four (4) consecutive bacterial counts, somatic cell counts, coliform determinations, or cooling temperatures, taken on separate days exceed the standard for the milk as defined in this Regulation, the Department shall send a certified or hand-delivered written notice thereof to the person concerned. This notice shall be in effect so long as two (2) of the last four (4) consecutive samples exceed the standard. An additional sample shall be taken within twenty-one (21) days of the sending of such notice, but not before the lapse of three (3) days. Immediate suspension of permit shall be implemented whenever the standard is violated by three (3) of the last five (5) bacterial counts, coliform determinations, cooling temperatures or somatic cell counts.

H. Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues, and no milk shall be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.

I. When sampling for pathogenic organisms is conducted in association with a suspected outbreak of disease, and the samples test positive for pathogenic organisms, the Department shall immediately suspend the permit. The permit shall remain suspended until a representative sample containing a minimum of two (2) consecutive milkings are found to be free of pathogenic organisms.

J. Samples shall be analyzed at an official or appropriate officially designated laboratory. All sampling procedures and required laboratory examinations shall be in substantial compliance with the latest edition of Standard Methods for the Examination of Dairy Products (SMEDP) of the American Public Health Association, and the latest edition of Official Methods of Analysis (OMA) of the Association of Official Agricultural Chemists (AOAC) International. Such procedures, including the certification of sample collectors, and examinations shall be evaluated in accordance with the Evaluation of Milk Laboratories.

K. All violations of bacteria, coliform, somatic cell counts and cooling temperature standards shall be followed promptly by inspection to determine and correct the cause.

L. Laboratory Techniques - Procedures for the collection and holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading and reporting of results, shall be in substantial compliance with FDA 2400 Series forms, SMEDP and OMA.

1. The procedures shall be those specified therein for:

a. Standard plate count at 32°C (Agar or Petrifilm Method).

b. Alternate methods, including Plate Loop Count and the Bacto Scan FC and the Spiral Plate Count Method for viable counts for raw milk.

c. Coliform test with solid media or Petrifilm method at 32°C, and the Petrifilm High Sensitivity Coliform Count Method for all milk.

d. Beta lactam methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA for detecting drug residues in raw milk shall be used for each drug of concern. Regulatory action shall be taken on all confirmed positive results. A result shall be considered positive if it has been obtained by using a method that has been evaluated and deemed acceptable by FDA at levels established in memoranda transmitted periodically by FDA.

e. Screening and confirmatory methods for the detection of abnormal milk: The results of the screening test or confirmatory test shall be recorded on the official records of the dairy farm and a copy of the results sent to the milk producer.

(1) Milk (Non-Goat): Any of the following confirmatory or screening tests shall be used: Direct Microscopic Somatic Cell Counting Single Strip Procedure, Electronic Somatic Cell Counting or Flow Cytometry/Opto-Electronic Somatic Cell Counting.

(2) Goat Milk: In addition to the above mentioned tests, the California Mastitis Test may be used for screening raw goat milk samples, to indicate a range of somatic cell levels, as long as the somatic cell standard for goat milk remains 1,000,000/mL. Laboratories using the Wisconsin Mastitis Test or California Mastitis Test for goat milk shall confirm samples of herd milk that exceeds 18mm, or a value of one (1), respectively. Any of the following confirmatory or screening tests shall be used: Direct Microscopic Somatic Cell Counting Single Strip Procedure, Electronic Somatic Cell Counting or Flow Cytometry/Opto-Electronic Somatic Cell Counting. Pyronine Y-Methyl green stain or “New York modification” shall be used in the confirmatory test for Direct Microscopic Somatic Cell Counts in goat milk.

f. Any other tests that have been approved by the Food and Drug Administration or the Centers for Disease Control and Prevention to be equally accurate, precise, and practical.

g. All standards used in the development and use of drug residue detection methods designed for Grade “A” PMO monitoring programs will be referenced to a United States Pharmacopeia (USP) standard when available. When a USP standard is not available, then the original method shall define the standard to be used.

M. Sampling Procedures - SMEDP guidance for sampling of milk shall be used:

1. When bacterial counts and temperature determinations are made of several samples of the same milk collected from the same producer on the same day, these values are averaged arithmetically, and the results recorded as the count or temperature determinations of the milk for that day. All counts and temperatures should be recorded on a milk-ledger form for dairy farms as soon as reported by the laboratory.

2. A computer or other information retrieval system may be used.

N. Sampling Raw Milk - When samples of raw milk are taken, they shall be randomly drawn following adequate agitation. Sampling procedures shall not contaminate the sample of remaining milk in the tank or other type of container. Each sample shall be labeled. The label shall contain identification, temperature when collected, and date and hour collected. The sample shall be immediately placed under refrigeration.

Samples shall not be submerged in a coolant or handled in any manner which may cause contamination. All samples shall be maintained at 40°F (4°C) or below until analyzed. At no time shall the period of time between collection and analysis exceed forty eight (48) hours. Samples shall be collected by personnel who have been certified as sample collectors by Certified State Milk Sanitation Rating Officers.

SECTION VII. Standards for Raw Milk for Human Consumption.

A. General

1. All Grade “A” raw milk for human consumption shall be produced to conform with the following chemical, bacteriological, and temperature standards, and the sanitation requirements of this section.

