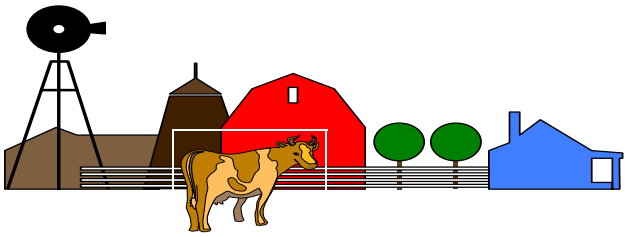

Dairy Farm Sanitation and Inspection

FD375

2009 Revision

PURPOSE AND DESCRIPTION

The purpose of this course is to give the participant a basic understanding of the operation, requirements and inspection techniques to be applied on Grade “A” dairy farms. The course principles are based on the current requirements and Administrative Procedures of the Grade “A” Pasteurized Milk Ordinance, the most recent Memoranda of Interpretation, and field expertise of the Training Officers, Food & Drug Administration Regional Milk Specialists and state and local dairy farm inspection personnel.

This training manual should not be used in place of the Grade “A” Pasteurized Milk Ordinance.

FOREWORD

This course is designed primarily for state and local milk regulatory personnel assigned the responsibility for the inspection of Grade "A" dairy farms. The course is also pertinent to dairy field supervisors, industry consultants, plant quality control supervisors, military food and milk specialists, and others involved in the control of food and milk supplies.

The course includes classroom studies and in some cases, field exercises, which are used to apply the learned principles. Classroom discussions are encouraged and problem solving sessions are employed during the course. The participant is given the basics of good farm sanitation practices along with those basic requirements applicable to each sanitation requirement.

This edition, of the manual, is based on the most current revision of the Grade "A" Pasteurized Milk Ordinance (PMO), including applicable memorandums. All of the raw (r) items in the PMO are covered along with the applicable Administrative Procedures that explain satisfactory compliance with each item.

Perhaps one of the most significant aspects of the course is the open exchange of ideas among the class participants during the week. Although this manual is not meant to be a replacement for the PMO requirements, it can be an excellent reference guide for dairy farm sanitarians. It should be used as a "workbook", which may develop or reinforce familiarity with the application of each of the requirements.

Reference materials used in the development of this manual were; a) current edition of the PMO, b) the 3-A Sanitary Standards and Accepted Practices, and c) numerous Memoranda applicable to the principles and requirements of sanitation on Grade "A" dairy farms.

INTRODUCTION

It is the responsibility of the state and regulatory agencies to maintain a supply of quality milk for the consumer. Without regulations and guidelines, milk quality as we know it may not exist.

During the inspection, every part of the dairy farm operation is to be inspected and evaluated for compliance with the current state and federal regulations. Some dairy farmers view much of this interest in their affairs as unwarranted intrusion, but that attitude is a narrowing one. No matter how capable an operator, wholesomeness and quality of the milk supply cannot be guaranteed without outside help and expertise. The milk sanitarian can be a valuable resource to the dairy operation. In turn, this places a high responsibility on the expertise, knowledge and "advice" of the milk sanitarian. It also demands that he or she become true milk production "specialist", with regulatory being the primary duty while assuming an advisory or consultant attitude to assist the dairy operator resolve quality or dairy related problems.

To the dairy farm owner/operator, the milk regulations and laws are most directly represented by the official with the clipboard--the dairy inspector. The regulatory inspector (sanitarian) should be a professional in the field of milk sanitation and production as well as a representative of the regulatory agency. He or she must work closely with the producer and be able to apply the regulations in a fair and equitable manner.

Although the dairy inspector’s ideas may differ from the producer, their objectives are very similar. The inspector is concerned with assuring the producer’s milk is safe, free of adulterants, excessive micro-organisms and chemicals (including drug residues), and meets the requirements of state and federal regulations.

Communication is a critical element in the relationship between the inspector and milk producer. It is very important that the farm inspector take extra efforts to assure the producer is familiar with the requirements, how they are applied and the public health reason(s) for each. If items are debited on the inspection form, they must be explained to the producer in detail. The farm inspector may provide suggestions on how the producer may correct the condition, for the item in violation; however these should only be suggestions. This policy leads to a cooperative working relationship between regulatory and the milk industry and will serve as a preventative measure for misunderstandings relative to compliance with the milk regulations. Of course this avenue of communication

is a two way street and all parties involved should be willing to discuss matters of farm sanitation and inspection openly so that issues may be resolved with minimum difficulties on a time schedule agreeable to both the inspector and producer. If a time schedule cannot be agreed upon the inspector shall be the final authority on the required timeframe.

If the dairyman's standards are consistent with or exceed the regulations, a routine inspection will evolve into a visit to the facility to help identify problems which will assist the dairyman in producing a quality product. Good dairy practices and trained employees should produce satisfactory inspection results and an excellent rapport between the inspector and the milk producer. The receptive and cooperative dairy farmer will discover that these professionals, considering the exposure and familiarization with many different types of milking operations, may be able to offer practical solutions.

ACKNOWLEDGMENT

This training manual was originally prepared by the Food and Drug Administration Division of Human Resource Development University (ORAU).

Special recognition is given to CAPT Richard D. Eubanks, USPHS, the Center of Veterinary Medicine (CVM), the Center for Food Safety and Applied Nutrition (CFSAN) and FDA's Regional Milk Specialist.

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CHAPTER 1

Background and History

Since milk is a food substance with the characteristics of high nutrients it also has the qualities and properties to readily support microbial growth. Milk cows on the farm are exposed to many sources of potential contamination. Some of these contaminants may be the water or food source; exposure to manure; flies and other insects; contact with diseased animals in the housing or corral areas; injuries to the udder; poor milking practices; mal-adjusted milking machines; and contamination during calving or treatment.

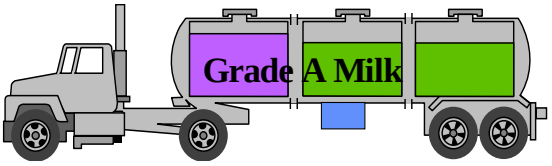
Early indications and studies implicated milk as the vehicle of many communicable diseases to the consumer. Some of the most notable outbreaks were tuberculosis and brucellosis a bacterial disease caused by *Brucella abortus* (Undulant Fever), salmonellosis, diphtheria, scarlet fever, septic sore throat and the dysenteries of the food infection type. More recently, *Salmonella, Listeria, Staphylococcus aureus, Yersinia,* and *Campylobacter* have been responsible for human illnesses due to the consumption of unpasteurized or contaminated milk and milk products. Q fever (*Coxiella burnetii)* a febrile *rickettsial* illness is also known as one of the pathogens responsible for milk borne outbreaks. This organism was responsible for the 1957 enactment of more stringent pasteurization requirements.

Massachusetts in 1856 developed the first milk control laws. Later New York City adopted standards (1901) in order to handle some of the unsanitary problems found in many of the “slop dairies”, which were using brewery grain wastes for feeding. Chicago became the first city to require pasteurization in 1908. It was not until 1924 when the State of Alabama in conjunction with the United States Public Health Service (USPHS) developed the first Federal Milk Code. This was the first effort to standardize the milk regulations into a national code.

Many states followed suit and adopted similar regulations to control the ever increasing number of small dairy farms throughout the nation from a sanitary aspect. This first "PMO" was published by the USPHS and made available to the interested municipalities and states for adoption as state law.

The USPHS had no real regulatory jurisdiction over the states or cities for the control of milk supplies. The exception was (and remains in effect) on interstate carriers and in many government facilities. Many states and municipalities therefore readily accepted the USPHS promulgated milk *Ordinance* for their use and adoption.

One problem in controlling the movement and sanitary assurance of milk supplies is that milk is a food product **often transported** between cities and states. This shipping of milk created concerns between the states which resulted in regulatory inspectors traveling outside their jurisdictions to inspect an imported milk supply. These policies often times created confusion among the shippers because of occasional non-uniformities in regulations and local interpretations.



There was a definite need for a national uniform program to oversee and govern the shipment of milk products in interstate and intrastate commerce. In 1952, a group of states met in St. Louis, MO, along with the U. S. Public Health Service and created what is now known as the National Conference on Interstate Milk Shipments (NCIMS). This conference has been one of the most successful national entities in existence and its sole purpose is to promote uniformity, allow reciprocity, and to provide the "best possible milk supply for all the people".

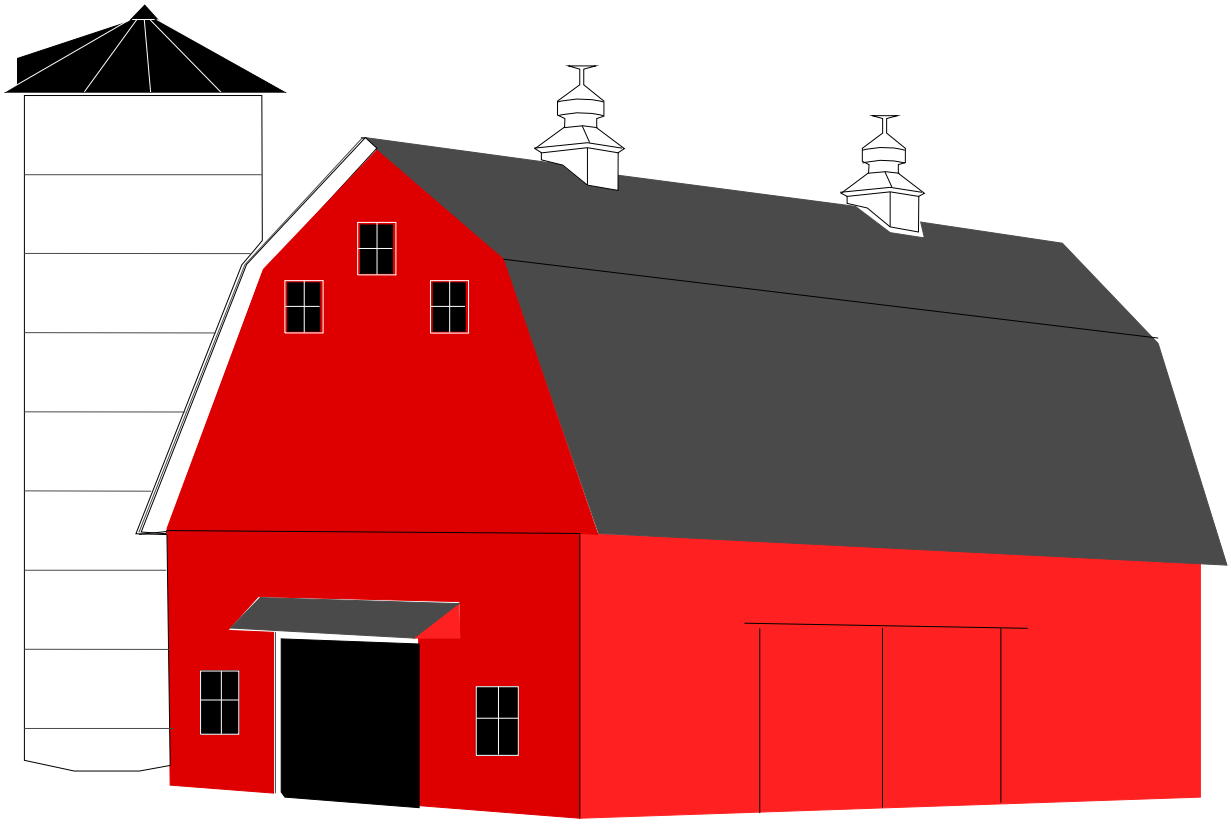
Milk is one of the most tightly regulated and inspected food supplies in the nation. Producer dairies are inspected a minimum of twice a year, with many agencies inspecting on a quarterly or monthly schedule. Interstate listed shippers are surveyed at least once every 24 months and the results of these ratings are published in the NCIMS periodical. All milk shippers listed are also subject to federal (FDA) audits or "check ratings" to assure published rating validity.

Raw milk is sampled at the farm bulk milk tank, from the milk tanker, and at the plant from the storage silo tanks. Individual farm supplies are tested for compliance with bacteria, temperature, somatic cell and antibiotic standards. Periodic testing is also done for pesticide residues. Some regulatory agencies perform sediment and added water tests. Each dairy herd is also monitored for the presence of Tuberculosis and Brucellosis infections and must remain on the “Certified” list for the state to maintain their “Certified Tuberculosis and Brucellosis Free” status.

Often the purveyor performs other quality test including milk fat, added water, acidity, total solids, specific animal drug residues, pre-incubation and laboratory pasteurized quality tests, and keeping quality (shelf life) tests.

Laboratory and sampling personnel are trained and certified according to strict guidelines and must renew their certificates on a routine basis.

This is only a partial explanation of the total national milk control program. Specifics on NCIMS agreements, procedures, and rating or survey methods are found in the most current revision of the *Procedures Governing the Cooperative State-Public Health Service/FDA Program of the National Conference on Interstate Milk Shipments* and the *Methods of Making Sanitation Ratings of Milk Shippers.*



CHAPTER 2

Definitions and Administrative Requirements

SECTIONS 1 - 6

SECTION 1-DEFINITIONS

The following definitions are those applicable to the dairy farm and are copied verbatim from the PMO.

MILK - Milk is the product defined in the *Code of Federal Regulations,* Title 21, Section 131.110. This reads as follows:

> "Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows."

In the final packaged form, milk shall contain not less than 8.25% milk solids not fat (SNF) and not less than 3.25% milk fat.

A. **ABNORMALITIES OF MILK**: The following types of lacteal secretions are not suitable for sale for Grade "A" purposes.

A-1. **Abnormal Milk**: Milk that is visibly changed in color, odor and/or texture.
A-2. **Undesirable Milk**: Milk that, prior to the milking of the animal, is expected to be unsuitable for sale, such as milk containing colostrum.
A-3. **Contaminated Milk**: Milk that is un-saleable or 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 FDA or the Environmental Protection Agency (EPA).

C. **AUTOMATIC MILKING INSTALLATION (AMI):** The term automatic milking installation covers 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.

D. **BULK MILK HAULER/SAMPLER:** A bulk milk hauler/sampler is any person who collects official samples and may transport raw milk from a farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any State to sample such products.

E. **BULK MILK PICKUP TANKER:** A bulk milk pickup tanker is a vehicle, including the truck, tank and those appurtenances necessary for its use, used by a bulk milk hauler/sampler to transport bulk raw milk for pasteurization from a dairy farm to a milk plant, receiving station, or transfer station.

G. **CLEAN:** Direct product contact surfaces that have had the effective and thorough removal of product and/or contaminants.

H. **CLEAN-IN-PLACE (CIP) CLEANING:** The removal of soil from product contact surfaces in their process position by circulating, spraying, or flowing chemical solutions and water rinses onto and over the surfaces to be cleaned. Components of the equipment, which are not designed to be cleaned-in-place, are removed from the equipment to be cleaned out-of-place (COP) or manually cleaned. Product contact surfaces shall be inspectable, except when the cleanability by CIP has been documented and accepted by the Regulatory Agency. In such accepted equipment, all product and solution contact surfaces do not have to be readily accessible for inspection, i.e., permanently installed pipelines and silo tanks.

I. **COMMON NAME:** The generic term commonly used for domestic animals, i.e., cattle, goats, sheep, horses, water buffalo, etc. (Refer to the **NOTE:** on page 26.)

K. **COOLING POND:** A cooling pond is a man-made structure designed for the specific purpose of cooling cows.

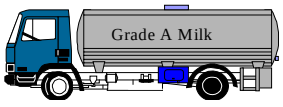
L. **DAIRY FARM:** A dairy farm is any place or premises where one (1) or more lactating animals (cows, goats, sheep, water buffalo, or other hooved mammal) are kept for milking purposes, and from which a part or all of the milk or milk product(s) is provided, sold or offered for sale to a milk plant, receiving station or transfer station. (Refer to the **NOTE:** on page 26.)

Q. **GOAT MILK:** Goat milk is 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 2½ percent milk fat and not less than 7½ percent milk solids not fat. Goat milk shall be produced according to the sanitary standards of this *Ordinance*. The word "milk" shall be interpreted to include goat milk.

S. **HOOVED MAMMALS MILK:** Hooved mammals milk is the normal lacteal secretion, 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 *Ordinance*. (Refer to the **NOTE:** on page 26)

W. **MILK PRODUCER:** A milk producer is any person who operates a dairy farm and provides sells or offers milk for sale to a milk plant, receiving station or transfer station.

Y. **MILK TANK TRUCK:** A milk tank truck is the term used to describe both a bulk milk pickup tanker and a milk transport tank.



Z. **MILK TANK TRUCK CLEANING FACILITY:** Any place, premises, or establishment, separate from a milk plant, receiving station or transfer station, where a milk tank truck is cleaned and sanitized.

AA. **MILK TANK TRUCK DRIVER:** A milk tank truck driver is any person who transports raw or pasteurized milk or milk products to or from a milk plant, receiving station or transfer station. Any transportation of a direct farm pickup requires the milk tank truck driver to have responsibility for accompanying official samples.

BB. **MILK TRANSPORT TANK:** A milk transport tank is a vehicle, including the truck and tank, used by a bulk milk hauler/sampler to transport bulk shipments of milk and milk products, from a milk plant, receiving station or transfer station to another milk plant, receiving station or transfer station.

CC. **MILK TRANSPORTATION COMPANY:** A milk transportation company is the person responsible for a milk tank truck(s).

DD. **OFFICIAL LABORATORY:** An official laboratory is a biological, chemical or physical laboratory, which is under the direct supervision of the Regulatory Agency.

EE. **OFFICIALLY DESIGNATED LABORATORY:** An officially designated laboratory is a commercial laboratory authorized to do official work by the Regulatory Agency, or a milk industry laboratory officially designated by the Regulatory Agency for the examination of producer samples of Grade “A” raw milk for pasteurization and commingled milk tank truck samples of raw milk for drug residues and bacterial limits.

JJ. **REGULATORY AGENCY:** The Regulatory Agency shall mean the ... of the …[1]or their authorized representative. The term, "Regulatory Agency", whenever it appears in the *Ordinance* shall mean the appropriate agency having jurisdiction and control over the matters embraced within this *Ordinance*.

KK. **SANITIZATION:** Is the application of any effective method or substance to properly cleaned surfaces for the destruction of pathogens, and other microorganisms, as far as is practicable. Such treatment shall not adversely affect the equipment, the milk and/or milk product, or the health of consumers, and shall be acceptable to the Regulatory Agency.

LL. **SHEEP MILK:** Sheep milk is 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 *Ordinance*. The word "milk" shall be interpreted to include sheep milk.

PP. **WATER BUFFALO MILK:** Water buffalo milk is 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 *Ordinance*. The word “milk” shall be interpreted to include water buffalo milk. (Refer to the **NOTE:** on page 26.)

“NOTE” from page 26 referenced in definitions I, L, S and PP: Milk from animals not currently in the *Grade "A" PMO* may be labeled as Grade “A” and IMS listed upon FDA’s acceptance of validated *Grade "A" PMO*, Section 6 and Appendix N. test methods for the animal to be added.

SECTION 2 - ADULTERATED OR MISBRANDED MILK OR MILK PRODUCTS

No person shall, within the ... of ..., or its jurisdiction, produce, provide, sell, offer, or expose for sale or have in possession with intent to sell any milk or milk product, which is adulterated or misbranded. Provided, that in an emergency, the sale of pasteurized milk and milk products, which do not fully meet the requirements of this *Ordinance*, may be authorized by the Regulatory Agency.

Any adulterated or misbranded milk or milk products, may be impounded by the Regulatory Agency and disposed of in accordance with applicable laws or regulations.

According to the Food, Drug, & Cosmetic Act, as amended, adulterated food is food that:

1. Contains any poisonous or deleterious substance which may render it injurious to health, (unless naturally occurring substances are present which are not ordinarily injurious to health)

2. Contains a new animal drug which is unsafe.

3. Contains a pesticide

4. Contains an unsafe food additive.

5. Contains any filthy, putrid, or decomposed substance.

6. Has been prepared, packaged or held under unsanitary conditions.

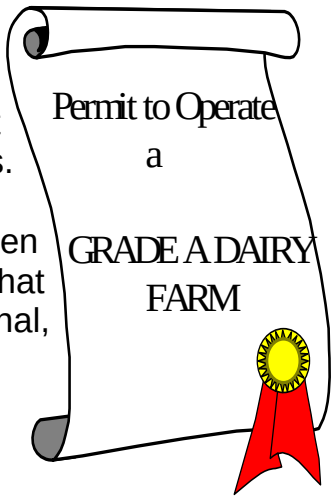
7. Is the product of a diseased animal.

8. Contains excess parts of radiation.

9. If any substance has been substituted wholly or in part.

SECTION 3: PERMITS

Generally the permit section of the PMO requires that:



1. It is unlawful to sell, offer for sale or have in storage any milk product without possession of a valid permit from the regulatory agency. This permit is not transferable with respect to persons and/or locations.

   Note: Milk is considered to be offered for sale when collected on a dairy farm in a quantity in excess of that normally required for the dairy producer's personal, family, and/or on-farm use.

2. Compliance with the *Ordinance* is necessary to receive and retain a permit.

3. Suspension is required upon;

   a) violation of the *Ordinance*, or

   b) upon interference with regulatory agency inspections, or

   c) upon any situation which creates an **imminent hazard to the public health.**

   (This section also provides for notice of **intent to suspend** upon violation of the *Ordinance* and hearing provisions.)

4. Provides for **revocation of permit** for serious or **repeated violations**.

5. The regulatory agency may forego permit suspension, provided the milk is not offered for sale as a Grade "A"milk or milk product.