2. No process or manipulation other than appropriate refrigeration shall be applied to milk for the purpose of removing or deactivating microorganisms.

Table 1. Chemical, Physical, Bacteriological, and Temperature Standards		
GRADE “A” RAW MILK FOR HUMAN CONSUMPTION	Temperature	Cooled to 10°C (50°F) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45°F) or less within two (2) hours after milking, provided, that the blend temperature after the first and subsequent milkings does not exceed 10°C (50°F).
	Bacterial Limits	Individual producer milk not to exceed 10,000 per mL
	Drugs	No positive results on drug residue detection methods as referenced in Section VI - Laboratory Techniques.
	Somatic Cell Count*	Individual producer milk not to exceed 500,000 per mL.
	Coliform	Not to exceed 10 per gram.
	Pathogenic Organisms: **Escherichia Coli 0157:H7 **Salmonella **Listeria Monocytogenes **Campylobacter	Individual producer milk not to exceed zero (0) organisms

*Goat Milk 1,000,000 per mL

B. Sanitation Requirements for Grade A Raw Milk For Human Consumption.

1. Milk with Abnormalities

a. Lactating animals which show evidence of the secretion of milk with abnormalities in one (1) or more quarters, based upon bacteriological, chemical or physical examination, shall be milked last or with separate equipment and the milk shall be discarded.

b. Lactating animals that have been treated with, or have consumed, chemical, medicinal or radioactive agents, which are capable of being secreted in the milk and which, in the judgment of the Department, may be deleterious to human health, shall be milked last or with separate equipment and the

milk disposed of as the Department may direct. (For applicability to automatic milking installations (AMI's), refer to Appendix Q of the PMO.)

c. Milk from lactating animals being treated with medicinal agents, which are capable of being secreted in the milk, shall not be offered for sale for such period as is recommended by the attending veterinarian or as indicated on the package label of the medicinal agent.

d. Milk from lactating animals treated with or exposed to insecticides not approved for use on dairy animals by the United States Environmental Protection Agency shall not be offered for sale.

e. The Department may require additional tests for the detection of milk with abnormalities as it deems necessary.

f. Bloody, stringy, off-colored milk, or milk that is abnormal to sight or odor, shall be handled and disposed of as to preclude the infection of other lactating animals and the contamination of milk utensils.

g. Lactating animals secreting milk with abnormalities shall be milked last or in separate equipment which effectively prevents the contamination of the wholesome supply. Milking equipment used on animals with abnormalities in their milk shall be maintained clean to reduce the possibility of re-infecting or cross infection of the dairy animals.

h. Equipment, utensils, and containers used for the handling of milk with abnormalities shall not be used for the handling of milk to be offered for sale, unless they are first cleaned and effectively sanitized.

i. Processed animal waste derivatives used as a feed ingredient for any portion of the total ration of the lactating dairy animal shall:

(1) be properly processed in accordance with at least those requirements contained in the Model Regulations for Processed Animal Wastes developed by the Association of American Feed Control Officials; and

(2) not contain levels of deleterious substances, harmful pathogenic organisms, or other toxic substances which are secreted in the milk at any level that may be deleterious to human health.

j. Unprocessed poultry litter and unprocessed recycled animal body discharges shall not be fed to lactating dairy animals.

2. Milking Barn, or Parlor Construction

A milking barn or parlor shall be provided on all dairy farms in which the milking herd shall be housed during milking time operations.

a. All floors must be constructed of concrete or equal impervious material; convalescent (maternity) pens located in milking areas of stanchion-type barns may be used when they comply with the guidelines specified in Appendix C. III. of the PMO. Floors shall be easily cleaned and shall be graded to drain and maintained in good repair and free of excessive breaks or worn areas that may create pools.

b. Walls and ceilings shall be smooth, painted or finished in an approved manner, and are in good repair. Ceilings shall be dust-tight; approved materials include wood, tile, smooth-surfaced concrete, cement plaster, brick, or other equivalent materials with light colored surfaces. Walls, partitions, doors, shelves, windows, and ceilings shall be kept in good repair; and surfaces shall be refinished whenever wear

or discoloration is evident. Whenever feed is stored overhead, ceilings shall be constructed to prevent the sifting of chaff and dust into the milking barn, stable or parlor. If a hay opening is provided from the loft into the milking portion of the barn, such opening shall be provided with a dust-tight door which shall be kept closed during milking operations.

c. Separate stalls or pens for horses, calves, and bulls shall be provided. Such portions of the barn that are not separated by tight partitions shall comply with all requirements of this item.

d. Natural and/or artificial light well distributed for day and/or night milking must be provided to insure that all surfaces and particularly the working areas will be plainly visible. The equivalent of at least ten (10) foot-candles (110 lux) of light in all working areas shall be provided.

e. Sufficient air space and air circulation to prevent condensation and excessive odors will be provided.

f. There will be no overcrowding which will be evidenced by the presence of calves, cows, or other barnyard animals in walks or feed alleys. Inadequate ventilation and excessive odors may also be evidence of an overcrowded barn. It is recommended that pit areas in parlors should be at least six (6) feet in width from overhang when cows are milked on two (2) sides, and six (6) feet working areas when single row of stalls. Ceiling height shall be at least seven (7) feet in areas where cows stand;

g. There must be dust-tight covered boxes or bins, or separate storage facilities for ground, chopped, or concentrated feed. A dust-tight partition, provided with doors that are kept closed except when in actual use, shall separate the milking portion of the barn from any feed room or silo in which feed is ground or mixed, or in which sweet feed is stored. When conditions warrant, the Department may approve a barn without four (4) walls extending from floor to roof, or a shed-type barn provided the requirement of Section VII.B.3. prohibiting animals and fowl from entering the barn is satisfied. Lactating animal-housing areas (stables without stanchions, such as loose housing stables, pen stables, resting barns, free stall barns, holding barns, loafing sheds, and wandering sheds) may be of shed-type construction, provided no milking is conducted therein. (These structures are classified as part of the cowyard under Section VII.B.4.)

3. Milking Barn, Stable or Parlor Cleanliness

a. The interior of the milking barn, stable, or parlor shall be kept clean. Floors, walls, ceilings, windows, pipelines, and equipment shall be free of filth and/or litter and shall be clean. Outside surfaces of pipeline systems located in the milking barn, stable, or parlor must be kept reasonably clean.

b. Gutter cleaners must be kept reasonably clean.

c. Swine and fowl shall be kept out of the milking barn.

d. All pens, calf stalls, and bull pens, if not separated from the milking barn, stable, or parlor, must be kept clean.

e. Feed shall be stored in a manner that will not increase the dust content of the air or interfere with the cleaning of the floor (as in covered, dust-tight boxes or bins). Open feed dollies or carts may be used for distributing the feed, but not storing food, in the milking area.

f. Milk stools, surcingles, and antikickers shall be kept clean and stored above the floor in a clean place in the milking barn, stable, parlor or milkhouse, when not in use.

g. Food mangers shall be kept clean so as not to attract flies; leftover feed in feed mangers must appear fresh and not be wet or soggy.

4. Cowyard

a. The cowyard, which is interpreted to be the enclosed or unenclosed area approximately adjacent to the milking barn in which the lactating animals may congregate, including animal-housing areas and feed lots, shall be graded and drained and shall have no standing pools of water or accumulations of organic wastes.

b. Wastes from the barn or milkhouse shall not be allowed to pool in the cowyard. Depressions and soggy areas shall be filled, and lactating animal lanes kept reasonably dry. Cowyards which are muddy due to recent rains should not be considered as violating this item.

c. Manure, soiled bedding, and waste feed shall not be stored or permitted to accumulate in such a manner as to permit the soiling of lactating animals' udders and flanks. Animal-housing areas (stables without stanchions, such as loose-housing stables, pen stables, resting barns, holding barns, loafing sheds, wandering sheds, free-stall housing) shall be considered part of the cowyard. Manure packs shall be solid to the footing of the animal.

d. In loafing or lactating animal housing areas, lactating animal droppings and soiled bedding shall be removed, or clean bedding added, at sufficiently frequent intervals to prevent the soiling of the lactating animal's udder and flanks.

e. Cooling ponds shall be allowed provided they are constructed and maintained in a manner that does not result in the visible soiling of flanks, udders, bellies, and tails of lactating animals exiting the pond.

f. Waste feed shall not be allowed to accumulate.

g. Swine shall be kept out of the cowyard.

h. Cowyards shall be kept reasonably free of animal droppings. Animal droppings shall not be allowed to accumulate in piles that are accessible to the animals.

5. Milkhouse or Room—Construction and Facilities

a. A separate milkhouse or room of sufficient size shall be provided, in which the cooling, handling, and storing of milk and the washing, sanitizing, and storing of milk containers and utensils shall be conducted, except as provided for in Section VII.B.12 of this Regulation.

b. The milkhouse shall be provided with a smooth floor constructed of concrete or equally impervious material graded to drain and maintained in good repair. Floors shall be sloped to drains so that there are no pools of standing water. Liquid waste shall be disposed of in a sanitary manner; all floor drains shall be accessible and shall be trapped if connected to a sanitary sewer system.

c. The joints between floors and walls shall be watertight. d. The walls and ceilings shall be constructed of smooth material, in good repair, well painted, or finished in an equally suitable manner. Surfaces and joints shall be tight and smooth. Acceptable materials include sheet metal, tile, cement block, brick, concrete, cement plaster, or similar materials of light color. Surfaces up to splash height shall be non-absorbent and easily cleanable.

e. The milkhouse shall have adequate natural and/or artificial light and be well ventilated. A minimum of twenty (20) foot-candles (220 lux) of light shall be provided at all working areas from natural and/or artificial light for milkhouse operations.

f. The milkhouse shall be used for no other purpose than milkhouse operations; there shall be no direct opening into any barn, stable, parlor or into a room used for domestic purposes. A direct opening between the milkhouse and milking barn, stable or parlor is permitted when a tight-fitting self-closing solid door(s) hinged to be single or double acting is provided and opens outward from the milk room. A vestibule, if used, must comply with the applicable milkhouse construction requirements. Screened vents in the wall between the milkhouse and a breezeway, which separates the milkhouse from the milking parlor, are permitted, provided animals are not housed within the milking facility.

g. Water under pressure shall be piped into the milkhouse.

h. The milkhouse shall be adequately ventilated to minimize odors and condensation on floors, walls, ceilings, and clean utensils.

i. Vents, if installed, and lighting fixtures shall be located to preclude the contamination of bulk milk tanks or clean utensil storage area.