6. Allows for the imposition of a monetary penalty in lieu of a permit suspension, provided the milk in violation is not sold or offered for sale as a Grade "A" milk or milk product.

7. Permit is reinstated as follows:

    a. **Suspended for sanitation violations** - Within one week of receipt of notification from the producer that the violations have been corrected. An inspection of the facility shall be made to determine that the establishment is in compliance. If in compliance, the permit is reinstated. This is required to be an “empty tank” inspection.

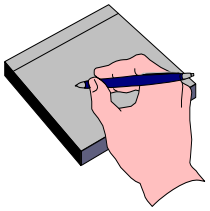
    b. **Suspended for violation of bacterial or cooling standards** - Within one week after receipt of notification from the producer, an inspection of the facility shall be made to ascertain that the conditions responsible for the violation(s) have been corrected. If in compliance, a temporary permit is issued. This is also required to be an “empty tank” inspection.

    c. **Suspended for violation of the somatic cell count standard** - A temporary permit may be issued following acceptable re-sampling of the herd's milk supply. Full reinstatement of the permit shall be made following an accelerated sampling program. (Samples taken at no more than two per week on separate days within a three week period).

    d. **Suspended for drug residues** – The suspended permit shall be reinstated in accordance with the provisions of Appendix N, of the *Ordinance*.

SECTION 4: LABELING

Portions of the Labeling section applicable to individual producer farm requirements are as follows:

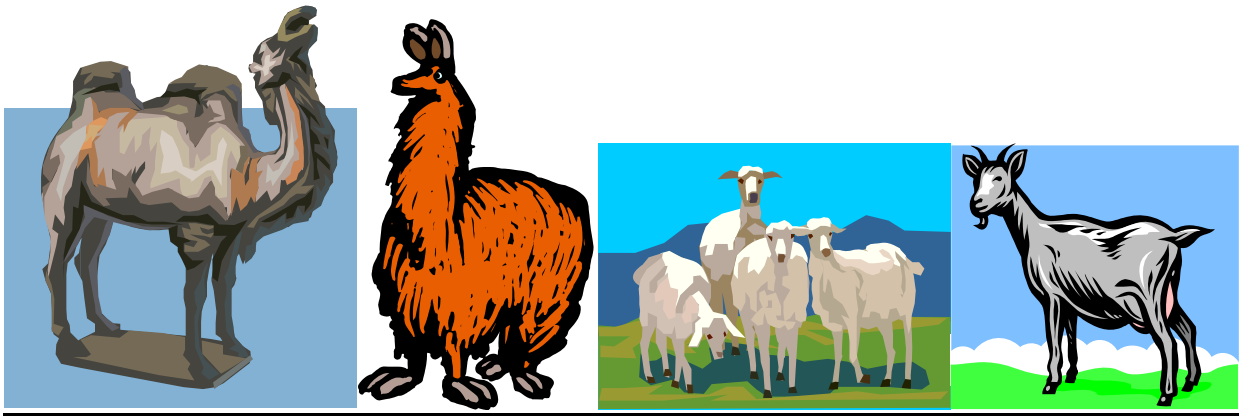


1. All milk tank trucks shall be marked with the **name and address of the milk plant or hauler.**

2. **Each milk tank truck containing milk shall be accompanied by documentation (weight ticket or manifest) which shall include the IMS BTU Identification Number(s) or the IMS Listed Plant Number (for farm groups listed with a plant).** Each BTU shall be assigned an identification number beginning with the 2 digit State code, which shall be included on the FDA form 2359i (Rating Form).

3. All cans of raw milk from individual dairy farms shall be identified by the name or number of the individual milk producer.

4. The common name of the hooved mammal producing the milk shall precede the name of the milk or milk product when the product is or is made from other than cow's milk. As an example, "Goat", "Sheep", "Water Buffalo", or "Other Hooved Mammal" milk or milk products respectively.



SECTION 5: INSPECTION OF DAIRY FARMS

1. Inspection of the farm is required **prior to the issuance of a permit.**

2. Each dairy farm shall be inspected at least **once every 6 months*. (This is the legal minimum and not the desired frequency).** A copy of the inspection report is to be provided to the producer and a copy is kept on file at the regulatory agency. The producer's copy is either posted or made available to the regulatory agency upon request. It shall not be defaced.

   * Regulatory Agencies desiring to inspect dairy farms under the Performance Based Dairy Farm Inspection system shall follow the requirements outlined in Appendix P of the PMO.

3. FDA has consistently defined the inspection of a Grade “A” dairy farm includes the milkhouse, milking barn, stable and parlor, adjacent storage areas, cowyard and cattle housing areas, surroundings, waste disposal areas and the water supply and its distribution system. These areas may include dairy animal maternity areas, animal treatment areas or hospital barns, replacement heifer areas, offices, utility rooms, tool sheds, (drug cabinets, refrigerators, etc.) or other areas where drugs, used to treat dairy animals, may be used or stored.

   With regard to drug storage, labeling and use, the scope of a dairy farm operation/inspection extends beyond the milkhouse, milking barn or parlor. FDA believes the following areas are part of the milking operation: any area reasonably expected to contain drugs used to treat lactating animals, lactating animals that may soon be placed in or returned to the milking herd, or other lactating animal intended for milk production (replacement heifers). Private residences and vehicles are not included without the permission of the owner or their authorized agent.

4. Occasionally, inspections should be made at milking time to determine compliance with milking practices. Each dairy farm permitted should have at least one inspection made during milking time on their official inspection records.

   On larger dairies milking 15 - 20 hours per day the regulatory inspection should be planned to include "down time" or non-milking time inspections. This is to provide the inspector an opportunity to examine milk contact surfaces of equipment for construction and cleanliness.

5. The dairy farm is subject to permit suspension if two successive inspections disclose violations of the same requirement.

6. Except for imminent health hazards, no penalty is imposed on the producer upon the first violation of any requirement of the *Ordinance*; however, issuance of the inspection report is considered as sufficient notice to the producer to correct any item not in compliance.

7. Appendix B provides the current requirements for the inspection of Bulk milk pickup tankers and appurtenances. These tankers require inspection by the regulatory agency least once every 12 months, using FDA form 2399B. Hauler pickup and sampling procedures must be inspected /evaluated at least every 24 months using FDA form 2399.

Here is a good thing to remember.....

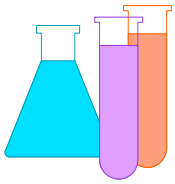
<u>AND IT'S IN THE PMO!!</u>

"EXPERIENCE HAS DEMONSTRATED THAT STRICT ENFORCEMENT OF THE ORDINANCE LEADS TO A BETTER AND FRIENDLIER RELATIONSHIP BETWEEN THE REGULATORY AGENCY AND THE MILK INDUSTRY THAN DOES A POLICY OF ENFORCEMENT, WHICH SEEKS TO EXCUSE VIOLATIONS AND TO DEFER PENALTY THEREOF. THE SANITARIAN'S CRITERION OF SATISFACTORY COMPLIANCE SHOULD BE NEITHER TOO LENIENT NOR UNREASONABLY STRINGENT. WHEN A VIOLATION IS DISCOVERED, THE SANITARIAN SHOULD POINT OUT TO THE MILK PRODUCER, BULK MILK HAULER/SAMPLER, ... THE REQUIREMENT THAT HAS BEEN VIOLATED, DISCUSS A METHOD FOR CORRECTION AND SET A TIME FOR CORRECTING THE VIOLATED REQUIREMENT

Chapter 3

The Examination of Milk and Milk Products

SECTION 6 and 7



1. The **universal sampling program -** This refers to the responsibility of the milk hauler to collect a representative sample of milk from each farm bulk tank prior to transferring the milk from the farm bulk tank. If the hauler is properly licensed and/or permitted these samples may be used as official samples as designated by the regulatory agency. If the universal samples are used as official samples, a system of randomization of the selected samples must be used by the regulatory agency to assure validity of the sampling program.

2. During **any consecutive six month period at least four samples of raw milk shall be collected from each Grade "A" dairy farm.** Two samples may be collected in one month and be counted for minimum frequency purposes as long as the two sampling dates are separated by at least 20 days. **The results of all officially collected samples shall be used for determination of compliance with the established chemical, bacterial, and temperature standards.**

3. Samples must be taken while in possession of the producer, i.e., either from the farm bulk milk tank or producer owned and operated milk tank truck.

4. Samples shall be analyzed for:

BACTERIAL COUNTS	DRUG RESIDUES
SOMATIC CELL COUNTS	COOLING TEMPERATURES

*(Commingled milk may be used for testing of pesticides; however the commingled milk sampled **must represent all producers** in the sample.)*

5. Enforcement of the standards:

a All violations of bacteria, somatic cell counts, and temperatures shall be promptly followed-up by inspection to determine and correct the cause.

b When two of the last four samples exceed the limit for bacterial, somatic cell or temperature standards (taken on separate days) a notice is issued by the regulatory agency.

c Within 21 days of sending the notice (but not before 3 days) an additional sample must be taken**.**

d When three of the last five samples exceed the limits, the permit shall be immediately suspended (or product not offered for Grade A sale or use).

e The regulatory agency may issue a temporary permit after determining by a facility inspection that the conditions responsible for the problem have been corrected.

f When a permit as been suspended due to high somatic cell counts, reinstatement may be based on **re-sampling**, this indicates that the milk supply is within acceptable standards.

g Whenever a drug residue test is positive, the milk must not be offered for sale or consumption until subsequent samples prove the milk to be free of residues. Also an investigation shall be made to determine the cause, and the cause shall be corrected.

Under the requirements of Appendix N, the producer permit must also be immediately suspended, or equally effective measures shall be taken to prevent the sale of milk containing drug residues. The penalty shall be the value of the milk on the contaminated load plus any costs associated with disposition of the contaminated milk. Then the producer responsible must receive a drug residue prevention education program and farm procedure changes to prevent future residues. These programs are administered by the state regulatory authority.

Permits that have been suspended may be reinstated, to allow the sale of milk for human food when a representative sample taken from the producers milk, prior to commingling, is no longer positive for drug residues.

Note: Positive drug screening tests[(1)] resulting from samples taken by the producer of their own farm bulk or cow-side testing are not required to be reported to the regulatory agency.

[(1)] *Acceptable screening tests are listed, along with approved levels of testing following this section.*

6. Sampling Procedures:

All sampling procedures and required laboratory examinations must be in compliance with the most current edition of *Standard Methods for the Examination of Dairy Products* and *Official Methods of Analysis of the Association of Official Analytical Chemists.*

The sampling certification program shall be in accordance with the most current revision of the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments.*

All official farm bulk milk samples must be collected by a regulatory agency certified sampler or by a milk tanker hauler/sampler under the Universal Sampling Program. These samplers must be evaluated once every two (2) years. This evaluation includes examining sampling equipment (coolers, dippers, single service straws, sample containers, etc) and observing and evaluating sampling techniques at the farm.

The State Sampling Surveillance Officer(s) (SSO) oversee and monitor this program. FDA Milk Specialists certify these SSO's by conducting a side by side comparison of sampling procedure observations using the items listed on the appropriate inspection or evaluation report form. The State SSO's, in turn, may delegate certification and evaluation duties to selected milk sanitarians as necessary. This delegation may only be passed down one time. An active on-going sampler training program, including milk haulers, must be in effect and an effective enforcement program must ensure proper procedures are followed. Appendix B of the PMO outlines in detail the requirements for a

sampler training program.

Every precaution must be taken to assure that these official samples are collected in accordance with "Standard Methods" since the sample results will be used for compliance with the minimum established standards (bacteria, somatic cell count, temperature, and drug residue).

NOTE: Milk from animals not currently in the Grade “A” PMO may be labeled as Grade “A” and IMS listed upon FDA’s acceptance of validated Grade “A” PMO, Section 6 and Appendix N test methods for the animal to be added.

MILK DRUG RESIDUE SCREENING TEST DETECTION CONCENTRATIONS[1]
BETA lactams

DRUG	AMOXICILLIN	AMPICILLIN	CEFTIOFUR	CEPHAPIRIN	CLOXACILLIN	PENICILLIN
TOLERANCE OR SAFE LEVEL	10 ppb	10 ppb	100 ppb[2]	20 ppb	10 ppb	5 ppb
SCREENING TEST						
CHARM *B. stearothermophilus* TABLET DISK ASSAY[3, 4, 5]	7.5	6.7	ND[6]	11.7	48[7]	3.8
CHARM II TABLET BETA lactam TEST (COMPETITIVE ASSAY)[3]	7.5	5.7	47	4.2	70[7]	3.0
CHARM II TABLET BETA lactam TEST (SEQUENTIAL ASSAY)[5]	8.1	6.6	58	4.1	50[7]	3.4
CHARM II TABLET BETA lactam TEST (QUANTITATIVE ASSAY)[8]	8.1	6.6	58	4.1	8.5	3.4
CHARM II TEST FOR CLOXACILLIN IN MILK (COMPETITIVE ASSAY)[3, 9]	ND[6]	ND[6]	ND[6]	ND[6]	8.5	ND[6]
CHARM SL BETA lactam TEST[10]	5.6	8.5	77	13.7	50[7]	3.6
CHARM SL6™ BETA lactam TEST	7.1	9.6	72	18.7	8.3	4.2
CHARM SL3™ BETA lactam TEST	7.8	8.7	51	16.0	100[7]	4.2
DELVOTEST P 5 PACK (READER)[3, 11]	4.6	4.0	ND[6]	8.2	NA[12]	2.1
DELVOTEST P 5 PACK (VISUAL)[3, 4, 13]	4.6	4.0	ND[6]	8.2	NA[12]	2.1
DELVOTEST P/DELVOTEST P MINI[4,5]	7.7	5.1	NA[12]	7.0	30[7]	3.1
DELVOTEST SP/DELVOTEST SP MINI	6.0	7.9	NA[12]	7.7	33[7]	2.7
PENZYME MILK TEST[4,5]	6.0	7.0	500[7]	11.6	80[7]	5.0
PENZYME III TEST PROCEDURE[4]	5.3	5.6	500[7]	14.3	NA[12]	4.3
New SNAP BETA lactam TEST KIT[14]	7.3	5.8	12	11.7	50[7]	3.0

FOOTNOTES:

1. Parts per billion (ppb), which can be detected 90% of the time with 95% confidence. Additional drug level response data are provided for each test in the following Tables and should be considered when selecting drug residue monitoring tests. The 90/95% concentrations (ppb) were determined by fitting a statistical model to the dose response data designed to estimate this value. The lower, one-sided 95% confidence limit was used. This data was either collected at an independent laboratory or the test samples were prepared at an independent laboratory.
2. The ceftiofur tolerance is based on measuring the sum of ceftiofur and desfuroylceftiofur related metabolites in milk as desfuroylceftiofur. The screening test detection concentrations for ceftiofur were evaluated using milk containing ceftiofur and desfuroylceftiofur related metabolites from treated animals. Due to the approval of "Spectramast", an intramammary ceftiofur product, the safe level of 50 ppb as parent ceftiofur is no linger used.
3. This test is acceptable for use to detect Beta lactam residues when used with bovine pasteurized whole and skim milk.
4. Refer to M-I-01-4 for certification requirements to use this visual test.
5. This test is acceptable for testing raw, commingled goat milk.
6. ND indicates "Not Detected".
7. 90/95% concentrations were not determined for sensitivities significantly above the tolerance/safe level.
8. Test sensitivity when presumptive positive milk samples are verified in accordance with label directions using the Charm II Tablet Sequential Assay and the Charm II Test for Cloxacillin in Milk.
9. For Appendix N bulk milk tanker screening, this test must be used in combination with other approved screening methods in order to detect at least four (4) of the six (6) targeted Beta lactam drugs.
10. The Charm SL Beta lactam Test is acceptable for testing raw, commingled goat milk (M-I-03-3).
11. The DelvoScan Reader option for the Delvotest 5 P Pack has not been validated in fat-free chocolate, whole chocolate, half & half, heavy cream and pasteurized goat milk.
12. NA indicates "Data Not Available".
13. The Delvotest 5 P Pack (VISUAL) is acceptable to detect ampicillin, amoxicillin, cephapirin and penicillin residues in bovine fat-free chocolate, whole chocolate, half & half, and heavy cream and pasteurized goat milk.
14. The visual reading option is not available with the New Snap BETA lactam Test.

MILK DRUG RESIDUE SCREENING TEST DETECTION CONCENTRATIONS [1]
SULFONAMIDES

DRUG	SULFADIMETHOXINE	SULFAMETHAZINE	SULFATHIAZOLE	SULFADIAZINE
TOLERANCE/SAFE LEVEL (ppb)	10	10	10	10
SCREENING TEST				
CHARM II SULFA DRUG TEST (COMPETITIVE ASSAY)	4.0	9.4	7.3	4.9

[1]Parts per billion (ppb), which can be detected 90% of the time with 95% confidence. Additional drug level response data are provided for each test in the following table. The 90/95% concentrations (ppb) were determined by fitting a statistical model to the dose response data designed to estimate this value. The lower, one-sided 95% confidence limit was used. This data was either collected at an independent laboratory or the test samples were prepared at an independent laboratory.

MILK DRUG RESIDUE SCREENING TEST DETECTION CONCENTRATIONS [1]
TETRACYCLINES

DRUG	CHLORTETRACYCLINE	OXYTETRACYCLINE	TETRACYCLINE
TOLERANCE/SAFE LEVEL (ppb)	**300 (Chlortetracycline + Oxytetracycline + Tetracycline)**		
DRUG CONCENTRATION (ppb)			
CHARM II TETRACYCLINE DRUG TEST (COMPETITIVE ASSAY)	257	119	67

[1]Parts per billion (ppb), which can be detected 90% of the time with 95% confidence. Additional drug level response data are provided for each test in the following table. The 90/95% concentrations (ppb) were determined by fitting a statistical model to the dose response data designed to estimate this value. The lower, one-sided 95% confidence limit was used. This data was either collected at an independent laboratory or the test samples were prepared at an independent laboratory.

SECTION 7: RAW MILK STANDARDS

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 the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings, does not exceed 10°C (50°F).
BACTERIAL LIMITS	Individual producer milk not to exceed 100,000 per ml prior to commingling with other Producer milk.
COMMINGLED	Not to exceed 300,000 per ml as commingled milk prior to pasteurization.
DRUGS	No positive results on drug residue detection methods as referenced in Section 6, Laboratory Techniques.[1]
SOMATIC CELL COUNT	Individual producer milk not to exceed 750,000/ml; individual goat milk to remain at 1,500,000/ml.

Note: Samples must be submitted to the Official Laboratory at <4.4^{o} C and tested within 36 hours of receipt. For SPC the samples are then well agitated, diluted, plated and incubated at 32^{o} C for 48 hours, then counted under magnification.

1. Beta lactam methods which have been independently evaluated or evaluated by FDA have been found acceptable by FDA for detecting drug residues in raw milk,.... at current safe or tolerance levels shall be used for each drug of concern.

NOTES:

Chapter 4

Sanitation Requirements for Grade A Raw Milk

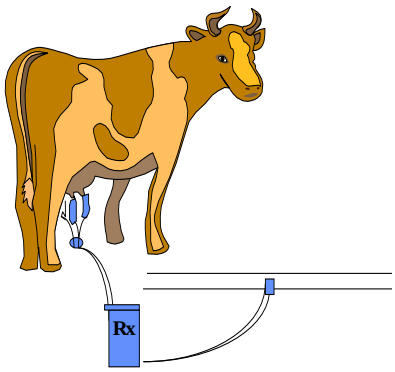
SECTION 7

The written requirements, administrative procedures, and public health reasons for each item may be found in the current edition of the *Ordinance*. The purpose of this training manual is not to replace the PMO, but to point out any special areas of concern or inspection emphasis that should be considered during regulatory dairy farm inspections. This manual may also be useful to the state and federal milk rating officers, dairy farm industry fieldperson, milking equipment installer's, veterinarians, the agricultural extension person and/or the dairy farmer. The comments in this training manual are not verbatim duplications of the Items, although some might be. This manual, however, may contain many statements that may be paraphrased from the PMO requirements, Public Health Reasons, Administrative Procedures or interpretive memorandums.

For applicability of items to Automatic Milking Installations (AMIs), refer to Appendix Q in the PMO.

Item 1r

ABNORMAL MILK



REQUIREMENT - *Lactating animals which show evidence of the secretion of abnormal milk in one or more quarters, based upon bacteriological, chemical, or physical examination, shall be milked last or with separate equipment and the milk shall be discarded. Lactating animals producing contaminated milk, that is, lactating animals which have been treated with, have consumed chemical, medicinal or radioactive agents, which are capable of being secreted in the milk and which, in the judgment of the Regulatory Agency, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the regulatory agency may direct.*

Public Health Reason: A number of diseases of lactating animals including salmonellosis, staphylococcal infection, and streptococcal infection may be transmitted to humans through the consumption of milk. These organisms may get into milk either directly from the udder or indirectly through infected body discharges which may drop, splash or be blown into the milk. Bovine mastitis is an inflammatory and, generally, highly communicable disease of the udder and incites bacteria like streptococcus (type B) and staphylococcus. Scarlet fever or septic sore throat, caused by hemolytic streptococci of human origin may be shed into the milk by an infected udder. Recent organisms of concern include E Coli, Listeria, and Yersinia. Healthy dairy animals are less likely to be carriers of these organisms and require less drug treatment which may get into the milk supply

NOTE: Drug residues in milk have become an item of high significance and are a sensitive issue for both regulatory and the industry involved.

Some practices which may result in contamination of milk supplies may be:

1. Using common milking equipment (claws, hoses, etc,) to milk treated animals, within the normal milking string, may lead to contamination.

2. Non-adherence to recommended milk withholding times on treated cows.

3. Milking treated cows into a vessel located in the milkroom may lead to possible contamination of the milk supply through splash, incidental contamination or direct spillage into the bulk tank, single service filters, cleaning brushes, etc.

4. The use of insecticides such as back rub bags containing an insecticide that is not U.S. EPA approved for use on dairy animals.

5. The use of unapproved drugs on lactating animals or failure to follow drug treatment directions on the drug labeling.

6. The use of animal feeds containing unsafe levels of animal drugs or other chemicals. (Includes grazing on treated areas contaminated due to recent treatment with herbicides or pesticides OR the feeding of agriculture harvest or processing by products or waste contaminated with chemicals).

7. The feeding of grains contaminated with naturally occurring toxins (aflatoxin, vomitoxin which is termed DON, deoxynivalenol and caused from the growth of fusarium mold in wheat)

8. The feeding of protein animal feed to dairy animals or other ruminants (four-stomached animals), that are composed wholly or partially of rendered tissue.

9. Feed made from processed animal waste must meet all requirements of Association of American Feed Control Officials (AAFCO) Model Regulations for Processed Animal Wastes.

10. Unprocessed poultry litter and unprocessed recycled animal body discharges are not fed to lactating dairy animals

11. Milking equipment used on lactating animals with abnormalities in their milk must be kept clean.

Item 2r

MILKING BARN, STABLE, OR PARLOR - CONSTRUCTION

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

Public Health Reason: When milking is done elsewhere than in a suitable place provided for this purpose, the milk may become contaminated. Floors constructed of concrete or other impervious material can be kept clean more easily than floors constructed of wood, earth, or similarly porous materials and are; therefore, more apt to be kept clean. Painted, or properly finished walls and ceilings encourage cleanliness. Tight ceilings reduce the likelihood of dust and extraneous material from getting into the milk. Adequate lighting makes it more probable that the barn will be clean, and that the lactating animals will be milked in a sanitary manner.

The areas used for milking purposes shall:

1. Have floors, gutters and feed troughs constructed of concrete or equally impervious materials: *Provided*, convalescent (maternity) pens located in milking areas of stanchion-type barns may be used when they comply with the guidelines specified in Appendix C, II, III, and IV.

2. Have walls and ceilings which are smooth, painted, or finished in an approved manner, in good repair. The ceiling must be dust tight.

3. Have separate stalls or pens for horses, calves, and bulls.

4. Be provided with natural and/or artificial light, well distributed for day and/or night milking. (10 ft. candle minimum).

5. Provide sufficient air space and air circulation to prevent condensation and excessive odors.

6. Not be overcrowded.

7. Have dust tight covered boxes, bins, or separate storage facilities for round chopped or concentrated feed.

Inspectional areas of emphasis or special problem areas may be:

1. Many milking area construction items are maintained nearly as well as the milk room area; however, sometimes complacency prevails and the floors, walls, and other construction requirements in the milking parlor or barn may be ignored or put-off until time allows.

2. Wooden stanchions may become worn or rotten and in need of replacement or painting; pipe railing stanchions, feeders, or door/gates may become excessively corroded, impairing their cleaning properties.

3. Floor areas where cows stand may become excessively worn, building structures may settle exposing large cracks in the walls or floor junctures.

4. Inadequate ventilation usually results in rusty metal partitions peeling paint, excessive odors, and electrical problems. Adequate ventilation especially becomes a problem during the winter months, when moisture levels are high, and windows are kept closed. Adequate heaters are necessary to reduce condensation and ventilation is necessary to remove odors from the milking area.

5. All walking surfaces must be constructed of concrete or equally impervious material. Gutter cross walks, splash guards that are not impervious quickly becomes rough and become water and manure soaked, making them impossible to clean.

6. Animals (calves, heifers, dry cows, bulls,) and other livestock may be found housed in the milking barn, causing overcrowding and often unsanitary conditions.

7. Hay loft door(s) opening into the milking area are required to remain closed during milking times. Doors to feed rooms or silos that open into the milking area must be kept closed, except when in use. Open feed dollies may be used for feed distribution, but not for storage in the milking area.

8. Bull pens, calving areas, and horse stalls must be completely partitioned from the milking area. If not, then they must meet all the requirements of the milking area.

Item 3r

MILKING BARN, STABLE OR PARLOR - CLEANLINESS

REQUIREMENT: *The interior shall be kept clean. Floors, walls, ceilings, windows, pipelines, and equipment shall be free of filth and/or litter and shall be clean. Swine and fowl shall be kept out of the milking area.*

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.

Surcingles, or belly straps, milk stools and antikickers shall be kept clean and stored above the floor.

Public Health Reason: A clean interior reduces the chances of milk or milk equipment contamination during milking times. The presence of other animals increases the potential for the spread of disease. Clean milk stools and surcingles reduce the likelihood of contamination of the milker's hands between the milking of one (1) lactating animal and the milking of another.

Inspectional areas of emphasis or special problem areas may be:

1. Excessive manure build-up on stanchions, floors, walls, underneath floor mats, tail (splash) plates, partitions, etc.

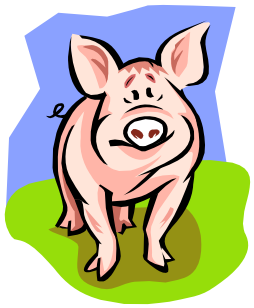
2. Excessive cobwebs, fly specks, feed dust; on ceilings, milk/CIP lines, and stanchions.

3. Litter and trash in the breezeway.

4. Birds nesting in the milking barn.

5. Soggy, left over feed in the feeders or mangers.

6. Swine in the milking area.



7. Ineffective dry (brush and lime) cleaning methods used when water under pressure is available in the milking area.

8. Heavy buildup of manure in gutters in the milking area.

9. The use of milk stools has all but disappeared from milking dairy farms; however the intent of this item is satisfied only when there are no "similar" type stools, chairs, or other padded (unclean-able) surfaces in the milking area.

10. Surcingles and antikickers must be cleaned after each milking operation and stored in a clean place above the floor when not in use.

11. A breezeway is defined as the open area between the milkroom and milking parlor (no close-able doors).

Item 4r

COWYARD

REQUIREMENT: *The cowyard shall be graded and drained and shall have no standing pools of water or accumulations of organic wastes. Provided, that 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. 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. Waste feed shall not be allowed to accumulate. Manure packs shall be properly drained and shall provide a reasonably firm footing. Swine shall be kept out of the cowyard.*

Public Health Reason: The cowyard is interpreted to be that enclosed or unenclosed area in which the lactating animals are apt to congregate, approximately adjacent to the barn, including animal-housing areas. This area is; therefore, particularly apt to become filthy with manure droppings, which may result in the soiling of the lactating animal's udders and flanks. The grading and drainage of the cowyard, as far as practicable, is required because wet conditions are conducive to fly breeding and make it difficult to keep manure removed and the lactating animals clean. If manure and barn sweepings are allowed to accumulate in the cowyard, fly breeding will be promoted, and the lactating animals, because of their habit of lying down, will be more apt to have manure-soiled udders. Lactating animals should not have access to piles of manure, in order to avoid the soiling of udders and the spread of diseases among dairy animals.

Inspectional areas of emphasis or special problem areas may be:

1. Large piles of manure accessible to milking herd in the cowyard.

2. Low, poorly drained areas in the milking herd cowyard in which pools of surface drainage and liquid waste accumulate.

3. Soggy, muddy low areas around and adjacent to the milking herd watering troughs.

4. Buildup of manure underneath and along side of the corral fences.

5. Accumulation of waste feed in the cattle housing areas.

6. Barn or milk house waste runs into the cowyard and creates pools of waste liquids accessible to the milking herd.

7. Free-stalls have heavy accumulation of manure in stall areas and alley-ways. Cow mattresses may only be used if they are no larger than the individual cow stalls and are properly maintained.

8. Approaches to the milking barn are soggy, with depressed areas which may cause injury to the udder.

9. Swine are penned in the milking herd loafing shed.

10. Uneven step-downs or excessively steep or tall steps for the cow entrances or exits to the milking area conducive to animal injury.

11. Improperly maintained manure packs. A manure pack is generally feasible only for dairies located in dryer climates. Soil is mixed or layered with animal waste and is allowed to dry and become firmly packed and solid to the footing of the lactating animals. Well maintained manure packs will usually present no problems even during brief rainy periods. Manure packs are not to be confused with manure piles in the cattle housing areas.

Item 5r

MILKHOUSE OR ROOM-CONSTRUCTION AND FACILITIES

REQUIREMENT: *A 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 item 12r, of this section.*

Public Health Reason: Unless a suitable place is provided for the cooling, handling and storing of milk and for the; washing, sanitizing and storage of milk utensils, the milk or the utensils may become contaminated. Construction which permits easy cleaning promotes cleanliness. A well-drained floor of concrete or other impervious material promotes cleanliness. Ample light promotes cleanliness and proper ventilation reduces the likelihood of odors and condensation. A milkhouse that is separated from the barn, stable or parlor and the living quarters, provides a safeguard against the exposure of milk and milk equipment and utensils to contamination.

A. The milkhouse shall be provided with a smooth floor constructed of concrete or equally impervious material graded to drain and maintained in good repair. Liquid waste shall be disposed of in a sanitary manner. Floor drains shall be accessible and shall be trapped if connected to a sanitary sewer system.

B. The walls and ceilings shall be constructed of smooth material, in good repair, well painted or finished in an equally suitable manner.

C. The milkhouse shall have adequate natural and/or artificial light and be well ventilated. Minimum required lighting for the milkhouse is 20 foot candles.

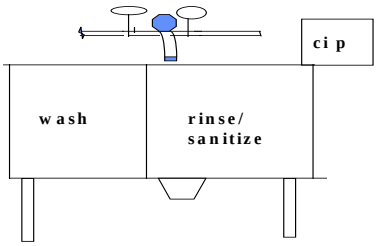
D. The milkhouse shall be used for no other purpose than milkhouse operations; there shall be no direct opening into any barn, stable or into a room used for domestic purposes. *Provided,* that a direct opening between the milkhouse and milking area is permitted when a tight-fitting self-closing door(s), hinged to be single or double acting, is provided. **Screen vents are permitted in the wall between a milkhouse and a breezeway which separates the milkho-**

use from the milking parlor, provided that animals are not housed within the milking facility.

NOTE: A breezeway has been described as an intervening open passageway between the milk room and the milking area, that is completely open (without doors) at both ends.

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

F. The milkhouse shall be equipped with a two compartment wash vat and adequate water heating facilities.



Requirements for: Transportation Tanks used for cooling and/or storage of milk on the farm.

1. A suitable shelter shall be provided for housing the milk tanker.

2. The shelter shall be adjacent to the milk house.

3. The shelter shall comply with requirements of the milkroom with respect to;
   - lighting
   - drainage
   - insect and rodent control
   - general maintenance

4. An accurate accessible temperature recoding device shall be installed in the milk line downstream for an effective cooling device which cools the milk to 7°C (45°F).

5. The milk shall be sampled at the direction of the regulatory agency so as to prevent contamination of the tanker or sample by a permitted milk sampler collector.

6. The tanker shall be cleaned and sanitized at the milk plant and sealed by the plant to prevent unauthorized opening or tampering.

Requirements for: Direct Loading of Transportation Tanks used for storage of milk on the farm.

1. The milk hose connection is made from within the milkroom and the milk tank truck connection is protected from the outside environment. This requirement is met by providing an opening in the milkroom from the outside that allows the rear end of the tanker to directly seal to the milk house wall and be accessible to make the connection from the inside of the milkroom.

2. The manhole of the tanker must be sealed after cleaning and sanitizing at the plant or acceptable permitted wash station.

3. A sanitary liquid level or sensing device must be installed in the tanker or line to prevent overfilling of the tanker. This sensing device shall deactivate the milk pump or sound an alarm when activated. This prevents unsanitary conditions caused by milk spills around the exterior of the milk house.

4. There shall be a temperature recorder installed downstream from the cooling device to verify the milk is at or below 7°C (45°F).

5. Sampling must be accomplished to assure the milk is not contaminated during sampling, by a permitted (licensed) milk sampler, or the equivalent, and must be accomplished following adequate agitation to assure a representative, homogenous sample as required by the Standard Methods for Examination of Dairy Products, current edition.

6. The tanker shall be parked on a self-draining concrete or equally impervious surface during filling and storage.

7. Temperature recording records shall be maintained on the premises for a period of a minimum of six (6) months.

Inspectional areas of emphasis or special problem areas may be:

1. There are large cracks or holes in the milkhouse floor or there are standing pools of water on the milkhouse floor.

2. The walls are in need of repair or repainting.

3. Window sills and/or door jambs are rotten and in poor repair.

4. There are excessive odors and condensation is dripping from the walls and ceilings.

5. Excessive peeling paint on the walls and ceilings.

6. The hoseport is in poor repair, and/or the milkhouse windows are broken.

7. The outside slab underneath the hoseport is cracked and too small to protect the hose, and /or covered with dirt/mud or weeds.

8. There is a light fixture directly over the bulk tank lid.

9. The door leading from the milkhouse into the milking area is not tight or self-closing.

10. The milkhouse is being used for purposes other than milkhouse operation such as washing of fruits or vegetables, mixing of calf medicated supplement, washing of cow preparation towels, working on machinery, etc.

11. If the dairy has installed a CIP vat for recirculation of milk pipelines and appurtenances this vat may be accepted as one part of the two compartment vat if acceptable to the State Regulatory Authority. Where CIP 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 Regulatory Agency, on an individual farm basis.

Item 6r

MILKHOUSE OR ROOM-CLEANLINESS

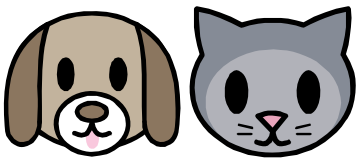
REQUIREMENT: *The floors, walls, ceilings, windows, tables, shelves, cabinets, wash vats, non-product contact surfaces of milk containers, utensils and equipment and other milkhouse equipment shall be clean. Only articles directly related to the milkhouse activities shall be permitted in the milkhouse. The milkhouse shall be free of trash, animals and fowl.*

Public Health Reason: Cleanliness in the milkhouse reduces the likelihood of contamination of the milk.

Inspectional areas of emphasis or special problem areas may be:

This item deals with the general housekeeping and cleanliness of the milk room. It does not relate to milk contact surfaces, nor completely separate storerooms located near the milk room. Any room which serves any function of a milk room; i.e., a separate utensil washing room, would be considered as part of the milk room and must meet all applicable milk room cleanliness and maintenance requirements.

1. Trash and debris underneath the bulk tank and utensil sink.
2. Unclean handwashing sink.
3. Cluttered desk or cabinet in the milkroom.
4. Algae and mold buildup on the walls and ceilings.
5. Cats or dogs in the milkroom.
6. Dust or farm tools on top of the bulk tank.
7. Unclean step ladder in the milkhouse.



8. Unclean hoseport.

9. Employee personal belongings are stored in the milkroom.

10. Outside surfaces of milking units not clean. (for those stored in the milkroom)

11. Unclean vestibule.

12. Calf buckets, bottles, etc., stored in the utensil sink or causing other unsanitary problems in the milkhouse.

13. Storerooms or offices which open directly into the milkroom, with no intervening solid door should be considered as parts of the milkroom and during inspection are subject to milk room requirements.

14. Vestibules are small intervening passageways or rooms connecting the milkroom to the milking area. The vestibule would have to be separated from the two areas with self-closing, solid doors. If constructed as stated, then this vestibule must meet all requirements of the milkroom.

Item 7r

TOILET

REQUIREMENT: *Every dairy farm shall be provided with one or more toilets, conveniently located and properly constructed, operated, and maintained in a sanitary manner. The waste shall be inaccessible to flies and shall not pollute the soil surfaces or contaminate any water supply.*

Public Health Reason: The organisms of typhoid fever, dysentery and gastrointestinal disorders may be present in the body waste of persons who have these diseases. In the case of typhoid fever, well persons (carriers) also may discharge the organisms in their body waste. If a toilet is not fly tight and constructed to prevent overflow, dangerous bacteria or viruses may be carried from the excreta to the milk, either by flies or through the pollution of ground or surface water to which lactating animals or humans have access.

Inspectional areas of emphasis or special problem areas may be:

1. Toilet facility should be constructed in accordance with the State Regulatory Agency recommendations. In most cases a toilet must be provided for farm employees.

2. Toilet room must be kept clean and provided with adequate toilet tissue and waste receptacles. Toilet room must never open directly into the milkroom, provided that toilet rooms that open directly into the milk room must be equipped with a tight fitting self-closing solid door.

3. Septic tanks should not be overflowing and there should be no breaks in sewerage lines.

4. Sewage from the toilet must never discharge into the animal waste lagoon.

5. Toilet room fixtures must be in good repair, the toilet bowl floor seal must not be leaking and the room and all fixtures must be kept clean.

6. There should be no evidence of used toilet paper on floor or in trash container that shows evidence of fecal material.

7. Pit privies must have fly tight pits, including self-closing risers and screened vents. There must be no openings into the pit where insects may gain entry.

8. Adequate lighting or ventilation and screens on windows or doors must be in good condition and effective against the entrance of insects.

NOTE: Flush toilets, pit privies, and chemical toilets are acceptable.

NOTE: Small family operations not employing persons on the dairy operation may be allowed to use their residence facilities provided the toilet room in their residence is convenient to the milking operation.

Item 8r

WATER SUPPLY

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

NOTE: See Chapter 5 on Dairy Farm Water Supplies

Item 9r

UTENSILS AND EQUIPMENT-CONSTRUCTION

REQUIREMENT: *All multi-use containers, equipment, and utensils used in the handling, storage, or transportation of milk shall be made of smooth, nonabsorbent, corrosion resistant, nontoxic materials, and shall be so constructed as to be easily cleaned. All containers, utensils, and equipment shall be in good repair. Multiple use woven material shall not be used for straining milk. All single service articles shall have been manufactured, packaged, transported, and handled in a sanitary manner and shall comply with the applicable requirements of Item 11p of this section. Articles intended for single service use shall not be reused.*

Farm holding/cooling tanks, welded sanitary piping, and transportation tanks shall comply with the applicable requirements of Items 10p and 11p of this section.

Public Health Reason: Milk containers and other utensils without flush joints and seams, without smooth, easily cleaned, and accessible surfaces, and not made of durable, non-corrodible material resistant, are apt to harbor accumulations in which undesirable bacterial growth is supported. Single-service articles which have not been manufactured and handled in a sanitary manner may contaminate the milk.

Guidelines for milk contact construction criteria may be found in the 3A Sanitary Standards and Accepted Practices, No. 606-##, Design, Fabrication and Installation of Milking and Milk Handling equipment and Standard 13-## which is the 3A Sanitary Standards for Farm Milk Cooling and Holding Tanks. (## is the most current revision)

Both of these standards provide guidelines for milk equipment materials, fabrication, and application to pipeline milking systems, milking system vacuum requirements, operation, maintenance and service.

According to the Administrative Procedures, stainless steel must be of the _____series or equivalent to be acceptable for use in milk contact surfaces.

Other materials acceptable for contact surfaces are;
1)_____,
2)_____, and
3)_____. Further, the 3-A Sanitary Standards require these surfaces have a finish at least as smooth as _____ ground finish on stainless steel sheets.

The farm milk cooling tank standards provide specifications for different types of tanks, installation, protection of the product therein, measuring device requirements and cooling requirements.

Items 10p and 11p of the PMO provide construction requirements for milk contact surfaces and CIP circuits. **Generally**, **all equipment which meets 3-A Sanitary Standards and has been awarded the 3-A Symbol complies with the sanitary design and construction requirements of the PMO.**

A milk contact surface has been defined as all surfaces which are exposed to the product and surfaces from which contaminants may _____, _____, or ___ _____ into the product.

Inspectional areas of emphasis or special problem areas may be:

1. Rough welds, corrosion in milk contact surfaces.

2. Use of barbed "t's" in milk or CIP lines.

3. Inadequate inspection access points on milk lines. By-passes around plate or tubular coolers.

4. Improperly installed milk lines, milk receivers and sanitary traps. The vacuum line connecting the milk receiver to the trap should be installed in accordance with the 3-A Standard Number 606-##. This trap must be installed adjacent to the milk receiver and connected by readily disassembled sanitary piping. The vertical rise of this connection shall not exceed 12 inches including the elbow and shall slope toward the trap at least 2 inches in the first 2 feet. The purpose of this configuration is to prevent any liquid collected in the trap from getting into the milk receiver.

5. Use of unapproved materials in milk or cleaning circuits, i.e., radiator hose, PVC or galvanized piping, duct tape, etc.

6. Discolored, opaque, or rough and/or cracked flexible milk hoses or tubing. (Sunlight sometimes will remove opaqueness from milk tygon tubing).

7. Open threads in product zones.

8. Direct read milk measuring tubes must be installed to be easily cleanable, readily accessible for inspection and designed so that all product in the gauge will discarded so that no product will enter the tank outlet line nor re-enter the tank. The valves serving these tubes must be close-coupled. (See 3-A Standard Number 13-##). Close coupled is defined in this Standard as being no more than the smaller of twice the nominal diameter of the passage, or five (5) inches maximum. (## is the most current revision)

9. The internal parts of plate coolers should be periodically examined for construction and cleaning problems. Pay special attention to the gaskets and inner plate surfaces and check them thoroughly for cracks, holes, or buildup of milk solids or fat deposits. Plate coolers that have more than one section (pass) must have special consideration to provide for draining following mechanical cleaning. By-pass lines fitted onto plate coolers must be so installed to eliminate any dead end lines that would allow the accumulation of milk during the milking operations.