j. The milkhouse shall be equipped with a wash-and-rinse vat having at least two (2) compartments. Each compartment must be of sufficient size to accommodate the largest utensil or container used. The cleaning-in-place vat for milk pipelines and milk machines may be accepted as one (1) part of the two (2)-compartment vat; provided that the cleaning-in-place station rack in or on the vat and milking machine inflations and appurtenances are completely removed from the vat during the washing, rinsing, and/or sanitizing of other utensils and equipment. Where mechanical cleaning/recirculated systems eliminate the need for handwashing of equipment, the presence of the second wash vat compartment may be optional if so determined by the Department on an individual farm basis.

k. Each milkhouse shall be provided with facilities for heating water in sufficient quantity and to such temperatures for the effective cleaning of all equipment and utensils.

6. Milkhouse or Room – Cleanliness

a. The floors, walls, ceilings, windows, tables, shelves, cabinets, wash vats, non-product contact surfaces of milk containers, utensils, and equipment, and other milkhouse equipment shall be kept clean. Vestibules, if provided, shall be kept clean.

b. Only articles directly related to milkhouse activities shall be permitted in the milkhouse.

c. The milkhouse shall be kept free of trash, animals, and fowl.

d. Incidental articles such as desks, refrigerators, and storage cabinets may be in the milkhouse provided they are kept clean, ample space is available to conduct the normal operations in the milkhouse, and they will not cause contamination of the milk.

7. Toilet

a. Every dairy farm shall be provided with one (1) or more toilets, conveniently located and properly constructed, operated, maintained and utilized in a sanitary manner. There shall be at least one (1) flush toilet connected to a public sewer system or to an individual sewage-disposal system or a chemical toilet,

earth pit privy or other type of privy. Such sewerage systems shall be constructed and operated in accordance with applicable Department regulations and statutes.

b. The waste shall be inaccessible to flies and shall not pollute the soil surface or contaminate any water supply. Vents of earth pits shall be screened.

c. No privy shall open directly into the milkhouse.

d. The toilet room, including all fixtures and facilities, shall be kept clean and free of insects and odors.

e. Where flush toilets are used, doors to toilet rooms shall be tight and self-closing. All outer openings in toilet rooms shall be screened or otherwise protected against the entrance of insects.

8. Water Supply

a. Water for milkhouse and milking operations shall be from an approved supply properly located, protected, and operated, and shall be easily accessible, adequate, and of a safe, sanitary quality.

b. No cross-connection shall exist between a safe water supply and any unsafe or questionable water supply, or any other source of pollution.

c. There shall be no submerged inlets through which a safe water supply may be contaminated.

d. The well or other source of water shall be located and constructed in such a manner that neither underground nor surface contamination from any sewerage systems, privy, or other source of pollution can reach such water supply.

e. New individual water supplies and water supply systems that have been repaired or otherwise become contaminated shall be thoroughly disinfected before being placed in use. The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected.

f. All containers and tanks used in the transportation of water shall be sealed and protected from possible contamination. These containers and tanks shall be subjected to a thorough cleaning and a bacteriological treatment prior to filling with potable water to be used at the dairy farm. To minimize the possibility of contamination of the water during its transfer from the potable tanks to the elevated or groundwater storage at the dairy farm, a suitable pump, hose, and fittings shall be provided. When the pump, hose and fittings are not being used, the outlets shall be capped and stored in a suitable dust-proof enclosure to prevent their contamination. The storage tank at the dairy farm shall be constructed of impervious material provided with a dust and rainproof cover, and provided with an approved-type vent and roof hatch. All new reservoirs, or reservoirs which have been cleaned, shall be disinfected prior to placing them into service.

g. Samples for bacteriological examination shall be taken upon the initial approval of the physical structure based upon the requirements of this Regulation, when any repair or alteration of the water supply system has been made, and at least every three (3) years, provided that:

(1) water supplies with buried well casing seals installed prior to the adoption of this section shall be tested at intervals no greater than six (6) months apart. Whenever such samples indicate either the presence of bacteria of the coliform group, or whenever the well casing, pump or seal needs replacing or

repair, the well casing and seal shall be brought above the ground surface and shall comply with all other applicable construction criteria of this section.

(2) when water is hauled to the dairy farm, such water shall be sampled for bacteriological examination at the point of use and submitted to a laboratory at least four (4) times in separate months during any consecutive six (6) months.

h. Bacteriological examinations shall be conducted in a laboratory acceptable to the Department.

i. To determine if water samples have been taken at the frequency established in this section, the interval shall include the designated period plus the remaining days of the month in which the sample is due.

j. Current records of water test results shall be retained on file with the Department or as the Department directs.