10. Some "butterfly" type valves may be difficult to disassemble and inspect. Some are even impossible without a full mechanics tool kit. Judgment must be used in determining whether these valves meet the requirements. Once taken apart the inner gaskets should be examined for construction compliance. The so called "green bodied" valve is not acceptable for use in product or cleaning solution lines.

11. Any Dairy Herd Information Association (DHIA) testing equipment and appurtenances must be evaluated for construction (and storage and cleaning) problems.

12. Milk pipelines should be provided with access points for inspection. In systems with welded pipelines diameters of 2" or more, inspection points, in addition to entrances and exits, are to be provided at intervals sufficient to determine general condition of the interior surfaces. Circular pipelines should follow the recommendations of the state regulatory agency for access/inspection points. In many states, access points are required at four equi-distant points in these rotary type milking barns.

13. **Use of flexible lines between bottom fill bulk tanks** for functional purposes is allowed, however these flexible hoses must meet the following requirements:

    - Must be readily drainable and as short as practical.
    - Have permanent sanitary fittings
    - Must be properly supported to maintain uniform slope and alignment.
    - The transfer hose must be a part of the CIP system.

BULK MILK TANKER REQUIREMENTS

1. All bulk milk tankers must meet the construction requirements of Items 10p and 11p of the PMO. Specific construction and fabrication guidelines may be found in the 3A Sanitary Standards, Number 05-13.

2. Vehicles must be kept clean, inside and out.

3. Inspectors must guard against back hauling practices which may contaminate the milk supply. The hauling of any non-food or toxic substances in milk tankers is strictly prohibited and should be considered a violation of the PMO.

4. Tankers shall be insulated sufficiently to permit no more that a 2^{o} F temperature rise in an 18 hour period measured with the tanker filled with water. This determination shall be made when the average temperature differential between the water and the atmospheric temperature is 30^{o} F.

5. Tanker manholes shall be located so that the distance from either end of the tank shall not exceed 18 feet, 6 inches. (This does not apply to tankers with permanently installed mechanical cleaning devices.)

6. The upper edge of the manhole cover shall be not less than 3/8 inch higher than the surrounding area and if an exterior flange is incorporated, it shall slope and drain away from the opening. **Provided, that adequate drain holes may be located in the dam so as to prevent the flooding of the dam up to the minimum level of 3/8 inch.** Judgment must be used in the evaluation of this item so that the dam area must protect the tank manhole entrance while the tanker is traveling or parked on inclines or slopes which may flood the manhole entrance.

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 Ordinance.

NOTES:

Item 10r

UTENSILS AND EQUIPMENT-CLEANING

REQUIREMENT: *The product contact surfaces of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be cleaned after each usage.*

Public Health Reason: Milk cannot be kept clean or free of contamination if permitted to come into contact with unclean containers, utensils or equipment.

Inspectional areas of emphasis or special problem areas may be:

1. Generally, the farm inspector should evaluate milk contact surfaces during non-milking time inspections. These evaluations should be keyed in areas where cleaning problems will be readily visible.

2. Some of these key areas to evaluate for cleanliness might be the bulk tank, bulk tank agitator paddle, milk tank inlets such as measuring stick or inlet pipe openings, bulk tank outlet valve, the milk receiver, a representative number of inflations, the milk lines, the milk inlets of the milk lines, the bulk tank "swing line", the weigh jar probes, etc.

3. Even the sanitary trap and line attaching it to the milk receiver is classified officially as milk contact surfaces and should be inspected regularly for any cleaning problems.

4. A milk contact surface that is not clean is one of the most significant sources of microbial growth and the subsequent contamination of milk. Residues will promote the growth of microorganisms which will grossly contaminate succeeding portions of milk. A small residue on any milk contact surface will promote bacterial growth and deposit or "seed" the milk supply with undesirable microbes. It is very important that the milk contact surfaces be cleaned immediately after each usage to remove all milk residues, and subsequently, all nutrients which bacteria need for growth. Thus, the importance of clean equipment is required to prevent the contamination of milk with microorganisms, some of which may be pathogenic.

Below is an example of a method used to clean the milking equipment following each milking. Other methods may be used; however most will follow the example provided.

NOTE*: Some newer installations have installed combination milk receiver/CIP tanks. These must be reviewed individually for compliance with Items 5r (Cleaning Facilities), Item 8r (Water Supply), Item 9r (Construction), Item 14r (Protection from Contamination) and Items 10r & 11r (Equipment Cleaning and Sanitizing).*

Begin with, rinsing all milk contact surfaces with clean cool or tepid water, never hot since this can "set" protein on the inner surfaces, coagulate the milk or actually cook milk onto the surfaces, or damage the equipment. This pre-rinse also effectively removes any excess milk and foam which could affect or weaken the cleaning properties of the washing chemicals.

Next is the washing cycle. Almost all operations use the CIP method of cleaning. The recommended amount of acceptable dairy cleaner (usually chlorinated) is added to the cleaning compartment utensil sink with the necessary properties such as surfactant, wetting, dissolving, emulsifying, deflocculating, dispersion, rinsing, and buffering agents. Household type detergents therefore should **never** be substituted and used for cleaning dairy equipment and utensils. Testing for water hardness may be necessary to determine proper cleaning compounds to be used on those dairy farms with individual water systems.

Following the wash cycle the milk equipment is rinsed thoroughly with clean water and stored to completely drain and must be protected from contamination.

5. The equipment should be evaluated for the following materials or deposits:

   - **Milk protein residues** - These are evidenced by layered deposits of milk fat which have been ineffectively cleaned over a period of time. These residues will be white to yellowish in color. Heavy residues will have a white-yellow tint and are usually visible with the help of a bright light source. These heavy deposits may appear as a solid sheet or in a streaked pattern on the surface. Milk protein films will often appear as streaks on the surface, some of them even displaying a multi-color streaking, often termed "rainbow sheen". The use of _____ _____ will remove most milk fat/protein deposits from equipment.

- **Milk solids deposits** - These are often termed "milk stone" and are the hard deposits left on inadequately cleaned milking equipment. These deposits appear chalky and are very difficult to remove without the use of proper chemical cleaning methods. Routinely using _____ _____ will help prevent the buildup of milk solids on the milk equipment.

- **Water mineral deposits** - Hard water, or water with excessive amounts of minerals, tend to cause discolorations or even leave "crusty" deposits on milk contact surfaces. These deposits will inhibit effective cleaning procedures and adjustments to the chemical cleaners or installation of water softeners will help alleviate the problem. These deposits are best removed by using acid washes on a regular basis, recommended use following each chlorinated alkaline cleaning.

- **High iron content water** - Water high in iron will stain surfaces and cause cleaning problems. Use of chemicals, specifically, acid rinses, will help dissolve these deposits.

6. A separate CIP manifold is required in all new or extensively remodeled facilities.

RESIDUE IDENTIFICATION CHART

RESIDUE	DESCRIPTION	CAUSE	REMOVAL	PREVENTION
PROTEIN	Blue rainbow hue varnish like, "apple sauce" or yellow varnish-like appearance	1.Using non-chlorinated cleaner 2.Inadequate pre-rinse 3.Improper cleaning	Chlorinated alkaline detergent	1.Adequate pre-rinse 2.Proper cleaning w/proper use dilution after each usage 3.Chlorinated alkaline detergent
MILKSTONE	White to yellow, chalky white to grey water spots and film, bluish cast to stainless steel.	Minerals from milk	Acid wash	Regular and proper cleaning procedures coupled w/acidified rinse
FAT/ GREASE	Hanging water droplets or beading greasy look, Greasy (white) appearance, soft yellow films, dull surface	1.Low water temperatures 2.Improper detergent concentration, i.e., alkaline detergent solution below pH 10 3. Regular use of acids in place of alkaline detergent. 4. Rinsing only (not washing) after milking.	1. Proper water temperature, minimum of 120 deg F at end of wash cycle. 2.Correct concentration of alkaline detergent 3. For removing heavy deposits, use chlorinated alkaline detergent and acid rinse at twice the recommended strength.	Regular and proper cleaning procedures coupled w/acidified rinse
MINERAL (Calcium, Magnesium)	White (water-stone) chalky to gray	1.Rinse too hot, drop-out of minerals from water supply 2.Failure to use acid detergents 3.No acidified rinse or using acid rinse with hot water. 4.Alkaline detergent used cannot handle hard water at present concentration	Acid wash, at recommended strength, for a minimum of 10 minutes. Repeat as necessary.	1.Acid wash 2.Alkaline detergent used has good water conditioning (sequestering properties) 3.Water softener or treatment may be necessary 4. Acid rinse temperature below 120 deg F.
IRON	Red to brown/black	1.Water supply 2.Using chlorine with high iron water	Acid wash	1. Water treatment. 2. Proper selection of sanitizer. 3. Regular effective acid rinse.

PARTIAL PUMP-OUT OF TANKS AT THE FARM

This practice is allowed if the farm bulk tank is equipped with an acceptable seven (7) day recording device complying with Appendix H or other acceptable recording device to assure the bulk tank is cleaned at least every 72 hours.

If the tank does not have a recorder, then partial pumping is permitted if the tank is cleaned and sanitized prior to the next milking.

Emergency or inclement weather conditions, etc., variances may be allowed by the regulatory agency.

NOTES:

Item 11r

UTENSILS AND EQUIPMENT-SANITIZATION

REQUIREMENT: *The product contact surfaces of all multi-use containers, equipment, and utensils used in the handling, storage, or transportation of milk shall be sanitized before each usage.*

Public Health Reason: Mere cleaning of containers, equipment and utensils does not insure the removal or destruction of all disease organisms that may have been present. Even very small numbers remaining may grow to dangerous proportions, since many kinds of disease bacteria grow rapidly in milk. For this reason, all milk containers, equipment and utensils must be treated with an effective sanitizer before each usage.

Recommended practices to be used in properly sanitizing milk contact surfaces:

1. **Immediately prior to use (milking)**, the equipment is treated with an effective sanitizer. Most dairy farm operations use a chlorine rinse, circulated in the system assuring contact with all milk contact surfaces. This may require the loosening of milk line connections to allow contact with the inner gaskets and thread parts. This may also involve immersing the small parts in an approved sanitizer solution for at least the minimum recommended time.

2. It is important to remember that once the equipment has been properly sanitized it **must not be exposed to possible contamination** in any manner. For this reason, dairy equipment should be **sanitized immediately prior to use. The lids and covers must be left in place** and not lifted or uncovered following the sanitizing operation. Milk lines once sanitized must never be taken apart without rewashing and resanitizing. This practice will eliminate the many possibilities of contaminating the milk contact surfaces during extended periods of storage.

3. The sanitizer **must be labeled for food contact surfaces and used at the recommended strengths and temperatures.** Increasing the recommended strength of any sanitizer is not only damaging to the equipment, but also could leave toxic chemical residues on the equipment which will contaminate the milk supply. (The use of

household chlorine (bleach) is acceptable only if its accompanying labeling allows for the use in dairy operations and is available at the farm.) It is also important to use only acceptable sanitizer in the milking operation.

Appendix F of the PMO specifically provides directions for use of chemicals on non-porous food contact surfaces.

Sanitizers approved by the EPA for use on non-porous food contact surfaces and which comply with Section 178.1010 of the Code of Federal Regulations (CFR) are acceptable for use in sanitizing milk contact surfaces. The CFR list sanitizer chemical types, strengths and limitations under Subpart B-Substances utilized to control the Growth of Microorganisms.

4. Finally, **never follow the sanitizing operation with a clear water rinse.** This will remove the sanitizing residual and negate the purpose of sanitizing the milk equipment.

5. Although it may seem like sound reasoning to leave sanitizing solutions in the milk system between milkings, this practice, if used on a regular basis could be harmful to the milk equipment. Rubber gaskets and other surfaces may deteriorate or discolor upon prolonged exposure to certain chemicals and chlorine chemicals are corrosive to stainless surfaces.

SANITIZERS

Hypochlorite Calcium or sodium hypochlorite in powder or solution.	**50 ppm** **1 minute**	Limitations - unreliable in presence of large amounts of milk residue. When used in spray form doubling strength is recommended.	Test kits available - litmus paper type. Readily affected by organic in solution.
Organic Chlorine Compounds	**200 ppm - 7.2 pH** **100 ppm - 6.8 pH** **50 ppm - 6.4 pH**	Limitations - Significantly affected by pH (Trichloromelamine may not be used to sanitize milk surfaces)	Test kits available. Chloramine T is limited to low pH situations.
Quaternary Ammonium Compounds **n-alkyl, dimethyl, and ethylbenzyl benzyl ammonium chlorides,.**	**200 ppm,** **30 seconds,** **at pH level >5.0,** **at 24^{o} C(75^{o} F) or higher**	Limitations - affected by interfering substances in the water. (Extremely hard water will reduce effectiveness significantly). Affected by Ph and temperature of solution.	Test kits available. Less affected by organics in the solution. Stability is more than the cl2 sanitizer.
Iodine compounds **a halogen sanitizer combining iodine and non-ionic substances**	**12.5 ppm,** **temperatures up to 49^{o} C(120^{o} F),** **1 minute,** **teat dips are used at over 2500 ppm**	Limitations - Colorations may appear on equipment.	Test kits available. Strength is relative to color of solution Iodophors are yellow or amber and the intensity is proportional to the concentration.
<u>HEAT</u> **STEAM** **HOT WATER**	**Exposure for 5 minutes after reaching 200^{o} F** **Exposure for 5 minutes at 170^{o} F**	Limitations-availability, economics, exposure times, practicality. same	n/a

Item 12r

UTENSILS AND EQUIPMENT-STORAGE

REQUIREMENT: *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: Provided, 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 CIP 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.*

Public Health Reason: Careless storage of milk containers, utensils and equipment, which previously have been properly treated, is apt to result in recontamination of such utensils, thus rendering them unsafe.

Inspectional areas of emphasis or special problem areas may be:

1. Extreme care must be used to protect the milk contact surfaces of equipment after cleaning during the storage period(s). Surfaces must not be left exposed to contamination after cleaning operations by splash, dust, insects, drippings, etc.

2. Equipment must be stored to assure complete draining/drying following the cleaning cycles. This includes all milk lines, inlets, the receiver, bulk milk tank, milking units (claws), etc. Allowing in-line filter units and/or the filters to contact unclean surfaces during installation (i.e., placing on the floor, shelving, or carried under the arm are only a few of the methods that have been observed during inspections) must never be allowed and violate this item.

3. Milk receivers and other equipment noted in the *Provision* are not to be located in milking areas where cattle are housed. These storage provisions are found in the PMO under Administrative Procedure1.

4. All manual cleaning of milk contact surfaces must be done in the milk-room.

5. Milk inlets that are not positioned either horizontally or upwards are in violation of this item of the PMO. (Downward positioned inlets will not allow for complete drainage of the system.)

6. Clean equipment must be stored off the floor on clean racks or other surfaces. Milking units that are cleaned in the milkroom may be left in the utensil sink following cleaning. This will protect them from contamination and facilitate subsequent sanitization prior to the next milking.

7. Failure to properly store the wash units located in the parlor (jetters) during milking is a violation of this item.

8. Single service milk filters, strainer pads, and similar single service articles that are in use must be stored in a suitable cabinet or container and protected against contamination. Filter box cabinets located in breezeways or other areas such as milking barns or parlors, storerooms, or office cabinets must be constructed to preclude any contaminating substances, dust, dirt, moisture, insects, etc.

   It is never a good practice to remove the filters from their original carton and place them in a cabinet for use since many containers or cabinets are not completely dust and moisture tight. Unopened filter boxes may be stored in the storeroom, office, or other clean area in a manner as not to be exposed to possible contamination.

Item 13r

MILKING-FLANKS, UDDERS, AND TEATS

REQUIREMENT: *Milking shall be done in the milking barn, stable, or parlor. The flanks, udders, bellies, and tails of all milking lactating animals shall be free from visible dirt. All brushing shall be completed prior to milking. The udders and teats of all milking lactating animals shall be clean and dry before milking. Teats shall be treated with a sanitizing solution just prior to the time of milking, and dry* ***before*** *milking. Wet hand milking is prohibited.*

Public Health Reason: If milking is done else where other than in a suitable place provided for this purpose, the milk may become contaminated. Cleanliness of the lactating animals is one of the most important factors affecting the bacterial count of the milk. Under usual farm conditions, lactating animals contaminate their udders by standing in polluted water or by lying down in the pasture or cowyard. Unless the udders and teats are clean and dry before milking, particles of filth or contaminated water are apt to drop or be drawn into the milk. Such contamination of the milk is particularly dangerous because manure may contain the organisms of brucellosis and tuberculosis, and polluted water may contain the organisms of typhoid fever and other intestinal diseases. Application of sanitizing solutions to the teats, followed by thorough drying just prior to the time of milking, has the advantage of giving an additional margin of safety with reference to such disease organisms as they are not removed by ordinary cleaning and it is helpful in the control of mastitis.

Inspectional areas of emphasis or special problem areas may be:

1. Dairy animal cleanliness plays an important role in total herd health and bacterial loads in the milk supply. This item is directly related to Item 4r, Cowyard Cleanliness, and must be evaluated on each farm inspection. Lactating animals with excessive manure on their flanks, bellies, tails, etc should never be brought into the milking area without first being thoroughly brushed, clipped or other effective measures to clean the animal. Effective maintenance of the cowyard and housing areas is a significant contributing factor to cleanliness of the milking herd.

2. Evaluate this requirement both at milking time and non-milking times.

Lactating animals with caked manure on their flanks should be considered as a violation, although some professional judgment is allowed.

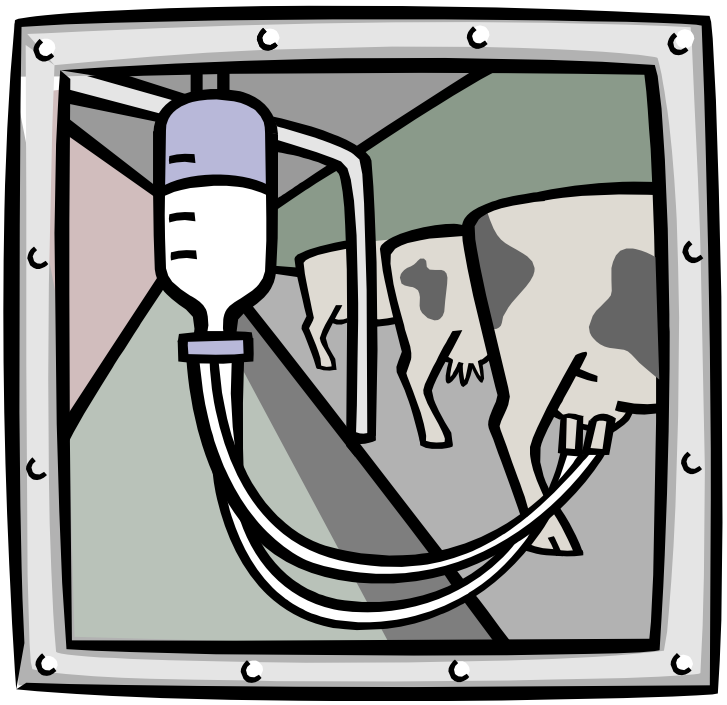
3. The length of teat hair should also be evaluated during milking. Teat hairs that become incorporated into the inflations during milking may serve as a microbial channel for contaminating the milk supply. These hairs may be trimmed or "carefully singed" to avoid this problem.

4. If automatic spray systems are used, the quality of water used is of utmost importance. The use of recycled water (water from plate coolers or compressors) in these systems must be closely monitored. Immediately prior to milking the teats must be **cleaned**, treated with a sanitizing solution and dry. Any of the acceptable sanitizers may be used, however strengths may have to be adjusted to accomplish an effective sanitization. The use of common towels, cloths, or sponges to wipe the udder must be discouraged as this simply transfers organisms from animal to animal.

5. As an alternative the FDA has declared that the sanitizing of teats shall not be required if the udder is dry and the teats have been thoroughly cleaned (not dry wiped) and dried (manually wiped dry) prior to milking. The determination of what constitutes a dry udder and cleaned and dried teats shall be made by the regulatory authority.

6. The so called practice of wet hand milking was a procedure used by hand milkers who would squirt the first few streams of milk onto their hands then grasp the teats between the thumb and first finger and pull straight down to force the milk out of the teat into a properly covered milking pail. The milk acted as a lubricant and some milkers thought it was a faster way of milking. The commonly accepted procedure for proper hand milking was to place the dry hand around the teat and gradually apply pressure from the top finger, then the second and on down. Thus gradually getting the milk out of the teat and then being repeated. This took more time than the wet hand milking, but was more sanitary and provided less chance for contamination. The 1935 PMO stated: “Milker’s hands shall be cleaned, rinsed with a bactericidal solution, and dried with a clean towel, immediately before milking and following any interruption in the milking operation. Wet-hand milking is prohibited. Convenient facilities shall be provided for the washing of milker’s hands.” It also stated: “Wethand milking increases the

likelihood of contaminating the milk." The following may answer the question, in that it was required in the 1935 PMO, that "every time a milker has finished milking a cow, has carried out and strained the milk, and has removed his stool to the next cow, he should rinse his hands in the solution. The first washing in the solution does not afford subsequent protection against recontamination from the cow's flanks, or even from the clothes and person of the milker."



Item 14r

PROTECTION FROM CONTAMINATION

REQUIREMENT: *Milking and milkhouse operations, equipment, and facilities shall be located and conducted to prevent any contamination of milk, equipment, containers, and utensils. No milk shall be strained, poured, transferred, or stored unless it is properly protected from contamination.*

After sanitization, all containers, utensils and equipment shall be handled in such a manner as to prevent contamination of any product-contact surface.