9. Utensils and Equipment – Construction

a. All multiuse containers, equipment, and utensils that are exposed to milk or milk products, or from which liquids may drip, drain or be drawn into milk or milk products, and used in the handling, storage, or transportation of milk shall be made of smooth, non-absorbent, corrosion-resistant, nontoxic materials, and shall be constructed to be easily cleaned. Acceptable materials include:

(1) stainless steel of the AISI (American Iron and Steel Institute) 300 series, or equally corrosion-resistant, nontoxic metal;

(2) heat-resistant glass; or

(3) plastic or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping, and distortion, under normal use conditions; are nontoxic, fat resistant, relatively nonabsorbent, relatively insoluble, do not release component chemicals or impart flavor or odor to the product, and which maintain their original properties under repeated use conditions.

b. All containers, utensils, and equipment shall be in good repair and shall be free of breaks, corrosion, pits, cracks or inclusions.

c. All milk pails used for hand milking and stripping shall be seamless and of the hooded type. Seamless hooded pails having an opening not exceeding one-third the area of that of an open pail of the same size shall be used for hand milking and hand stripping.

d. Strainers, if used, shall be constructed of perforated metal design, or single-service strainer media should be utilized. Multiple-use woven material shall not be used for straining milk.

e. All single-service articles shall be manufactured, packaged, transported, stored, and handled in a sanitary manner and shall comply with the applicable requirements of Section VIII. Articles intended for single-service use shall not be reused.

f. Farm holding/cooling tanks, welded sanitary piping, and transportation tanks shall comply with the applicable requirements of Section VII.B.9.a, g and h.

g. Mechanically cleaned milk pipelines and return-solution lines shall be self-draining. If gaskets are used, they shall be self-positioning and of material meeting specifications described in Section VII.B.9.a.(3), and shall be of such design, finish, and application as to form a smooth, flush interior surface. If gaskets are not used, all fittings shall have self-positioning faces designed to form a smooth, flush interior surface. All interior surfaces of welded joints in pipelines shall be smooth and free of pits, cracks, and inclusions.

h. Mechanically cleaned milk pipelines and return solution lines installed after the effective date of this Regulation shall have welded ferrule/flange fittings; rolled fittings shall not be used.

i. Detailed plans for cleaned-in-place pipeline systems shall be submitted to the Department for written approval prior to installation. No alteration or addition shall be made to any milk pipeline system without prior written approval of the Department.

j. All milking machines, including heads, milk claws, milk tubing, and other milk-contact surfaces shall be constructed to be easily cleaned and inspected. Pipelines, milking equipment, and appurtenances that require a screw driver or special tool shall be considered easily accessible for inspection, provided the necessary tools are available at the milkhous. Milking systems shall not have components incorporated in the return solution lines, that by design do not comply with the criteria for product-contact surfaces, such as:

(1) ball type plastic valves;

(2) plastic tees with barbed ridges to better grip the plastic or rubber hoses; and

(3) PVC water type piping.

k. Milk cans shall have umbrella-type lids.

l. Farm holding/cooling tanks, welded sanitary piping, and transportation tanks shall comply with the applicable requirements of this Regulation.

m. During filling, flexible plastic/rubber hoses may be used between the fill valves of bottom fill and top fill bulk milk storage tanks, when needed for functional purposes. Such hoses shall be drainable, be as short as practical, have sanitary fittings, and be supported to maintain uniform slope and alignment. The end fittings of such hoses shall be permanently attached in such a manner that will assure a crevice-free joint between the hose and the fitting and can be cleaned by mechanical means. The hoses shall be included as part of a mechanical cleaning system.

n. Transparent flexible plastic tubing (up to 150 feet in length) used in connection with milk transfer stations shall be considered acceptable if it meets the “3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20” and if it remains sufficiently clear that the interior surfaces can be properly inspected. Short lengths of flexible plastic tubing (eight [8] feet or less) may be inspected for cleanliness by sight or by use of a “rod”. The transparency or opacity of such tubing under this condition is not a factor in determining cleanliness.

NOTE: 3-A Sanitary Standards for Dairy Equipment are promulgated jointly by the Sanitary Standards Subcommittee of the Dairy Industry Committee, the Committee on Sanitary Procedure of the International Association for Food Protection, and the Milk Safety Branch, Food and Drug Administration, Public Health Service, Center for Food Safety and Applied Nutrition, Department of Health and Human Services.

Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this Regulation.

o. Whenever air under pressure is used for the agitation or movement of milk, or is directed at a milk-contact surface, it shall be free of oil, dust, rust, excessive moisture, extraneous materials and odor.

10. Utensils and Equipment – Cleaning

a. The product-contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of milk shall be cleaned after each milking or once every twenty-four (24) hours for continuous operations.

b. There shall be a separate wash manifold for all mechanically cleaned milk pipelines in all new or extensively remodeled facilities.

11. Utensils and Equipment – Sanitization

a. The product-contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage or transportation of milk shall be sanitized before each usage.

b. Sanitization shall be achieved by use of the following methods:

(1) Complete immersion in hot water at a temperature of at least 77°C (170°F), for at least five (5) minutes, or exposure to a flow of hot water at a temperature of at least 77°C (170°F), as determined by the use of a suitable accurate thermometer (at the outlet) for at least five (5) minutes;

(2) Complete immersion for at least one (1) minute in or exposure for at least one (1) minute to a flow of a chemical sanitizer of acceptable strength. All product-contact surfaces must be wetted by the sanitizing solution, and piping so treated must be filled. Sanitizing sprays may be used. Chemical solutions, once used, shall not be reused for sanitizing but may be reused for other purposes; or

(3) By any method which has been demonstrated to be equally effective.

12. Utensils and Equipment – Storage

a. All containers, utensils, and equipment used in the handling, storage, or transportation of milk, unless stored in sanitizing solutions, shall be stored to assure complete drainage and shall be protected from contamination prior to use, except that pipeline milking equipment such as milker claws, inflations, weigh jars, meters, milk hoses, milk receivers, tubular coolers, plate coolers and milk pumps which are designed for mechanical cleaning and other equipment, as accepted by FDA, which meets these criteria, may be stored in the milking barn or parlor, provided this equipment is designed, installed and operated to protect the product and solution-contact surfaces from contamination at all times.

b. Strainer pads, parchment papers, gaskets, and similar single-service articles shall be stored in a suitable container or cabinet and protected against contamination.

13. Utensils and Equipment – Handling

After sanitization, all containers, utensils, and equipment shall be handled in a manner that prevents contamination of any product-contact surface.

a. Sanitized product-contact surfaces, including farm cooling holding tank openings and outlets, shall be protected against contact with unsanitized equipment and utensils, hands, clothing, splash, condensation, and other sources of contamination.

b. Any sanitized product-contact surface which has been otherwise exposed to contamination shall be cleaned and sanitized before being used.

14. Milking – Flanks, Udders, and Teats

a. Milking shall be done in the milking barn or parlor.

b. The flanks, udders, bellies, and tails of all milking cows shall be free from visible dirt. All brushing shall be completed prior to milking.

c. The udders and teats shall be cleaned and treated with a sanitizing solution just prior to the time of milking, and shall be relatively dry before milking. Sanitizing solutions shall be used in accordance with manufacturer specifications and recommendations.

d. Wet hand milking is prohibited.

e. Flanks, bellies, tails and udders shall be clipped as often as necessary to facilitate cleaning of these areas.

15. Drug and Chemical Control

a. Cleaners and Sanitizers

(1) Cleaners and sanitizers shall be stored in dedicated end-use containers which properly identify the contents.

(2) Bulk cleaners and sanitizers that are transferred from the manufacturer's or distributor's container shall be stored only in an end-use container that is properly labeled with the container's contents.

(3) The manufacturer's or distributor's label for each cleaner and sanitizer, including the product name, chemical description, use directions, precautionary and warning statement, first aid instructions, container storage and maintenance instructions and the name and address of the manufacturer or distributor, shall be maintained on the premises and be readily accessible for reference or inspection.

b. Drugs

(1) Drugs shall be properly labeled to include the name and address of the manufacturer or distributor for over-the-counter (OTC) drugs or veterinary practitioner dispensing the product for prescription and extra label use drugs. Drug labels shall also include:

(a) directions for use and prescribed withholding times;

(b) cautionary statements, if needed; and

(c) active ingredient(s) in the drug product.

(2) Drugs dispensed by a pharmacy on the order of a veterinarian shall have labeling that includes the name of the prescribing veterinarian and the name and address of the dispensing pharmacy; the address of the prescribing veterinarian may be included on the labeling.

(3) Drugs intended for treatment of non-lactating dairy animals shall be segregated from those drugs used for lactating animals in separate shelves in cabinets, refrigerators or other storage facilities.

(4) Unapproved drugs shall not be used and shall not be stored in the milkhouse, milking barn, stable or parlor.

(5) Animal drugs and drug administration equipment shall be stored in such a way that milk, milking equipment, wash vats and hand sinks are not subject to contamination by the drugs.

(6) Equipment used to administer drugs shall not be cleaned in the wash vats.

NOTE: Topical antiseptics and wound dressings, unless intended for direct injection into the teat, vaccines and other biologics, and dosage form vitamins and/or mineral products are exempt from labeling and storage requirements, except when it is determined that they are stored in such a manner that they may contaminate the milk or milk product-contact surfaces of containers, utensils or equipment.

16. Milking – Transfer and Protection of Milk

a. Each pail or container of milk shall be taken immediately from the milking barn or parlor to the milkhouse. No milk shall be strained, poured, transferred, or stored outside the milkhouse.

b. The milk receiving receptacle shall be raised above the floor.

17. Personnel

a. Adequate handwashing facilities shall be provided, including a lavatory fixture with hot and cold, or warm running water, soap or detergent, and individual sanitary towels, or other approved hand drying devices, convenient to the milkhouse, milking barn, stable, parlor and flush toilet, and shall be used for no other purpose. Utensil wash and rinse vats shall not be considered as handwashing facilities.

b. Hands shall be washed clean and dried with an individual sanitary towel or other approved hand drying device immediately before milking, before performing any milkhouse function, and immediately after the interruption of any of these activities. Milkers shall wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment.

c. No person who by medical examination or supervisory observation is shown to have or appears to have an illness, open lesion (including boils, sores, or infected wounds) or any other abnormal source of microbial contamination shall work at any dairy farm in any capacity that brings them into contact with the production, handling, storage, or transportation of milk, containers, equipment, and/or utensils. Any producer or distributor of milk who suspects that any employee has contracted any disease in a communicable form or has become a carrier of such disease shall notify the Department immediately.

d. When reasonable cause exists to suspect the possibility of transmission of infection or disease from any person concerned with the handling of milk, the Department may:

(1) order the immediate exclusion of that person from milk handling;

(2) order the immediate exclusion of the milk supply concerned from distribution and consumption;

(3) order adequate medical and bacteriological examination of the person to determine if the infection or disease is present; or

(4) order any combination of the previous measures.