Vehicles used to transport milk from the dairy farm to the milk plant, receiving station or transfer station 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 the milk.

Public Health Reason: Because of the nature of milk and its susceptibility to contamination by disease producing bacteria and other contaminants, every effort should be made to provide adequate protection for the milk at all times. This should include the proper placement of equipment so that work areas in the milking barn and milkhouse are not overcrowded. The quality of any air which is used for the agitation or movement of milk or is directed at a milk contact surface should be such that it will not contaminate the milk. The effect of sanitization of equipment can be nullified if the equipment is not protected after sanitizing. To protect milk during transportation, delivery vehicles must be properly constructed and operated.

Inspectional areas of emphasis and special problem areas may be:

1. This item pertains to the protection of the milk supply from contamination by adulterants including, bacteria, drugs and chemicals.

2. When there is milk in the bulk tank, all openings must be protected or capped to prevent the entry of contaminants. This includes, but is not limited to CIP recirculating pumps and hoses that are permanently affixed to the tank, lids and covers, CIP chemical wash units, etc. This

item also applies to agitator openings in particular those bulk headed tanks with the agitator located in areas not meeting all requirements of the milkroom (storeroom, machine room, outside, etc.)

3. Any air directed towards milk contact surfaces must be from a clean source and be adequately filtered. Guidelines for air handling systems are found in Appendix H, of the PMO. This includes air blows for automatic back flush systems and air injectors used for CIP milk pipeline installations. Filters should be in good condition and should be replaced regularly and installed in a clean environment.

4. All cleaners and sanitizer must bear a label which provides the product name, chemical description, use directions, precautionary statements, first aid instructions, container storage instructions, and the name and address of the manufacturer. This requirement pertains to the storage container and dedicated end-use containers only and does not generally apply to the transfer buckets, scoops, dippers, etc.

5. During milking, the CIP lines terminating into the utensil sink must be effectively disconnected (a minimum of two pipe diameters above the overflow of the sink) **if these lines directly connect to the milk line/circuit in the milking area.** The use of an equal diameter open “T” fitting located twice the diameter (2D) above the overflow rim of the sink would satisfy this requirement.

NOTE: Each system must be evaluated and traced out thoroughly since many CIP lines connect directly into the milk line near the receiver or at the most distant end of the milk line, while other systems may only be connected to the wash "jetters" for inflation CIP.

Other conditions which may violate this item:

1. Uncapped bulk tank outlets, following sanitization or with milk in the tank,

2. Milk transfer pumps and hoses that have been sanitized that are not protected from contamination,

3. The improper handling or storage of sanitized milk contact surfaces, (i.e., milking units, inflations, etc. in contact with floor or other unclean surfaces).

4. Contamination of a **sanitized** milk bulk tank or other milking appurtenances prior to use without re-sanitization,

5. Any opening which would allow for contamination of the milk stored in the bulk tank,

6. Agitators not located in the milkroom need to be properly protected, or

7. Measuring lines on bulk milk tanks need to be designed so that backflow of the measured milk does not reenter the tank. And is properly drained to the floor, prior to load-out.

Item 15r

DRUG AND CHEMICAL CONTROL

Cleaners and Sanitizers Identification

Requirement: *Cleaners and Sanitizers shall be stored in properly identified, dedicated end use containers.*
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.
Animal drugs shall be properly labeled and segregated (lactating from non-lactating). Unapproved drugs shall not be used.

Public Health Reason: Accidental misuse of cleaners or sanitizers can result in adulteration of the milk. Animal drugs can result in adverse reactions in people sensitive to those residues and can contribute to the development of drug resistant human pathogens.

If cleaners and/or sanitizers are purchased in bulk and transferred to a container at the dairy farm, this container must meet the following requirements:

1. Be a specifically designed and maintained dedicated end-use container for use of the specified chemical agent.

2. The end-use container must contain a label which shall include 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.**

NOTE: Information regarding Veterinary Drugs, Extra-label use and Drug storage requirements are addressed in Chapter 6.

Item 16r

HANDWASHING FACILITIES

REQUIREMENT: *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, convenient to the milkhouse, milking barn, stable, parlor and flush toilet.*

Public Health Reason: Adequate handwashing facilities are essential to personal cleanliness and minimize the likelihood of contamination of the milk. Handwashing facilities are required in order to increase the assurance that milker's and bulk milk hauler/sampler's hands will be washed.

Inspectional areas of emphasis or special problem areas may be:

1. On each dairy farm there must be a handwashing lavatory fixture convenient to the milkhouse, toilet and the milking operations. An item could possibly be satisfied with **one handwashing sink convenient to all three locations**, however compliance of this item is judged on an individual farm basis.

   For instance: Many inspectors use the "two door" method to evaluate convenience of the handwashing facility. That is, if there are two doors separating the handwashing facility and any one of the three areas listed above then it may not be convenient for the user. Remember that the handwashing facility should also be convenient for the hauler/sampler, milker, and inspector.

2. The handwashing lavatory fixture must always be provided with adequate soap and individual towels and must be kept clean and free of debris.

3. It must never be used as a storage area for items such as outlet valves, drink cans, insecticide bombs, medication devices, brushes, etc.

4. Hot and cold or warm running water must be provided to the handwashing facilities.

5. An existing ring/basin facility may be used, the basin shall be in place for use and water, soap, and individual towels are provided.

6. Utensil wash and rinse vats shall not be used as handwashing facilities.

Item 17r

PERSONAL CLEANLINESS

REQUIREMENT: *Hands shall be washed clean and dried with an individual sanitary towel immediately before milking, before performing any milkhouse function, and immediately after the interruption of any of these activities. Milkers and bulk milk haulers/samplers shall wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment.*

Public Health Reason: The reasons for clean hands of the persons doing the milking are similar to those for the cleanliness of the lactating animal's udder. The milker's hands may have been exposed to contamination during the course of normal duties on the farm and at milking time. Because the hands of all workers frequently come into contact with their clothing it is important that the clothes worn, during milking and the handling of milk, be clean.

Inspectional areas of emphasis or special problem areas may be:

1. Observation for compliance with this item is usually made during milking time. The milker must have clean outer clothing, use good personal hygienic practices, and wash his/her hands before handling milking equipment, after each visit to the toilet or after any interruption in the normal work duties.

2. The use of tobacco in any form should be discouraged while performing milking operations.

Item 18r

RAW MILK COOLING

REQUIREMENT: *Raw milk for pasteurization shall be cooled to 10^{o} C (50^{o} F)or less within 4 hours or less of the commencement of the first milking, and to 7° (45 °F) or less within 2 hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10^{o} C (50^{o} F).*

Public Health Reason: Milk Produced by disease-free lactating animals and under clean conditions usually contains relatively few bacteria immediately after milking. These can multiply to enormous numbers in a few hours unless the milk is cooled. However, when the milk is cooled quickly to 7°C (45°F) or less, there is only a slow increase in the numbers of bacteria. Usually, the bacteria in milk are harmless, and if this were always true, there would be no reason to cool milk, except to delay souring. There is, however, no way for the dairy-operator or regulating officer to be absolutely sure that no disease bacteria have entered the milk, even though observance of the other items of this *Ordinance* will greatly reduce this likelihood. The likelihood of transmitting disease is much increased when the milk contains large numbers of disease bacteria. Therefore, it is extremely important for milk to be cooled quickly, so that small numbers of bacteria which may have entered will not multiply.

Inspectional areas of emphasis or special problem areas may be:

1. Meeting the cooling requirement may not be difficult on smaller farms milking only twice daily with adequately sized and properly operating farm bulk tanks. There may be cooling problems, however on those larger farms milking larger herds on extended schedules. The practice of 3 x day milking may add to this problem.

   This is especially true on those farms which have recently expanded using the same bulk tank and attempting to cool twice the amount of milk. The refrigeration unit may not be capable to handle the increased load and milk temperatures may never attain the 45^{o} F requirement within two hours after milking. Therefore the NCIMS has voted to allow milk to be cooled to <50

degrees within 4 hours of starting the first milking. Many of these problems have been alleviated by adding pre-coolers and larger more efficient bulk tanks at the facility.

2. Milk tank cooling requirements are also found in 3-A Standard, Number 13-## (## is the most current revision).

   This Standard requires that farm bulk milk tanks must be designed to cool the milk in the tank from 90^{o} F to 50^{o} F within the first hour after being filled to the corresponding volume and from 50^{o} F to 40^{o} F within the next hour.

   This Standard is based on the following criteria:

   - Everyday pick up filled to 50% of its rated capacity.
   - Every other day pick-up filled to 25% of its rated capacity.
   - Second or subsequent milkings it must prevent the blend temperature to rise above 50^{o} F during the addition of milk.

   NOTE: The cooling capacity is determined at ambient temperature of 90^{o} F for water cooled condensers are used and using refrigerant condensing temperatures not less than 103^{o} F.

3. Recirculated cooling water (ice banks or sweet water tanks) must meet the bacteriological standards of Appendix G; be properly protected; and be sampled semiannually by the regulatory agency. Samples shall be analyzed in a regulatory agency or in an EPA approved laboratory.

4. After January 1, 2000, all newly manufactured farm bulk tanks shall be equipped with an approved temperature recording device and shall meet the additional requirements in the PMO. Such as, no overlapping on the charts and the charts must be maintained for six months. In addition, recording devices shall be verified every six months.

ITEM 19r

INSECT AND RODENT CONTROL

REQUIREMENT: *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. Milkhouses shall be free of insects and rodents. Surroundings shall be kept neat, clean and free of conditions, which might harbor or be conducive to the breeding of insects and rodents. Feed shall be stored in such a manner that it will not attract birds, rodents or insects.*

Public Health Reason: Proper manure disposal reduces the breeding of flies, which are considered capable of transmitting infection by physical contact or through excreta to milk or milk containers, utensils or equipment. Insects visit unsanitary places, they may carry pathogenic organisms on their bodies and they may carry living bacteria for as long as 4 weeks within their bodies, and they may pass them on to succeeding generations by infecting their eggs. Effective screening tends to prevent the presence of flies, which are a public health menace. Flies may contaminate the milk with microorganisms, which may multiply and become sufficiently numerous to present a public health hazard. The surroundings of a dairy should be kept neat and clean in order to reduce insect and rodent harborages.

Inspectional areas of emphasis and special problem areas may be:

General: This item provides for the effective control of insects and rodents, the prevention of milk adulteration with pesticides and the maintenance of clean and neat surroundings.

1. Specific guidelines are provided for manure disposal practices. Manure piled on the ground surface during fly breeding season may not be stored longer than 4 days. If the manure is stored in a concrete manure bin the period may be extended to a 7 day maximum.

2. Practices must be used on the dairy farm premises to minimize fly breeding and rodent harborage activities. This includes; manure disposal practices, effective garbage and refuse disposal, and maintenance of surroundings in a neat and clean condition. Manure packs in cattle housing areas (loafing areas,

stables, free-stall housing, etc) must be properly bedded and managed to prevent fly breeding.

3. Prime areas for fly breeding are also found associated and adjacent to feeding and feed storage areas. Spilled or decaying feeds around silos provide the necessary organic and moisture conditions to facilitate fly breeding. These areas must be regularly cleaned, including feed bunks and other feed storage areas where stable flies (*Stomoxys calcitrans)* tend to breed.

   House flies (*Musca domestica)* will readily lay their eggs in manure, decaying silage, or other highly organic matter. Since flies prefer moisture conditions in excess of 30 percent moisture, fly populations will increase significantly following unusually wet seasons.

4. **Good sanitation practices are the best fly control program.** Although research has demonstrated that some biological control has proven effective, i.e., releasing a small wasp *(Muscidifurax raptor)* which stings only fly pupae, this program has only limited temporary use.

   Relying on continued application of pesticides has not been shown to be an effective measure in the overall control of house and stable flies. Flies will develop resistance to most all chemicals and can be harmful to natural predators and parasites of flies.

5. Outside refuse containers are to be kept covered and relatively clean. Used single service filters must be kept in a fly tight container and disposed of in a timely manner.

   The life cycle, of a fly, progresses from the egg - larva - pupa to adult stage and this life cycle may be influenced greatly by the environmental conditions.

   Remember that flies will complete their life cycle in 7 - 10 days when temperatures are between 85^{o} F - 95^{o} F and in approximately 20 days when temperatures are cooler at 50^{o} F - 60^{o} F.

6. Pesticides use on dairy farms must be approved for dairy farm usage by the Environmental Protection Agency (EPA), and the label on the pesticide container must contain the EPA Registration Number, name of the pesticide, chemical composition, methods of use, including strengths, cautions against use on certain food animals, and any other restriction for use on dairy farms.

7. Automatic electronic timer insecticide misters must be installed so that they cannot operate during milking and/or equipment cleaning periods. (This is best accomplished by inter-wiring the timing device with the vacuum pump so that insecticides may not be dispensed when the vacuum system is activated). They must also be installed so as not to contaminate the milk or feed in the milking area and are prohibited from being installed in the milkhouse; provided that small canister type approved insecticide "bombs" may be used in accordance with manufacturers' recommendations. Only approved pesticides may be used in these devices.

8. Only those pesticides approved for use in the milkhouse may be used and/or stored in the milkhouse. The use of vapona type strips is discouraged and small canister mister must only be used in accordance with the manufacturers' instructions. Paints containing insecticide must not be used in the milkroom. "Sticky" fly paper should not be allowed in the milkhouse as they tend to become over laden with dead insects which then become a cleanliness problem.

9. Milkhouse doors shall be tight and self closing and there shall not be any direct opening to the outside that is not effectively protected against the entrance of vermin into the milkroom. This includes overhead vents and windows. Screen doors must open outward which helps in preventing flies from entering the milkroom.

10. Effective measures to prevent contamination of the milk or milk contact surfaces must be taken.

11. Feed must be stored so as not to attract flies. Feed dollies, carts, fully automated feeding systems, or other feed containers may be exempt from the use of covers provided they do not attract birds, insects, or rodents.

NOTES:

CHAPTER 5

Dairy Farm Water Supplies

Item 8r

GRADE "A" DAIRY FARM WATER SUPPLIES

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

Public health reason: A dairy farm water supply should be accessible in order to encourage its use in ample quantity in cleaning operations; it should be adequate so that cleaning and rinsing will be thorough; and it should be of a safe, sanitary quality in order to avoid contamination of milk utensils.
A polluted water supply, used in the rinsing of the dairy utensils and containers, may be more dangerous than a similar water supply which is used for drinking purposes only. Bacteria grow much faster in milk than in water and the severity of an attack of a given disease depends largely upon the size of the dose of disease organisms taken into the system. Therefore, a small number of disease organisms consumed in a glass of water from a polluted well may possibly result in no harm; whereas, if left on milk utensil, which has been rinsed with the water, they may after several hours growth, in the milk, increase in such numbers as to cause disease when consumed.

This item is deemed to be satisfied when:

1. The water supply for the milkhouse and milking operations is approved as safe by the state water control authority, and in the case of individual water systems, complies with the specifications outlined in Appendix D and the bacteriological standards outlined in Appendix G, of the PMO.

2. No cross connections exists between a safe water supply and any unsafe or questionable water supply, or any other source of pollution.

3. There are no submerged inlets through which a safe water supply may be contaminated.

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

5. New individual water supplies and water supply systems which have been repaired or otherwise become contaminated are thoroughly disinfected before being placed in use (see, PMO - Appendix D). The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected.

6. All containers and tanks used in the transportation of water are 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 ground water 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 so as 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 also 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 (see, PMO - Appendix D).

7. Samples for bacteriological examination are taken upon initial approval of the physical structure, based upon the requirements of this *Ordinance* and when any repair or alteration of the water supply system has been made, and at least every three years. ***Provided,*** **that water supplies with buried well casing seals, installed prior to the adoption of this section, shall be tested at intervals no greater than 6 months apart.**

   Whenever such samples indicate either the presence of bacteria of the coliform group, or whenever the well casing, pump or seal need 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.

   When water is hauled to the dairy farm, **such water shall be sampled at the point of use and at least four times in separate months in any consecutive six months,** for bacteriological examination at the point of use and submitted to an approved laboratory each month. Bacteriological examinations shall be conducted in a laboratory acceptable to the regulatory agency.

8. Individual wells located in "existing" pits shall comply with the following requirements.

   - Concrete floors sloped to drain.
   - Water tight walls extending a minimum of 15 inches above the established ground surface at all points
   - Sump pumps or gravity drains terminating at the surface at least 30 feet from the pit.
   - Impervious covers
   - Water pump mounted on a concrete surface 12 inches above the pit floor level

   NOTE: Only existing pits may be used on Grade “A” dairy farms. Existing pit wells have been interpreted as those in existence prior to adoption of the PMO pit well requirements (1978) as found in Appendix D of the *Ordinance.*

9. Current records of water test results shall be retained on file with the regulatory agency, or as the regulatory agency directs.

10. State water control authority requirements that are less stringent than the PMO shall be superseded by the PMO. The PMO, formal FDA interpretations of the PMO and other written FDA opinions shall be used in evaluating the acceptability of individual water supplies and water system construction requirements at dairy farms, dairy plants, and single service container manufacturing facilities. (State Water Control Authority requirements which are stricter than the PMO shall not be used to determine compliance during IMS ratings and check ratings.)

11. In regards to wooden storage tanks on farms. The PMO specifically requires impervious tanks be used on dairy farms. Currently the interpretation is that for existing wood tanks, professional judgment is to be used. All new reservoirs must meet the requirements.

LOCATION: Item 4 of the Administrative Procedures requires that the water source be located in an area so that it will not become contaminated by surface nor sewerage system contamination.

Table 10, in Appendix D of the PMO, requires that the water sources located in favorable (unconsolidated) subsoil formations be located a minimum of 50 feet from all sources of contamination such as:

- Human or animal excreta;
- Cesspools, dry wells, disposal and waste injection wells, and deep leaching pits;
- Areas of limited filtration or questionable aquifer formations, and/or
- Near sources of concentrated multiple contaminants.

LESSER DISTANCES ARE ACCEPTABLE ONLY AFTER APPROVAL OF THE STATE WATER AUTHORITY FOLLOWING A COMPREHENSIVE SANITARY SURVEY.

The sanitary survey should include engineering data covering source development, pollution hazard detection and assessment, and be conducted by trained and competent persons in public health engineering.

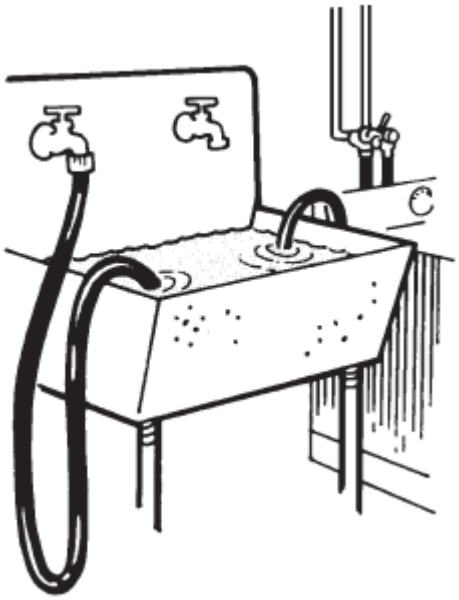
Surveys are continuously made on existing supplies compatible with the control of the health hazards and maintenance of a good sanitary quality water source.

Individual well construction standards may be found in Appendix D of the PMO.

Some of the more common violations found on dairy farms are:

a. Submerged inlets, including;

- Hoses or automatic filler valves located below overflow level in stock tanks;
- Hoses submerged in utensil wash vats, if there is a drain plug in the drain.



b. Wells located in or immediately adjacent to the cowyard;

c. Chemical injector systems that feed directly into the potable water supply without adequate protection (drums of udder wash or sanitizer);

d. Wells in pits without the required drain, cement floors, or impervious covers over the pit;

e. Improperly installed high pressure water pumps "unprotected" high pressure pumps are those which are not either:

- connected to a separate water supply.
- connected to a separate properly designed tank or reservoir, or
- fitted with a properly installed low pressure cut-off switch which deactivates the pump under a pre-set low pressure condition. This includes also a properly installed shut-off valve upstream from the switch.

NOTE: As a result of testing completed by the FDA, devices such as vacuum breakers/ backflow preventers and flap type check valves were not able to prevent the occurrence of negative pressure or suction on the line supplying these high pressure pumps.

f. Milkhouse water supply connected directly to unapproved water supplies

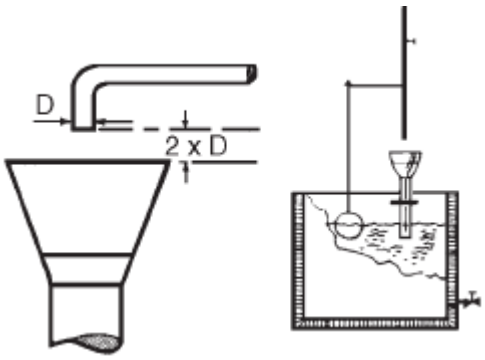
(such as back-up wells, that may be irrigation wells, or other unacceptable water supplies) are prohibited.

g. Incorrect type of vacuum breaker on systems (use of atmospheric devices to protect a pressure line).

h. Loose or missing well seal or cover.

i. Unprotected water tanks or reservoirs.

j. Inadequate air gaps, a proper air gap is defined as equal or great than twice the diameter of the inlet pipe from the overflow, but never less than one inch.



k. Water supplies inaccessible for inspection.

l. Unscreened well vents or other unprotected openings into the well.