18. Cooling

a. Raw milk shall be cooled to 10°C (50°F) or less within four (4) hours or less of the commencement of the first milking, and to 7°C (45° F.) or less within two (2) hours after the completion of milking, and shall be maintained at that temperature, including during packaging and transportation; except that, the blend temperature after the first milking and subsequent milking shall not exceed 10°C (50°F).

b. Recirculated cold water that is used in plate or tubular coolers or heat exchangers shall be from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the bacteriological standards set by the Department.

c. All farm bulk milk tanks manufactured after January 1, 2000, shall be equipped with an approved temperature-recording device.

(1) The recording device shall be operated continuously and be maintained in a properly functioning manner. Circular charts shall not overlap.

(2) The recording device shall be verified every six (6) months and documented in a manner acceptable to the Department using an accurate (+/-1°C (2°F)) thermometer that has been calibrated by a traceable standard thermometer, within the past six (6) months, with the results and date recorded and the thermometer being properly identified, or by using a traceable standard thermometer that has been calibrated within the last year.

(3) Recording thermometer charts shall be maintained on the premises for a period of a minimum of six (6) months and available to the Department.

(4) The recording thermometer should be installed in an area convenient to the milk storage tank and acceptable to the Department.

(5) The recording thermometer sensor shall be located to permit the registering of the temperature of the contents when the tank contains no more than ten (10) percent of its calibrated capacity.

(6) The recording thermometer shall comply with the current technical specifications for tank recording thermometers.

(7) A recording thermometer and/or any other device that meets the intent of this Regulation and technical specifications, and is acceptable to the Department, can be used to monitor/record the bulk tank temperature.

(8) The recording thermometer charts shall properly identify the producer, date, and signature of the person removing the chart.

19. Vehicles.

Vehicles used to transport milk shall be constructed and operated to protect their contents from sun, freezing, and contamination. Such vehicles shall be kept clean, inside and out; and no substance capable of contaminating milk shall be transported with milk.

20. Insect and Rodent Control.

a. Effective measures shall be taken to prevent the contamination of milk, containers, equipment, and utensils by insects and rodents, and by chemicals used to control such vermin.

b. Milkrooms shall be free of insects and rodents.

c. Surroundings shall be kept neat, clean, and free of conditions which might harbor or be conducive to the breeding of insects and rodents.

d. Feed shall be stored in such a manner that it will not attract birds, rodents or insects.

e. Manure packs in loafing areas, stables without stanchions, pen stables, resting barns, wandering sheds, and free-stall housing shall be properly bedded and managed to prevent fly breeding.

f. Milkrooms shall be effectively screened or otherwise protected against the entrance of vermin, including hose ports and floor drains through walls.

g. Outer milkhouse doors shall be tight and self-closing. Screen doors shall open outward.

h. Only pesticides approved for use by the Department and/or registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control.

i. Pesticides shall be used only in accordance with manufacturer's directions.

SECTION VIII. Bottling, Packaging, Container Filling and Container Closure/Sealing.

A. Bottling, Packaging and Container Filling.

1. Bottling, packaging, and container filling of milk shall be done at the place of production in a sanitary manner by approved mechanical equipment. Bottling, packaging and container filling of milk may be conducted in the milkhouse or room.

2. Bottling or packaging machine supply tanks and bowls shall have covers which are smooth and easily cleanable and shall be constructed to prevent any contamination from reaching the inside of the filler tank or bowl. All covers shall be in place during operation.

3. A drip deflector shall be installed on each filler valve. The drip deflector shall be designed and adjusted to divert condensation away from the open container.

4. All containers, seals and caps shall be from an approved Interstate Milk Shippers listed facility.

5. All containers, seals and caps shall be handled in a sanitary manner and protected against undue exposure during the operation.

6. When any lubricant is applied to the filler equipment or other milk contact surfaces, the lubricant shall be food grade and applied in a sanitary manner.

7. Containers shall be closed immediately after being filled.

B. Container Closure/Sealing.

1. All container caps, sealers and closures shall be stored in a clean, dry place protected from insects, rodents, dust, splash, or other contamination.

2. Only new containers, container caps, sealers and closures shall be used. Reusable glass containers must be approved by the Department prior to use.

3. All container closure/sealing shall be done at the place of production in a sanitary manner by approved mechanical equipment.

4. Hand capping or sealing of containers is prohibited.

5. If suitable mechanical equipment for the capping or closing of specific container(s) of 12.8 liters (three [3] gallons) or more is not available, other methods which eliminate all possibility of contamination may be approved by the Department. Approval of such methods shall be obtained prior to beginning operation.

6. Bottles and packages which have been imperfectly capped, sealed or closed shall have the contents emptied immediately into approved sanitary containers that are protected from contamination and maintained at 7°C (45°F) or less; when handled and stored properly, the contents may be repackaged in new containers at a later time.

7. All caps, seals and closures shall be designed and applied so that the sealed container is tamper-evident (removal cannot be made without detection), and the pouring lip shall be protected to at least its largest diameter.

8. Caps, sealers and closures shall not be left in the equipment at the end of an operating period. Caps, sealers and closures remaining in the chute between the hopper and the capping device shall be discarded.

9. Loose caps, sealers and closures may be returned to storage by enclosing them in a clean, protective wrap, plastic bag or container approved by the Department.

SECTION IX. Animal Health.