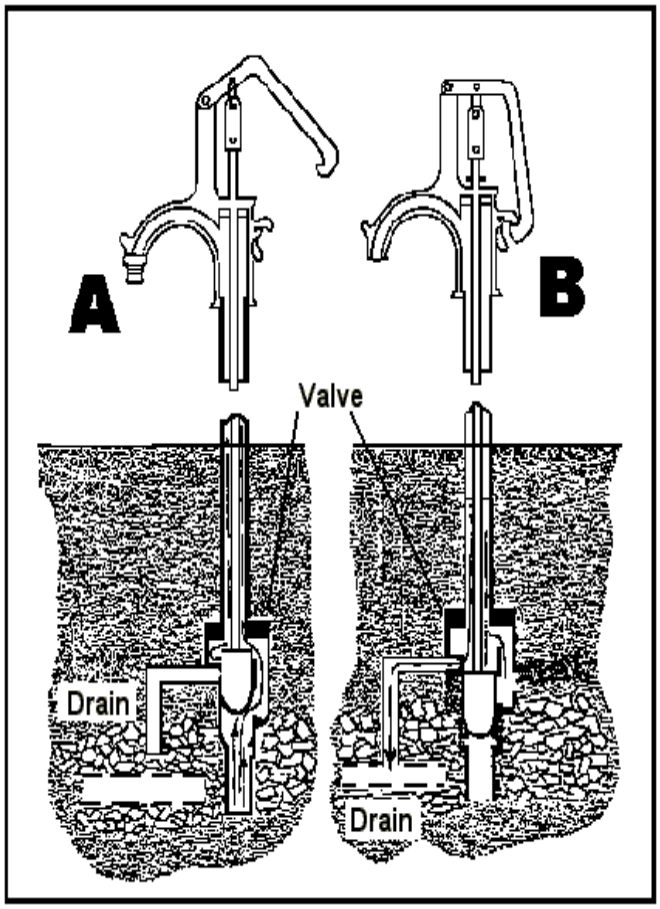
Some other violations may be:

- Unprotected springs.
- Tubular or plate cooler water with submerged inlet at the discharge.
- Potable water line runs through a non-potable source, such as stock tank feeder lines.
- Use of check valve(s) instead of an acceptable back siphonage device to protect a water line from back siphonage.
- Suction pipe, below the ground surface which is not fitted with a water-tight casing.
- Loose or ill-fitting manhole covers over a dug well or tank, or one without the necessary locked or bolted overlapping watertight cover.
- Abandoned uncapped well in close proximity to the well supplying the milkhouse.
- Reuse of air compressor cooling water or plate cooler water without the

necessary controls. (Requires 6 month sampling, proper protection, no submerged inlets, etc).

- Installation of “frost-free" hydrant (with internal drain) directly on the well slab or within 10 feet of the supply casing or in areas whereby the supply may become contaminated (cattle housing area, cowyard, adjacent to stock watering founts, etc). These installations may be acceptable if the hydrant is equipped with an acceptable back flow preventer or hose bibb type vacuum breaker.

- Use of untreated surface water (ponds, ditches, etc) or other unacceptable water supplies for udder washing and or sanitizing, the cleaning of milking area surfaces (floors, walls, etc) or other non-product contact surfaces (outside of pipelines, milking units, receiver units) is a violation of this item.



Frost-free Hydrants:

These hydrants are designed for use where freezing is a problem to allow year-round water service on private water supplies without the danger of damage to the pipes or hydrants.

The hydrants are connected to the water distribution system and possess a drain-back feature that allows the water standing in the column to drain below the frost line and discharge through a weep hole to a gravel bed or tile drain. When the water is turned on, the drain hole is automatically closed by a valve to allow water service (Figure A). When the hydrant is turned off, however, the valve opens the drain hole and permits the standing water in the hydrant column to escape through the drainpipe (Figure B).

The use of frost-proof hydrants incorporating this drain-back feature allows the possibility of back-siphonage of contaminated water into the water distribution system. This possibility can become a reality should a valve leak develop or a loss of pressure occur in the water distribution system.

Because the drain port is open when the hydrant is in the off position, it provides **a convenient route through which impure groundwater, insects and dirt can enter the hydrant**, thereby contaminating the water supply. Regardless of whether the hydrant is in the on or off position, contamination of the hydrant and water distribution system is possible under a variety of circumstances.

TABLE OF FARM WATER SUPPLY VIOLATIONS

The following Table was accepted by the NCIMS Executive Board for use as guidance in evaluating farm water supplies. The Table provides guidance, which may be used to differentiate between minor and major violations of Section 7, Item 8r of the *Grade "A" PMO* during State Ratings and FDA Check Ratings.

Primary Violation Areas as Defined by the *Grade "A" PMO*

1. Water supply is safe and complies with Appendix D.;
2. No cross-connections between safe and unsafe supplies;
3. No submerged inlets;
4. Well location and construction;
5. New individual water supplies disinfected prior to use;
6. All containers/tanks used to transport and protect water are protected from contamination;
7. Periodic sampling; and
8. Water testing records, current.

WELLS, SPRINGS AND CISTERNS: CONSTRUCTION AND LOCATION (Items A, D and F)	
Major	**Minor**
1. Any openings that allow direct contamination of the well water, such as: a. Well cap/cover not in proper position on top of casing to protect against contamination (i.e., missing, lying on ground, hanging off edge of casing, etc.); b. Well cap/cover not impervious; c. Opening in top of casing (i.e., vent hole, opening around electrical wires, etc.); d. Well casing or top cracked/perforated with openings to interior of well; e. Well seal not watertight; and f. Frost-free style water hydrant out of the top of the well casing. **2. Large hole/depression, indication of erosion around well casing or standing water around well casing.**	**1. Any openings that allow *indirect* contamination of the well water:** a. Well cap/cover not tight or overlapping (i.e., set screws, etc. not tightened) but in proper position to protect against contamination; b. Proper vent (turned down pipe) but unscreened or damaged screen; and c. Loose wires running from the outside of the well into the well casing from the side or underside of the well cap. **2. Slight depression around well with no evidence of standing water.**

WELLS, SPRINGS AND CISTERNS: CONSTRUCTION AND LOCATION
(Items A, D and F)

Major	Minor
3. Well pit does not meet the following requirements: a. Watertight construction (protected from ground water/rain water); b. Watertight impervious cover; c. Watertight impervious (concrete) floor sloped to drain; d. Operational sump pump or traceable drain to the surface; e. Dry floor in pit; and f. Well in bottom of pit protected from contamination using cover, seals, etc.	**3. Well pit does not meet the following requirements:** a. Concrete base for pump/machinery at least 12 inches (30.5 centimeters) above the pit floor; and b. Cover of the overlapping (shoe box) type.
4. Spring box not properly constructed or protected: a. Spring box and cover do not protect spring from direct contamination, (i.e., uncovered, openings in top, cracks in sides, etc.); b. Surface drainage not diverted away from spring; and c. Spring located in open pasture/field with livestock concentrating within 50 feet (15 meters) as evidenced by trampling of ground, accumulation of manure, or a stock tank or cattle feeding area within 50 feet (15 meters) of spring.	**4. Spring box not properly constructed or protected:** a. Overflow piping not screened; b. Spring box cover not overlapping; and c. Minor construction deficiencies.
5. Water reservoir/cistern/tank construction and use: a. Constructed to allow contamination of the potable water; and b. Transfer/distribution system constructed to allow contamination of the water supply or distribution system.	**5. Water reservoir/cistern/tank construction:** Minor construction problems.
6. Buried well seal: With a bad water sample not brought into compliance.	**6. Inaccessibility:** Except for seasonal conditions like snow and insulation wrap during winter months, the following water sources/supplies must be accessible for routine inspection and survey evaluation:

WELLS, SPRINGS AND CISTERNS: CONSTRUCTION AND LOCATION (Items A, D and F)		
Major		**Minor**
		a. Above ground wells and well pits; b. Cisterns, reservoirs and springs; and c. Stock watering vessels.
7. Well within 50 feet (15 meters) of contamination source (i.e., sewer lines, septic tank, drain field, cowyard, cattle housing areas without impervious floors, calf pens, waste disposal lagoons, buried gasoline tanks, herbicide/pesticide storage, etc.). **8. Well casing terminating below or at ground level. (Does not include well pits or buried well seals complying with Item 8r of the PMO).** **9. Well located in a known flood plain with well casing terminating less than 2 feet (0.6 meters) above the highest known flood level.** **10. Well located in open pasture/field with livestock concentrating within 50 feet (15 meters) of well as evidenced by trampling of the ground, accumulation of manure, or a stock tank or cattle feeding area within 50 feet (15 meters) of the well*** **11. Improperly constructed abandoned well(s) located within 10 feet (3 meters) of well(s) used as source of potable water for the dairy.**		**7. Frost-free style water hydrant located within 10 feet (3 meters) of the well without an approved atmospheric vacuum breaker or with the hose connection threads not cut off.** **8. Any pit not meeting the construction standards of the PMO, which is located within 10 feet (3 meters) of the well.**

* If there is no evidence of livestock concentration around a well casing that is located in a pasture, then this Item should not be debited.

WATER SAMPLING (Items E, G and H)	
Major	**Minor**
1. Last water sample unsatisfactory. **2. No record of an initial bacteriological sample on file prior to the issuance of a permit for new farms, without any additional sample results on file for the rating period.** **3. Continuous disinfection system, required by the Regulatory Agency, is not operational.** **4. On farms with interconnected wells, if the system is constructed and operated so that a single sample will represent all sources, then a single sample is sufficient. If a single sample does not represent all sources, then each individual well must be sampled at the required frequency (M-I-86-9).**	**1. Last sample on record tested safe, but the next sample was not collected/ analyzed within the required time frames:** a. New Permit: Then once every three (3) years; b. Buried Well Seal: Every six (6) months; c. Hauled Water: At least four (4) times in separate months during any consecutive six (6) months; and d. After Any Well Repair: Within thirty (30) days.

CROSS-CONNECTIONS AND SUBMERGED INLETS:
(Items B and C)

Major	Minor
1. <u>Submerged inlets:</u> Into non-potable water, (i.e.): a. Submerged line in a stock tank(s)/stock fountain(s); b. 2-compartment wash vat(s) containing water or with the drain plugged; c. Drinking cups; d. Pre-cooler outlet; e. Flush down tanks; f. CIP water discharge below the overflow of the make-up vat; and g. Chill water tank (sweet water, glycol, etc.).	**1. <u>Potential Submerged Inlets:</u>** a. Single-cased pipe in a stock tank or fountain; and b. Properly working stock tank float located below the overflow rim of the tank. (**<u>NOTE</u>**: If the float has stuck and it is submerged at the time of the inspection it is a five (5) point debit.)
2. <u>Permanent in-line high pressure pump</u> (power washer): Without acceptable protection, such as: a. Properly functioning low-pressure cut-off switch with a properly located test valve; and b. Other methods acceptable to the State Water Control Authority.	**2. <u>Portable high pressure water pump</u> (power washer): Without acceptable protection, such as:** a. Separate water supply or reservoir; b. Properly functioning low-pressure cut-off switch with a properly located test valve; and c. Other methods acceptable to the State Water Control Authority. (**<u>NOTE</u>:** Lack of a valve or improperly located valve, used to test the low-pressure cut-off switch is a two (2) point debit.)
3. Cleaner, sanitizer and udder wash injectors (pumps) with water supply connection not properly protected and supply container of greater than one (1) gallon size. Submerged inlet(s) in other chemical containers (i.e., bottles and/or containers of Roundup, 2-4D, etc.), regardless of the size of the chemical container.	
4. Anti-siphon vent-type backflow prevention device with vent plugged.	

CROSS-CONNECTIONS AND SUBMERGED INLETS: (Items B and C)		
Major		**Minor**
5. Use of non-functional or improper devices to protect against submerged inlets and/or cross-connections. 6. Stock tank(s) utilizing center ground pipe as an overflow, where the overflow is flooded and not draining. 7. Discharge hose connecting potable water system directly to the sewer system or manure handling system (i.e., water line terminating below the flood rim of a floor drain).		

RECLAIMED WATER NOT MEETING THE FOLLOWING CRITERIA: (Appendix D, IV. - Water Reclaimed from Heat Exchanger Processes) Major
1. Sampled before initial approval; 2. Sampled at least once in each six (6) month period; 3. Proper construction of the storage tank (i.e., protected from contamination); 4. No cross-connections between reclaimed water and non-potable water; and 5. Approved chemicals used if water is treated.

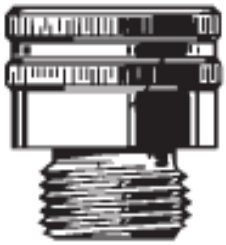
BACK SIPHONAGE PROTECTION DEVICES

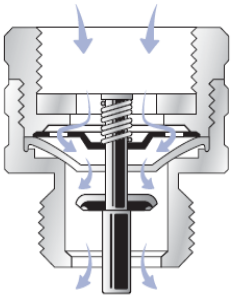
TYPE & PURPOSE	DESCRIPTION	APPLICATION	EXAMPLES
Atmospheric Type Vacuum Breaker	***Single float and disc with large atmospheric port***	***Cross connections not subject to backpressure or continuous pressure. Install at least 6" above fixture rim.***	***Properly designed faucets or other non pressure applications. (must be installed downstream from last shut-off valve)***
Hose Connection Vacuum Breakers	***Single check with atmospheric vacuum breaker vent***	***Installed directly on hose bibbs, utensil sinks and wall faucets. Not for continuous pressure.***	***Hose bibbs over wash vats, hose bibbs on wall or outside of buildings, hydrants***
Pressure Type Vacuum Breakers	***Spring loaded single float and disc with independent 1st check. Supplied with shut-off valves and ball type test cocks***	***Designed for installation in a continuous pressure line. To be installed 12" above the highest line and point of use downstream from the device and point of usage. Protection against back siphonage only***	***Livestock water systems, lawn sprinklers, chemical tanks, cooling towers***
Specialty Type Back Flow Preventer	***Two independent check valves with intermediate vacuum breaker and relief valve***	***For use in low hazard cross connections in small pipes under continuous pressure.***	***Dairy equipment, residential use, any low hazard cross connection with continuous pressure***
Reduced Pressure Zone Back Flow Preventer	***Two independent check valves with intermediate relief valve. Supplied with shut-off valves and ball type test cocks.***	***For use on continuous pressure situations subject to back pressure or back-siphonage where a high potential health hazard exists.***	***Processing tanks, cooling towers, sewerage treatment, boilers, toxic chemical applications.***

BACKFLOW PREVENTION DEVICES-Illustrations

I. ATMOSPHERIC TYPE -

Must be installed downstream from the last shut-off valve. Also must be installed 6 inches higher than what it is trying to protect. This device protects against back-siphonage back-flow only. It does not afford protection against back-pressure back-flow. This device is not allowed in constant pressure applications.



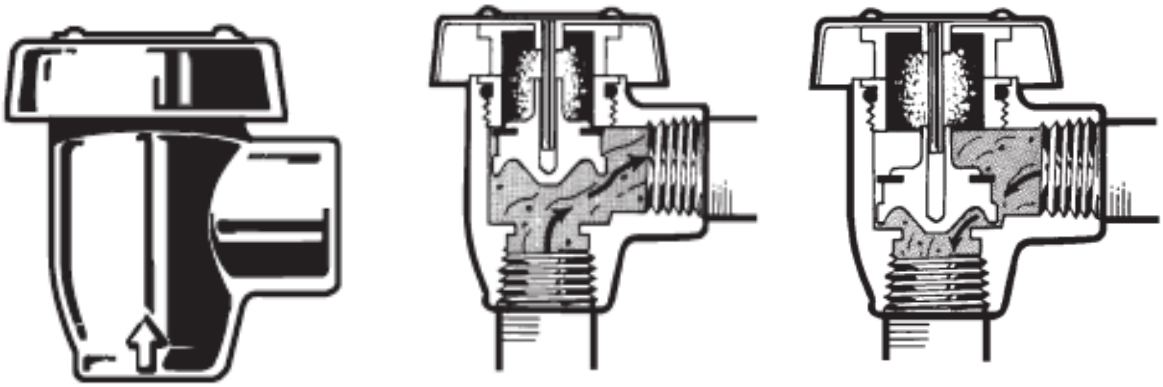


<u>Hose Bibb Breaker</u>

- High Hazard
- Not for continuous pressure

Atmospheric Vacuum Breaker (AVB)

- High Hazard
- Back siphonage
- Not for continuous pressure
- Installed vertically
- Installed 6 in. above the highest inlet downstream
- No cut-off valves downstream
- Solenoid before AVB



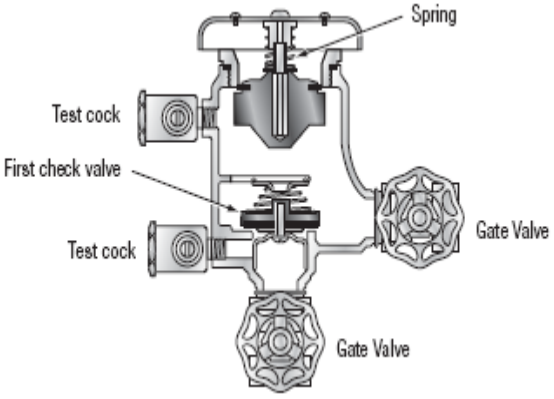
II. PRESSURE TYPE-

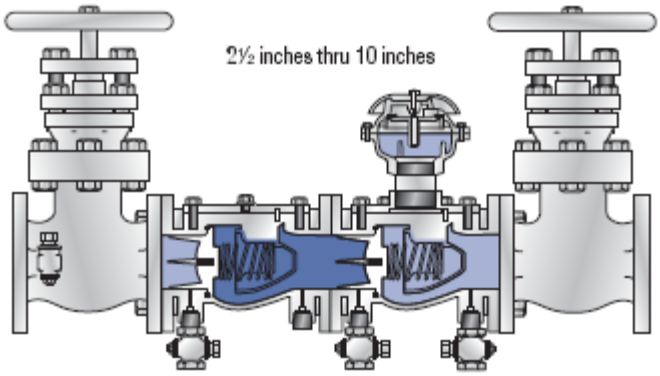
Designed for installation on water supply lines normally under constant pressure. This device protects against back-siphonage back-flow only. Must be installed 12 inches higher than what it is trying to protect. It is allowed in lines that are either under intermittent pressure or constant pressure. Therefore it may have shut off valves located after it.

<u>Spill Resistant Vacuum Breaker (SVB)/(PVB)</u>

- High hazard
- Back siphonage
- Continuous pressure-can have valves downstream
- Indoor use
- Spring loaded float disc
- Test cocks
- Installed 12 in higher than what you are trying to protect
- Installed vertically
- Checked annually, at installation, & taken in/out of service
- Chemical tower

PVB is used outside

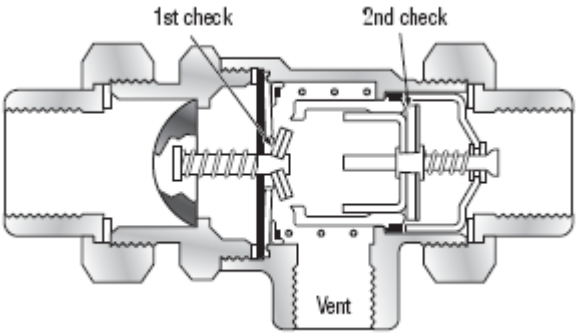




Double /Dual Check w / Atmospheric vent

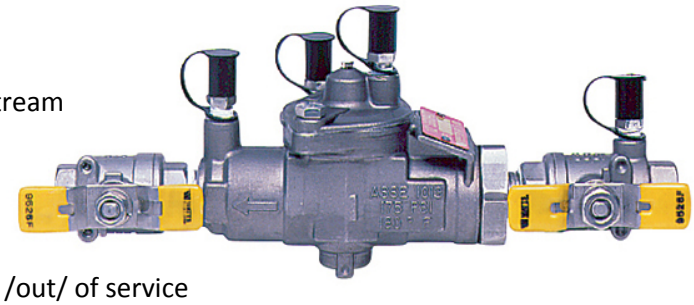
- Low hazard
- Back pressure / Back siphonage
- Continuous pressure
- Installed horizontally or vertically
- Located between pump & tank

CAUTION: Some local jurisdictions do not accept this device!

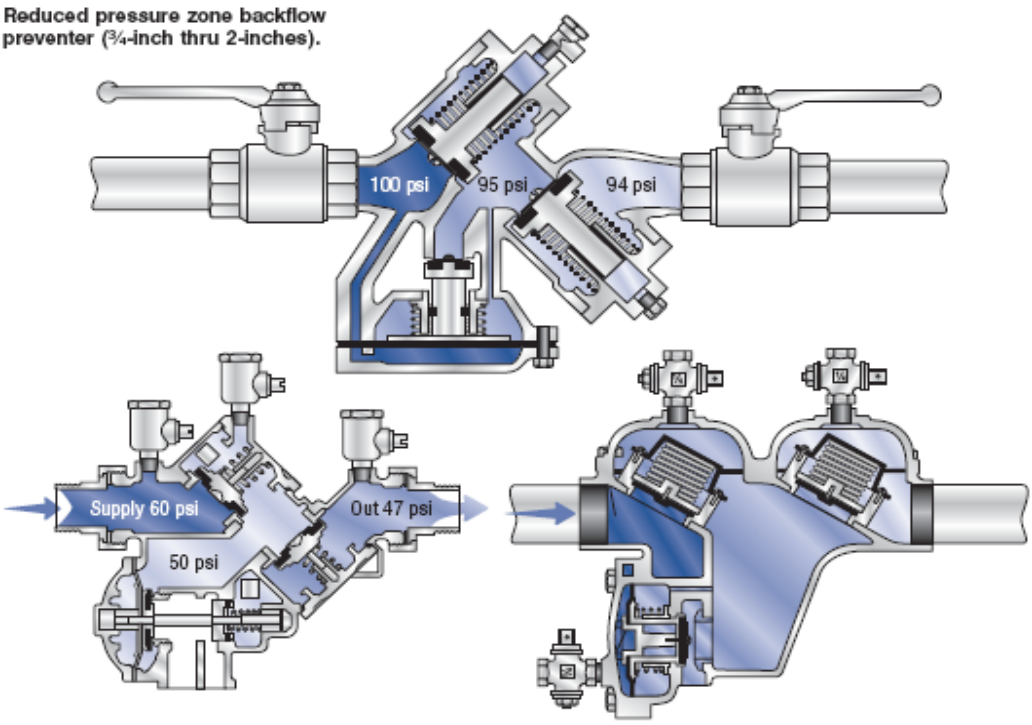


III. PRESSURE TYPE - Reduced Pressure Zone is allowed in all applications. It cannot be installed where it may become submerged, and it protects against both back-pressure back-flow and back-siphonage back-flow. It can be used in constant or intermittent pressure applications, and high and low hazard applications.

Reduced Pressure Zone (RP)



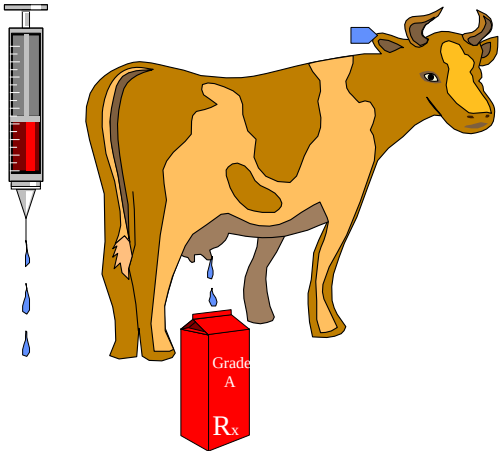
- High hazard
- Back pressure / Back siphonage
- Continuous pressure – can have valves down stream
- Bottom must be ≥ 12 above grade
- Cannot be installed in a pit
- Relief valve must be indirectly plumbed
- Installed horizontally unless approved
- Check annually, at installation & when taken in /out/ of service
- High pressure chemical washer
- Boilers



NOTES:

CHAPTER 6

Animal Drug Labeling And Storage



Item 15r

PMO DRUG LABELING AND STORAGE REQUIREMENTS

Requirement: *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.*
Animal drugs shall be properly labeled and segregated, lactating from non-lactating. Unapproved drugs shall not be used.

Public Health Reason: Animal drugs can result in adverse reactions in people sensitive to those residues and can contribute to the development of strains of drug resistant human pathogens.

This item is deemed to be satisfied when:

1. Equipment used to administer drugs is not cleaned in the wash vats and is stored so as not to contaminate the milk or milk-contact surfaces of equipment.

2. Drugs intended for treatment of non-lactating dairy animals are segregated from those drugs used for lactating animals. Separate shelves in cabinets, refrigerators or other storage facilities satisfy this item.

3. 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 Rx and extra label use drugs.

4. Drug labels shall also include:

    a. Directions for use – dosage/route of administration, duration of therapy, and

    b. prescribed withholding times – for meat and milk, even if zero, and

    c. Cautionary statements, if needed; and

    d. Active ingredient(s) in the drug product (no trade name).

In addition to the above requirements, unapproved and/or improperly labeled medicinals/drugs are not used to treat dairy animals and are not stored in the milkhouse, milking barn, stable or parlor. They should be stored in such a manner that they cannot contaminate the milk or milk product-contact surfaces of the containers, utensils or equipment.

NOTE: Topical antiseptics, wound dressings (unless intended for direct injection into the teat), vaccines and other biologic's, 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 surfaces of containers or utensils. (See document "Drugs on the Dairy Farm")

NOTE: LISTING OF DRUGS OR PRODUCT TRADE NAMES DOES NOT IMPLY AN ENDORSEMENT OF THEIR USE IN DAIRY CATTLE.

WHO IS RESPONSIBLE FOR COMPLYING WITH ITEM 15r?

The **dairy producer** is ultimately responsible for assuring that drugs are properly labeled, stored and used on the dairy operation. The minimum label requirements provide inspectional evidence that adequate directions for use of a drug product are available to the dairy producer and in the case of prescription (Rx) or extra-label-use (ELU) drugs, that a veterinarian has prescribed the product. If these labeling requirements are not met, the dairy producer may not have adequate directions for the safe and effective use of the drugs and residues may result.

WHY LABELING AND STORAGE REQUIREMENTS ARE IMPORTANT:

Drug residues most often occur on the dairy operation, not later in the milk processing channels. Many residues result from the failure to properly follow labeling directions; resulting in inadequate milk discards or slaughter withdrawal times. Other common causes of drug residues include the failure to adequately identify treated dairy animals and to keep appropriate records; improper ELU by a dairy producer; and the failure to milk treated lactating animals last or the use of common milking equipment or vacuum source to milk treated and non-treated lactating animals. The labeling and storage requirements exist as part of the overall efforts employed by Federal and State agencies, the National Conference on Interstate Milk Shipments (NCIMS), the dairy industry, dairy producers, and the veterinary medical profession to avoid drug residues in our milk supply. The requirements are intended **to ensure that the producer has adequate directions for use of the**

product in hand every time the drug is administered. Great emphasis is placed on proper drug labeling and storage in an attempt to heighten the producer's awareness of proper drug use and prevent accidental drug residues in our milk and meat products.

Accidents and mistakes cause the majority of the drug residues in milk.
Examples:

- Failure to follow drug use and withdrawal time directions
- Failure to identify treated cows and keep them out of the milking herd.
- Failure to keep adequate treatment and drug use records.
- Using common equipment to milk treated and not-treated cows.
- Pulling vacuum off the milk line to operate abnormal milking buckets.
- Multiple drugs and/or double dosing and following single dose discard/withdrawal times.

PMO DAIRY OPERATION INSPECTIONAL AREAS:

The proper labeling and storage of drugs on the dairy operation is important to ensuring that the producer has adequate directions for use in hand every time a drug is administered to assist in preventing drug residues. It is important that drugs are stored in areas where they may be reviewed during routine inspections, state ratings and FDA check-ratings. Such review provides verification that proper labeling and storage criteria, required under Item 15r of the PMO, are in compliance.

FDA has consistently defined that the inspection of a Grade “A” dairy operation includes the milkhouse, milking barn, stable or parlor, adjacent storage areas, cow yard and cattle housing areas, surroundings, waste disposal areas and the water supply and its distribution system. These areas may include dairy animal maternity areas, animal treatment areas or hospital barns, replacement heifer areas, offices, utility rooms, tool sheds (drug cabinets, refrigerators, etc.) or other areas where drugs, used to treat dairy animals, may be used or stored.

With regard to drug storage, labeling and use, the scope of a dairy operation/inspection extends beyond the milkhouse, milking barn or parlor. FDA believes the following areas are part of the milking operations: any area reasonably expected to contain drugs used to treat lactating cattle, cattle that may soon be placed in or returned to a milking herd, or other cattle intended for milk production (replacement heifers). Private residences and vehicles are not included without the permission of the owner or their authorized agent.

WHAT IS A DRUG?

A **drug** is defined in the PMO, Section 1, and Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act), as follows:

A. Articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

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

C. articles (other than food) intended to affect the structure or 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.

I. Vaccines and Other Biologics

Certain drugs are regulated as biologics under the Virus, Serum, and Toxin Act (VST Act) administered by the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services, through their Biologic Staff licensing, Biologic Laboratories, and Biologic Operations.

The VST Act prohibits the production for sale or interstate movement of worth less, contaminated, dangerous or harmful biologics intended for use in the diagnosis or treatment of animal diseases. Ordinarily, a biologic can be identified by the USDA License number on the label. Vaccines and biologics are exempt from the labeling provisions of the PMO. In general, biologics can be classified as the following:

Antigens Vaccines Bacterin Toxoids Antitoxins

Some biologics contain antibiotics as preservatives. The antibiotics are added to biologic products in accordance with the Code of Federal Regulations (CFR), Part 9 CFR 114.10. The concentrations of antibiotics used in the biologics are well below the levels that are capable of producing a residue in milk or meat.

II. Pesticides

Pesticides/rodenticides/insecticides are registered and regulated by the Environmental Protection Agency (EPA). Ordinarily, an EPA regulated product can be identified by an EPA registration number on the label. Only products labeled for use on or around dairy animals or milking equipment should be used and then only according to their labels. EPA regulated pesticides/rodenticides/insecticides are used only in accordance with the manufacturer's label directions and are used so as to prevent the contamination of milk, milk containers, utensils and equipment, feed and water.

Such products found on dairy farms will include sprays, dusts, and impregnated ear tags intended for the treatment or prevention of external parasites such as flies, screwworms, lice, and ticks and those products intended to act topically for control of cattle grubs.

The EPA also regulates sanitizer's applied to inanimate surfaces and/or drinking water of animals that do not include any direct or implied claims to control disease.

Using unapproved pesticides/rodenticides/insecticides or not in accordance with their label directions is considered a violation of Item 19r – Insect and Rodent Control of the PMO and would not be debited under item 15.

III. Feeds

Animal feeds are regulated by FDA and by State governments. An animal food is defined in Section 201(x) of the Act as "an article which is intended for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal".

Animal feeds should be differentiated from **medicated animal feeds which are drugs**. Medicated feeds should be properly labeled and stored to comply with the PMO Item 15r.

NOTE: A PRODUCT REGULATED BY FDA AS A DRUG MUST BE DIFFERENTIATED FROM A BIOLOGIC/VACCINE, A PESTICIDE, OR A NON-MEDICATED ANIMAL FEED.

Definitions of Drug Labeling Terms

Label: A display of written, printed, or graphic matter upon the immediate container of the article. [201(k) of the F.D.,&C Act] An example is the immediate container label.

Labeling: All labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article. [201(m) of the F.D.,&C Act]. The package insert, box or carton are examples of labeling.

Veterinary Prescription Drug (Rx Drug): A drug intended for veterinary use which because of toxicity, other potential for harmful effect, or the method of its use; the drug is not safe for animal use except under the supervision of a licensed veterinarian. Adequate directions for use by the lay person cannot be prepared, as such, the drug is restricted to use by or on the order of a licensed veterinarian. In other words, the drug is one for which adequate directions for lay use cannot be written and as such requires the supervision and knowledge of a veterinarian to ensure its safe and effective use. All veterinary prescription drugs are required to bear the statement:

"CAUTION: Federal (USA) Law restricts this drug to use by or on the order of a licensed veterinarian."

Over-The-Counter Drug (OTC): A drug which can be purchased and used by a layperson without the supervision of a veterinarian. The label of an OTC drug bears adequate directions for use by a layperson and is written to be understood by a layperson. (Ref. 21CFR 201.5).

NOTE: When used by a layperson in the absence of a veterinarian's order, an OTC drug must be used in accordance with its labeling.

DO NOT CONFUSE THE PRESCRIPTION LEGEND WITH ANY OF THE FOLLOWING OR SIMILAR STATEMENTS THAT MAY APPEAR ON OTC PRODUCTS:

"SALES TO GRADUATE VETERINARIANS ONLY"

"RESTRICTED DRUG - USE ONLY AS DIRECTED"

"FOR ANIMAL USE ONLY"

"FOR VETERINARY USE ONLY" ETC.

“CAUTION: FEDERAL LAW PROHIBITS THE USE OF THIS PRODUCT IN FOOD PRODUCING ANIMALS”

Extra Label Use:

Extra Label Use means actual use or intended use of a drug in animals in a manner not in accordance with its approved labeling.

Only a veterinarian may use a drug in an extra-label manner. Such extra-label use of drugs is provided for under the parameters described in FDA's Animal Medicinal use Clarification Act (AMDUCA) regulations in 21 CFR part 530. The AMDUCA allows veterinarians to prescribe FDA approved animal and human drugs for extra label purposes in their treatment of animals. Certain restrictions do apply such as no ELU in or on animal feed and certain drugs are prohibited from ELU in food animals. (See section on Prohibited Drugs).

Under AMDUCA, veterinarians must label all drugs used for extra label purposes to comply with the PMO drug labeling requirements.

Veterinarian-Client-Patient Relationship (VCPR), a major parameter for veterinary extra-label use:

An appropriate VCPR must exist before a veterinarian prescribes a drug for an extra-label use in food producing animals. A VCPR exists when:

1. the veterinarian has assumed the responsibility for making judgments regarding the health of the animal(s) and the need for medical treatment, and the client (owner or caretaker) has agreed to follow the instructions of the veterinarian; and when,

2. there is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animals are kept; .....and when,

3. the practicing veterinarian is readily available for follow-up in case of adverse reactions or failures of the regimen of therapy.

Extra-label use drugs must:

1. Bear the authorizing veterinarian's name and address.

2. Specify the active ingredient(s) of the drug.

3. Contain directions for use – to include dosage, route of administration and duration of therapy.

4. Specify meat and milk withholding times, even if zero.

5. Include necessary cautionary statements.

LABELING GUIDANCE

I. Drug Labeling Requirements for OTC, Rx and Extra Label Use.

A. Over-the-counter (OTC) drugs used as labeled must:

1. Bear a manufacturer's label with the active ingredient(s) and indications for use (which must include dosage, route of administration and duration of therapy) in LACTATING dairy cattle including meat and milk withholding times,

OR

2. Bear a manufacturer's label with the active ingredients and indications for use in NON-LACTATING cattle.

3. No other additional veterinary label is required when such OTC drugs are used according to label directions.

4. Instructions for use must include dosage, route of administration and duration of therapy.

B. Prescription (Rx) drugs used as labeled must:

1. Bear the prescribing veterinarian's name and address in addition to the manufacturer's label which must include the active ingredient(s) and indications for use (dosage, route of administration and duration of therapy) in LACTATING dairy cattle including meat and milk withholding times,

OR

2. Bear the prescribing veterinarian's name and address in addition to the manufacturer's label which must include the active ingredient(s) and indications for use in NON-LACTATING cattle,

REMEMBER - the prescription legend reads "Caution: Federal (USA) Law restricts this drug to use by or on the order of a licensed veterinarian."

NOTE: The requirement for displaying the active ingredient(s) on the label is fulfilled by listing the drug's common, generic, scientific, or chemical name. Listing of a trade name or brand name alone is not acceptable.

C. Labels for Small and Irregularly Shaped Containers

From the standpoint of administering the Pasteurized Milk Ordinance, the only exceptions to the PMO requirements for individual container labeling pertain to containers that are too small or are shaped in such a manner that they will not accommodate a label bearing all the required information. In these cases, the label issued by the dispensing veterinarian is required to be affixed to the next largest package size.

For example:

- **if a product that is too small to be labeled is packaged in a multi-vial carton; then a label affixed to the carton would be acceptable.** If the veterinarian does not want to prescribe a carton, then the vials should be put in a container (such as a Ziploc plastic bag) and the label affixed to the container.

- **Some products are packaged in single vial containers of sufficient size to accommodate a label but the immediate container is sealed within a hard plastic outer container**. Since the integrity of the seal is an indication of whether or not tampering has occurred, a label is permitted to be affixed to the outer container instead of requiring a label to be affixed to the immediate container itself.

- Many dairies use prescription intra-mammary infusion tubes for both lactating and non-lactating animals. **These tubes are packaged in multiple tube boxes and must bear a label with the prescribing veterinarians name and address.**

- **Labeling the outside of cases or cartons of drugs does not meet current labeling requirements. The smallest unit size that can practically be labeled is required to bear the PMO required information.**

D. Identification of the dispensing or prescribing veterinarian's name on the label:

A veterinarian's name and address is required on all prescription and extra-label use drugs. Many clinic labels will list more than one veterinarian's name. In such cases, the name of the individual who actually dispensed or prescribed the drug must be identified on the label. Identification is most often accomplished by underlining, circling, or checking the name of the veterinarian who dispensed or prescribed the drug.

Veterinarians may own or be full time employees on some dairy farms. All drugs in use or stored on the dairy operation of these farms must comply with the labeling and storage requirements of the PMO.

II. Drug Storage Requirements

The PMO addresses storage requirements which separate the lactating and non-lactating cattle drugs. A separate shelf in cabinets, refrigerators, or other storage facilities satisfies this item. Labeling the shelves (lactating/non-lactating) is recommended but not a PMO requirement.

1. **All drugs must be stored in such a manner that they cannot contaminate the milk or milk product contact surface of the equipment, containers or utensils**.

2. **Unapproved and/or improperly labeled drugs should not be used to treat dairy animals and are not to be stored in the milkhouse, milking barn, stable or parlor.**

3. **Drugs intended for the treatment of non-lactating animals are segregated from those drugs used for lactating animals.**

Storage areas designated for drugs for **LACTATING** animals include:

a. OTC drugs bearing the manufacturer's label indicating use in lactating cattle.

b. Rx drugs bearing the prescription label and the veterinarian's name and address indicating use in lactating cattle.

c. Drugs used in an extra-label manner bearing the authorizing veterinarian's label indicating an extra-label use in lactating cattle.

Storage areas designated for drugs for **NON-LACTATING** animals include:

a. OTC drugs bearing the manufacturer's label indicating use in non-lactating cattle.

b. Rx drugs bearing the prescription label and the veterinarian's name and address indicating use in non-lactating cattle.

c. Drugs used in an extra-label manner bearing the authorizing veterinarian's label indicating an extra-label use in non-lactating cattle.

A. Satisfactory Labeling of the Drug Product

The labeling of a shelf, wall or carton (intended for holding multiple labeled containers) is not discouraged, but will not satisfy the PMO requirements. If a shelf, wall or carton is labeled instead of the immediate container then adequate directions for use would not be in hand at the time the drug is administered. This is especially important when multiple people or crews treat cows on a farm. They need adequate directions for use, to avoid residues in the milk.

B. Posting of Drug Use Protocols

FDA encourages any mechanism a veterinarian or layperson may deem appropriate to educate the producer and his employees to strictly follow the labeled directions and veterinarian's instructions. The posting of a treatment protocol may have a positive effect in achieving adherence to label directions. However, the use of this or a similar mechanism would not obviate the need for individual container labeling. Not only is it required by the PMO and the F, D,&C Act, but, in addition, appropriate labeling ensures that adequate directions for use are present and in hand at the time of use.

C. Use of Package Inserts

Federal law allows drug sponsors to include the necessary use information on drug package inserts. Often the immediate container label of a drug (especially small vials) will state “see package insert”. If the PMO required drug labeling information (Item 15r) is included on the insert and not on the vial label the insert must be readily available at inspection time.

D. Veterinarian Prescriptions

Many veterinarians prefer to write prescriptions for drug distributors to fill and deliver prescription or extra-label use drugs to dairy farms. The PMO does not mandate who should dispense the drug or who should affix the necessary label information. In many States, there are regulations as to who may dispense veterinary drugs and who may label drug products. These regulations vary. The appropriate State agency should be consulted. For PMO purposes the drugs must be properly labeled at inspection time. The PMO does not specify who is allowed to label a product.

THE PRODUCER is responsible for assuring that the veterinarian has provided the specific label information required by the PMO. These minimum label requirements provide inspectional evidence that adequate directions for use of the product are available to the dairy farmer and, in the case of veterinary prescription drugs or extra-label use drugs, that a veterinarian has prescribed the product. If these requirements are not met, the producer may not have adequate directions for safe and effective use of the drugs.

Types of Drugs Exempt from the Labeling and Storage Requirements of the PASTEURIZED MILK ORDINANCE

These exemptions were adopted by the NCIMS in 1989 and 1991 as drugs that do not pose a human food safety concern.

Topical antiseptics, wound dressings, (unless intended for direct injection into the teat), vaccines and other biologic and dosage form vitamin and/or mineral products are exempt from the labeling and storage requirements of the PMO, **except** when it is determined that they are stored in such a manner that they may contaminate the milk or milk product surfaces of containers or utensils.

- **These products are not exempted from the labeling requirements of the FD&C Act**. The products may be sold as OTC or prescription drugs.

NOTE: During the course of routine inspections, we encourage state/local regulatory agencies to enforce the labeling and storage requirements for all drugs.

A. Hormones

Prostaglandins, oxytocin, and certain other pituitary hormones are exempt from the labeling requirements on State and Federal check ratings. (this is different from Ovarian and Adrenal Hormones)

1. Prostaglandins
    - Cloprostenol (Estrumate)
    - Dinoprost (Lutalyse)

2. Pituitary Hormones
    - Oxytocin
    - Luteinizing Hormones (PLH, LH)
    - Chorionic Gonadotropin (C.G., HCG)
    - Corticotropin (ACTH)
    - Follicle Stimulating Hormones (FSH)

B. Dosage Form Vitamin And/Or Mineral Products Exempt From The Labeling And Storage Requirements:

Some products in this category may be labeled and marketed as prescription or OTC, and may have species other than cattle on the label. They are exempt from the labeling and storage requirements. They must be stored in such a manner that they will not contaminate the milk or milk product surfaces of containers or utensils. The following is a list of products that are commonly used and stored on farms:

- Calcium products; injectable or oral use
- Calcium and dextrose products
- Calcium in combination with other minerals such as magnesium, potassium, and/or phosphorus
- Dextrose alone or in combination with other minerals
- Lactated Ringers
- Sodium Chloride
- Sterile Water
- Potassium Chloride alone or in combination with other minerals or dextrose
- Electrolytes for oral or injectable use
- Vitamin A and D
- Vitamin E and Selenium combinations
- Vitamin E alone
- Selenium compounds for oral use
- Vitamin B Complex
- Vitamin B1 (Thiamine)
- Vitamin B12 (Cyanocobalamin)
- Vitamin B6 (Pyridoxine)
- Vitamin B2 (Riboflavin)
- Vitamin C, and Vitamin K
- Choline
- Pantothenic Acid
- Folacin (Folic Acid, Pteroylglutamic Acid)
- Copper containing compounds for injection or oral use
- Iron containing compounds for injection or oral use
- Propylene Glycol
- Bicarbonate; injectable and oral formulations

C. Topical Antiseptics and Wound Dressings

Topical antiseptics and wound dressings (unless intended for direct injection into the teat) are exempt from the labeling requirements. Topically applied drugs that are not antiseptics or wound dressings must comply with all labeling, use, and storage requirements.