A. All milk for human consumption within the State of South Carolina shall be from healthy animals. Milk from unhealthy animals shall not be offered for sale, be given away, or combined with other milk, for human consumption.

B. All animals producing milk for human consumption shall be tested for brucellosis and tuberculosis every twelve (12) months. Animals showing positive by lesions or a positive test shall be reported to the Department, and:

1. Shall be separated, and kept separate, from the remainder of the herd;

2. A certificate, identifying each animal, signed by a licensed veterinarian and the director of the laboratory making the test, shall be filed with the Department;

3. Shall be retested by a licensed veterinarian at a frequency specified by the United States Department of Agriculture (USDA), and test results shall be filed with the Department; and

4. Disposition of diseased animals shall be conducted in accordance with guidelines published by the USDA and shall be reported to the Department.

C. For diseases other than brucellosis and tuberculosis, the Department shall require such physical, chemical, or bacteriological tests as it deems necessary. The diagnosis of other diseases in dairy animals shall be based upon the findings of a licensed veterinarian. Any diseased animal disclosed by such test(s) shall be disposed of as the Department directs.

D. Animals shipped into South Carolina for additions to herds shall have been tested for tuberculosis and brucellosis within thirty (30) days prior to being brought into the state, except that this shall not apply, with regard to brucellosis, to those cattle that have been vaccinated for brucellosis and are under thirty (30) months of age.

E. Records supporting the tests required in this section shall be available to the Department and be validated with the signature of a licensed veterinarian.

SECTION X. Recall.

Each producer of raw milk for human consumption shall develop and maintain procedures for the notification of regulatory officials, consumer notification, and product recall, and shall implement any of these procedures as necessary with respect to any product for which the producer or the Department knows or has reason to believe circumstances exist that may adversely affect its safety for the consumer. If the Department determines, based upon representative samples, risk analysis, information provided by the producer, and other information available to the Department, that the circumstances present an imminent hazard to the public health and that a form of consumer notice or product recall can effectively avoid or significantly minimize the threat to public health, the Department may order the producer to initiate a level of product recall or, if appropriate, issue a form of notification to customers. The producer shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem.

SECTION XI. Enforcement.

A. General.

This Regulation is issued under the authority of Sections 44-1-140(3) and 44-1-150, S.C. Code of Laws, 1976, as amended. It shall be enforced in accordance with interpretations and public health reasons approved by the Department.

B. Suspension of Permit

1. The Department may, without warning, notice or hearing, suspend the permit of any producer or distributor of raw milk whenever, in the opinion of the Department, an imminent health hazard exists. An imminent health hazard includes, but is not limited to, violations of bacterial, coliform, somatic cell, cooling temperature, or drug residue test standards, or the presence of pathogenic organisms. Upon such suspension of permit, all bottling and/or distribution activities shall immediately cease and remain ceased while the

permit is suspended. The suspension of permit shall remain in effect until the imminent health hazard has been corrected to the satisfaction of the Department.

2. The Department may otherwise temporarily suspend a permit for a violation of this Regulation when:

- a. it has reason to believe that a public health hazard exists;
- b. the permit holder has violated any of the requirements of this Regulation;
- c. the permit holder has interfered with the Department in the performance of its duties, including willful refusal to allow an authorized inspection/audit; or
- d. the permit holder exhibits hostile behavior toward a representative of the Department during the performance of duty.

3. A suspension of permit shall remain in effect until any violation has been corrected to the satisfaction of the Department.

C. Revocation of Permit. The Department may revoke a permit when:

1. the permit holder has repeated suspension(s); or
2. the permit holder physically threatens or intimidates a representative of the Department.

D. Reinstatement of Permit

1. Any producer whose permit has been suspended may make written application for the reinstatement of the permit. Any application for the reinstatement of a suspended permit must be in writing and must address all violations underlying the suspension and explain the steps taken to correct those violations.

2. Within one week of the receipt of such an application, the Department shall make an inspection of the applicant's establishment, and as many additional inspections thereafter as are deemed necessary, to determine that the applicant's establishment is complying with the requirements. When the findings justify, the permit shall be reinstated.

3. When the permit suspension has been due to a violation of any of the bacteriological, coliform, somatic cell, cooling temperature, or drug residue test standards, the Department may issue a temporary permit whenever resampling of the herd's milk supply indicates the milk supply to be within acceptable limits as prescribed in Section VII. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three(3)-week period, and the Department shall reinstate the permit upon compliance with the appropriate standards as determined in accordance with Section VI of this Regulation.

4. When a permit has been revoked, the holder of the revoked permit may make written application for a new permit; however, the Department may deny a new permit based upon past history.

E. Other Enforcement Provisions

1. In addition to the authority to suspend and revoke permits, the Department may seek enforcement and issue civil penalties in accordance with SC Code Ann. Section 44-1-150, S.C. Code of Laws, 1976, as

amended. The Department shall have the authority to assess and suspend civil penalties if the violations of this Regulation are corrected in a period of time established by the Department.

2. A Department decision involving the issuance, denial, renewal, modification, suspension, or revocation of a permit may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23. Any person to whom an order or enforcement letter is issued may appeal it pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23.

SECTION XII. Severability Clause.

Should any section, paragraph, sentence, clause or phrase of this Regulation be declared unconstitutional or invalid for any reason, the remainder of this Regulation shall not be affected thereby.