This category includes creams, ointments, sprays, wound dressings, some foot products, teat dips, tincture of iodine and others. The following is a list of commonly used topical antiseptics and wound dressings that are exempt from the labeling requirements. They should only be used topically and **must be stored so as not to contaminate the milk or product contact surfaces**.

- Iodine
- Alcohol
- Hydrogen peroxide
- Teat dips/Udder washes
- Chlorine bleach
- Formalin (for cattle foot baths)*see note below
- Blue Coat
- Kopertox
- Granulex Spray
- Trypzyme Aerosol
- Chlorhexidine** solutions, ointments, salves, and creams for topical use only

D. FOOTBATHS:

Medicated foot baths and sprays used to treat and control cattle foot rot and heal warts. Veterinarians prescribe and dairy producers routinely use medicated foot baths or sprays to control hoof disorders in dairy cattle. These baths and sprays often contain antibiotics such as oxytetracycline. To comply with the PMO these types of baths and sprays must be operated in a manner that will not contaminate the milk or surface of the milk product contact equipment. The use of antibiotics for foot baths/sprays constitutes extra label use. Veterinarians should comply with the labeling requirements for extra label use of drugs under PMO item 15r.

To prevent milk contamination, foot baths generally should be located on the exit side of the milking area (walk-through after milking). Spraying medication onto the cattle's hooves should not occur in the milking area during milking time.

NOTE: The Nolvasan (chlorhexidine) Cap-Tabs (boluses) and the Nolvasan Suspension (infusion tubes) for intrauterine treatments are no longer labeled for use in cattle. They are approved for use in horses only. They may be extra labeled by veterinarians.

E. Combination penicillin/streptomycin dihydrostreptomycin for injection or feed use:

Procaine penicillin combined with streptomycin and\or dihydrostreptomycin were removed from approval by FDA on November 19, 1992. Distribution ceased on June 1, 1993. If found on dairy farms during regulatory inspections or IMS ratings **after the expiration date has passed,** they are in violation of Item 15r of the *Ordinance* (see M-I-92-14, Dec 7, 1992). Intra-mammary infusion products containing the two drug combination are currently still approved legal products.

F. DMSO:

DMSO (dimethylsulfoxide) is a by-product of the paper industry and is able to carry some drugs rapidly through the skin and other tissues. There are no FDA approved uses for DMSO in food-producing animals. Approvals do exist for uses in horses and dogs.

Industrial grade DMSO is widely available for various non-medical uses such as paint remover and other solvent uses. DMSO is often found stored on dairy farms or mixed with other drugs intended for use in dairy animals. Such uses may lead to an increased chance of drug residues, off odor, and off flavor milk.

FDA considers the use of DMSO for any veterinary purposes other than approved uses in dogs and horses to be illegal.

DMSO is an unapproved new animal drug which is unsafe with the meaning of the Act. Such use causes the product to be adulterated under section 501(a)(5) of the Federal Food, Drug and Cosmetic Act.

The use of DMSO on dairy animals or the storage of DMSO in dairy farm drug cabinets violates item 15r of the PMO.

G. DIPYRONE

Dipyrone may adversely change the bone marrow if ingested by humans.

Dipyrone is not approved for any use in food producing animals. Dairy farmers, veterinarians and consultants should be aware that the use of dipyrone in food producing animals is illegal drug use. If Dipyrone is observed on a dairy farm during a rating or check rating after March 1, 1997, it is in violation of Item 15r(i) of the PMO.

Systemically Acting Drugs that are Applied Topically and Not Exempt From the Labeling and Storage Requirements

The following is a list of FDA approved drugs that are applied as tropical's for their systemic effect against internal parasites, cattle grubs, or external insects such as lice. **They are not topical antiseptics or wound dressings and they are not labeled for use in lactating dairy cattle; therefore, they are not exempt under Item 15r.**

DRUG	TRADE NAME EXAMPLES
Fenthion	**Spotton Cattle Insecticide** **Tiguvon Pour On**
Famphur and Xylene	**Purina Grub Kill** **Warbex Famphur Pour On**
Phosmet	**Star Bar GX-118** **Prolate 1-E**
Ivermectins and Avermectins	**Ivomec Pour On** **Doramectin Pour On**
Levamisole	**Tramisol Pour On** **Totalon**

Because of their potential to cause residues in milk, the use of these drugs on lactating dairy cattle or their storage with the lactating cattle drugs is a violation of Item 15r.

Pesticides/Rodenticides; Insecticide Sprays, Dusts, Powders and Pour-On

Pesticides/rodenticides/insecticides are usually regulated by the Environmental Protection Agency (EPA). Ordinarily, an EPA regulated product can be identified by an EPA registration number on the label. Only products labeled for use on or around dairy cattle or milking equipment should be used and only according to their labels. The inspector should check to make sure that dust bags and sprayers contain EPA approved products and that the directions for use are being followed.

Pesticides should be mixed correctly and applied no more frequently then specified on the label. EPA regulated pesticides and rodenticides are exempt from the labeling requirements of 15r but the improper labeling, use, or storage of pesticides or rodenticides violates section 19r of the PMO.

Ovarian Hormones and Adrenal Hormones

Ovarian (estrogens and progesterone) and Adrenalin (epinephrine) hormones are not exempted from the PMO drug labeling and storage requirements. Products may contain estrogen compounds such as ECP (estradiol cypionate). Such products may bear an Rx legend. None have ever been approved by FDA for use in animals. **ECP is no longer marketed in the U. S. It should not be used or stored on dairy operations.**

Progesterone is sometimes used for reproductive diseases in cattle. Such products are Rx and must comply with Item 15r of the PMO.

Epinephrine is a hormone from the adrenal glands, which is often used to treat shock in animals. Usually full strength epinephrine is labeled as an Rx drug. There are less concentrated OTC formulations. Such products should be properly labeled or extra-labeled by a veterinarian.

Medicated and Non-Medicated Cattle Feed and Blocks

Some cattle feeds and blocks contain drugs. They are called medicated feeds or blocks and as such must be labeled and stored properly. One common cause of violative drug residues is mistakenly feeding a medicated feed or block intended for use in calves or replacement heifers to the lactating herd.

All medicated feeds or blocks should be segregated from non-medicated feeds or blocks. Medicated feeds or blocks intended for non-lactating cattle must be stored inaccessible to lactating dairy cattle.

FDA's Extra Label Use regulations (AMDUCA) prohibits veterinarians from combining or mixing drugs in, or on animal feed.

Products labeled as food (feed) unless it is a medicated feed or block are exempt from the labeling and storage requirements. Products in this category include but are not limited to:

1. Non-medicated feeds

2. Non-medicated cattle blocks containing molasses, salt, trace minerals, and vitamins

3. Products containing yeast or lactobacillus organisms

Prohibited Drugs

Because of human food safety concerns, some drugs may not be used to treat food-producing animals, even in an extra-label manner. These include:

- Chloramphenicol
- Clenbuterol
- Diethylstibesterol (DES)
- Dimetridazole
- Ipronidazole
- Other Nitroimidazoles (metronidazole)
- Nitrofuran drugs, Furazolidone, and Nitrofurazone
- **FDA considers all sulfonamides, except the three sulfonamides approved for use in lactating dairy cattle, to be excluded from any use in female dairy cattle 20 months of age or older.**

  The three approved sulfonamides are;

  1. **sulfadimethoxine*,**
  2. **sulfabromomethazine, and**
  3. **sulfaethoxypyridazine**

  ***** The sulfadimethoxidine, Albon SR (sustained release) bolus is not approved for lactating cows and is prohibited from such use.

- Fluorquinolones
- Glycopeptides
- Phenylbutazone in female dairy cattle 20 months of age or older

A. NITROFURAN DRUGS: FURAZOLIDONE AND NIROFURAZONE

The withdrawal by FDA of 10 approvals for nitrofuran (furazolidone and nitrofurazone) on August 23, 1991, affected products that were approved for a variety of uses in swine and poultry.

Since that time, FDA has taken measures to prohibit the use of all nitrofuran drugs in food producing animals.

Nitrofuran drugs are listed with those of highest priority for regulatory attention regarding extra-label use in food-producing animals. The use of furazolidone, nitrofurazone or other nitrofuran in food-producing animals in any form is no longer allowed.

In addition, Nitrofuran drugs approved as topical nitrofuran drugs are not to be used or stored on dairy farms. These include salves, ointments, liquid, and spray or puffer dry powder topicals. (pink eye and wound treatments)

In the past there were two topical nitrofuran products labeled for use in cattle. In 1998 FDA revised the labeling for all topical nitrofurazone and furazolidone products to remove all claims for use in cattle and other food animals. **There are no longer any nitrofuran drugs approved for use in cattle.** Nirtofuran drugs in any form should not be used to treat dairy cattle or be stored with the dairy cattle drugs.

❖ Nitrofuran Solutions, Ointments, Sprays, and Creams:

There are powders, ointments, aerosols (sprays), and creams that contain furazolidone or nitrofurazone labeled for topical use in horses, dogs, and cats. These products were not withdrawn by FDA and may be legally marketed for their intended uses in non-food animals.

The use or storage on dairy farms of any withdrawn nitrofuran drug or the use of solutions, ointments, sprays and creams labeled as topicals for non-dairy animals violates item 15r of the PMO.

B. SULFANOMIDES:

Because, of the potential for sulfonamides to cause milk residues. The FDA stated position to the veterinary profession and dairy industry, is, **it is not acceptable to use any sulfonamide, except the three sulfonamides approved for use in lactating dairy cattle, to treat female dairy cattle 20 months of age or older.**

❖ Sulfamethazine:

There are approved products that contain sulfamethazine (SMZ) for use in young cattle. The approved products contain only SMZ and carry this or similar statement,

"WARNING: Do not use in female dairy cattle 20 months of age or **older.** Do not use in calves under one month of age or calves fed an all milk diet."

These approved products may be used on animals **less** than 20 months of age and stored with the non-lactating drugs.

❖ Other Sulfonamides, 510.450 Sulfonamides, and Combination Products

FDA has taken steps with respect to sulfonamide products marketed under 21CFR 510.450. This regulation provided for the marketing of sulfonamide products on an interim basis, pending the resolution of safety concerns. Based on scientific information, showing that the degree of thyroid response to sulfonamide exposure should be given greater significance in the evaluation of toxicity, FDA declared all sulfonamide drugs to be new animal drugs requiring approval. Sponsors of sulfonamide drugs were required to submit new animal drug applications containing toxicity studies.

The final rule revoking 21CFR 510.450 was published in the Federal Register August 9, 1990. All unapproved sulfonamide drugs are **subject to regulatory action.**

Rarely, supplies of these products may be encountered in drug distribution facilities and on dairy farms. Some products' labels bear indications for

use in lactating dairy cattle and some have milk withholding time warning statements. The producer should be informed about the status of these products and notified that they may cause a residue in milk. They should not be used or stored on dairy farms.

If a drug bears a **manufacturer's label** that includes indications for use in cattle or calves, and the product contains the following, it is an unapproved, illegal sulfonamide or a withdrawn 510.450 sulfonamide drug.

- **sulfathiazole,**
- **sulfapyridine,**
- **sulfamerazine,**
- **sulfa urea,**
- **sulfanilamide,**
- **sulfamethoxazole,**

- **sulfadiazine as a single ingredient or in combination with sulfamethazine or other sulfonamides or other drugs such as neomycin;**

OR

- **if a product contains SMZ as a single ingredient without the statements "Do not use in female dairy cattle 20 months of age or older. Do not use in calves under one month of age or calves fed an all milk diet,"**

OR

- **if a product contains SMZ in combination with other sulfonamides or drugs such as neomycin, with or without the "20 month" warning statement the product is an unapproved, illegal sulfonamide or a withdrawn 510.450 sulfonamide.**

NOTE: Veterinarians often extra label FDA approved human prescription sulfonamide drugs for oral use in calves. This is allowable under the AMDUCA.

❖ Sulfadimethoxine

There are FDA approved products containing sulfadimethoxine under various trade names like Albon, Albon SR, Agribon, and Agribon SR. They will be seen as injectables, solutions, or boluses labeled either OTC or RX for cattle and/or lactating dairy cattle. The sustained release boluses (SR) are not approved for use in lactating dairy cattle and may not be extra-labeled by a veterinarian for such use.

❖ Sulfabromomethazine and Sulfaethoxypyridazine

Sulfabromomethazine and sulfaethoxypyridazine are approved for use in lactating dairy cattle but not currently marketed. An inspector may encounter old stocks of previously marketed products that contain these sulfonamides; trade names like Sulfabrom boluses and S.E.Z. (sulfaethoxypyridazine) intravenous solution.

❖ Sulfachlorpyridazine and Sulfaquinoxaline

There are approved products for calves and female dairy cattle less than 20 months of age, mature bulls, and calves that contain sulfachlorpyridazine or sulfaquinoxaline. **They should not be used in lactating dairy cattle.** They should be stored with the non-lactating cattle drugs.

C. Homeopathic drugs, Colloidal Silver, Aloe Vera and other drugs

The PMO states that unapproved and/or improperly labeled medicinals/drugs are not used to treat dairy animals and are not stored in the milkhouse, milking barn, stable or parlor. The PMO further requires that all drugs be properly labeled and that drugs intended for the treatment of lactating dairy animals are segregated from those drugs to be used on non-lactating animals.

Examples of such drugs include; aloe vera, homeopathic drugs, drugs that are packaged for infusion (intra-mammary) or injection but labeled for oral (feed), topical, or other routes of administration.

❖ Homeopathic Drugs:

Homeopathy is an alternative therapeutic modality developed in the late 1700's by a German physician for use in humans. It is considered an unconventional form of veterinary practice. **FDA can find no justification for regulating veterinary homeopathic drugs any differently from other drugs subject to the FD&C Act. There are currently NO FDA APPROVED HOMEOPATHIC DRUGS for veterinary use.** If homeopathic drugs are found on dairy operations, they must comply with all labeling and storage requirements otherwise they may be considered to be unapproved drugs. Homeopathic drugs are subject to the same storage requirements as any other drug.

❖ Colloidal Silver:

Products containing colloidal silver are not to be used or stored on dairy farms. The use of colloidal silver containing products constitutes a potentially serious public health concern because of the possibility of residues in milk or meat. The consumption of silver by humans may result in argyria, a permanent ashen-grey or blue discoloration of the skin, conjunctiva and internal organs.

Colloidal silver containing products have never been approved by the FDA for treatment of animal disease in any species, and are considered a violation of Item 15r.

❖ **Aloe Vera:**

FDA has received complaints that aloe vera is being promoted for use as a treatment for mastitis and calf diarrhea, a cure for high somatic cell counts, and as an aid for increasing milk production. FDA is aware that firms are selling containers of aloe vera with no drug claims on the label to dairy producers and then providing the drug use claims either orally or by other printed materials or graphics (labeling).

No aloe vera product has been approved for the treatment of these serious diseases conditions or to increase milk production. Aloe vera products for animals bearing these types of claims are unapproved new animal drugs. Aloe vera products intended for animal use that do not bear adequate directions for animal use are "misbranded". The use of unapproved drugs violates Item 15r of the PMO.

D. Drugs Packaged for Injection or Udder Infusion but Labeled for Oral or Topical Use:

FDA has received several complaints about products packaged and labeled for oral, topical, or other routes of administration that are packaged in a manner customarily considered to be for parenteral (injection or udder infusion) administration. **Among these are aloe vera products labeled for topical use packaged in surjets/squeeze jets (squeeze tubes routinely used for intra-mammary infusion); probiotic and whey blend products labeled for oral use packaged in syringes with sterile diluents in vials with udder infusion cannulas and alcohol pads or packaged in sterile vials closed with a metal ring and rubber injection stopper.**

FDA's Compliance Policy Guide (CPG) 7125.39, entitled "Drugs packaged for Infusion or Injection for Food-Producing Animals" is available for guidance on this issue.

FDA is very concerned about the safety of products not approved for parenteral use which are infused or injected into food producing animals. FDA believes that the packaging and labeling of these products is a subterfuge to avoid the more stringent regulatory requirements for parenteral drugs. Products that are intended for oral or topical administration should not be packaged to facilitate parenteral (injection, udder infusion) administration. Such drugs will be considered to be misbranded if they do not contain directions for their packaged use.

PRACTICE QUESTIONS

1. The drug is labeled "For Veterinary Use Only". Does the product require the veterinarian's name and address?

2. You visit the farm and find chloramphenicol labeled for dogs prescribed by a veterinarian for use in dairy cattle. The label on this product bears the name and address of the veterinarian, the directions for use; cautionary statements and withholding time. Is this a violation of the PMO?

3. If a large dairy farm employs a full-time veterinarian do the drugs found on the farm have to be labeled and stored in accordance with the PMO?

4. You encounter a product labeled Clostridium vaccine for use in calves. The product is stored on the lactating cow drug shelf. Is this a violation of the PMO?

5. You encounter a topical product bearing the prescription legend in the dairy farm drug cabinet. The product label does not bear the name and address of the prescribing veterinarian. Is this a violation of the PMO?

6. You find a drug stored in a cabinet that is a veterinary prescription drug and bears a label with the name and address of a veterinary clinic. Does this satisfy the labeling requirements of the PMO?

7. You encounter an OTC drug with a label indicating use in pigs stored in the dairy farm drug cabinet. The farmer owns some pigs which are kept adjacent to the dairy facility. Can the farmer store his pig medications in this drug cabinet?

8. You are inspecting a dairy farm and you find a notebook listing the dosages and milk withholding times for all the drugs found in the storage cabinet. Each page in the notebook is signed and dated by a veterinarian and the clinic address is provided. The bottles of prescription drugs in the storage cabinet bear only the manufacturer's label. Does this satisfy the requirements of the PMO?

9. You encounter a drug which appears to have been compounded by a veterinarian. The product label bears the name and address of the prescribing veterinarian; directions for use; and a warning against use in pregnant cattle. The label directs the user to test the milk from the treated cow prior to use. Does the label need any additional information? Is this a violation of the PMO?

10. You are inspecting a drug storage cabinet and come across a case of the prescription drug oxytocin. A label is affixed to the case box with the name and address of the veterinarian. Is this a violation of the PMO?

11. You visit a farm and find several drugs stored in the lactating drug area labeled for extra-label use from the veterinarian without a milk withholding time. Do you debit the farmer?

12. You find three products containing a sulfonamide stored with the lactating drugs. One contains sulfadimethoxine, a second product contains sulfabromomethazine, and the third contains sulfaethoxypyridazine. What do you do?

Parts of a Label

The basic purpose of labeling is to enable drugs to be used safely and effectively by the layman in the case of OTC products, or by veterinarians in the case of prescription articles. It is the policy of the Center of Veterinary Medicine (CVM) to apply labeling requirements to manufacturers and distributors of drugs as uniformly as possible. The user of the drug should be provided with directions for use. Some of the information that should be on a label is listed below.

- **Which species:**
  - Cattle
  - Swine
  - Horses
  - Dogs
  - Cats
  - Etc.
- **Which class of livestock:**
  - Lactating Dairy Cattle
  - Non-lactating Dairy Cattle
  - Beef Cattle
  - Heifers
  - Calves
- **Which disease conditions:**
  - Mastitis
  - Udder Edema
  - Ketosis
  - Diarrhea
  - Pneumonia
  - Etc
- **Directions for Use**

- Dosage
    - amount
    - frequency
    - duration

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- **Route Of Administration**

    - Intramuscular
    - Subcutaneous
    - Intravenous
    - Oral
    - Intrauterine
    - Intramammary
    - Topical
    - Other

- **Precautions/Warnings/Adverse Reactions/ Contraindications**

    - Veterinary Prescription Legend
    - Milk Withholding Times
    - Slaughter Withdrawal Times
    - Preclusions against use in certain classes of cattle

- **Active Ingredients**

    - Storage Requirements
    - Temperature Range
    - Net Quantity of Contents

- **Expiration Date**

- **Name and Address of Manufacturer or Distributor**

Classes of Drugs

This section is intended to provide background information on many of the types of drugs that may be encountered on dairy farms. Included are common classes of drug compounds and a brief description and some common examples of those compounds. Some of the drugs listed are not approved for use in dairy cattle.

NOTE: LISTING OF DRUGS OR PRODUCT TRADE NAMES DOES NOT IMPLY AN ENDORSEMENT OF THEIR USE IN DAIRY CATTLE.

I. ANTIMICROBIAL DRUGS

Antibiotics and antibacterial products are drugs primarily intended for the treatment of infections caused by bacterial organisms and other microbes. These products are not effective for treating viral or fungal infections. They are however sometimes used to treat those secondary bacterial infections occurring simultaneously with viral and fungal infections.

Some of the more common bacterial infections in dairy cattle include mastitis (mammary infection), metritis (uterine infection), pneumonia (respiratory infection), some diarrheal infections, foot rot, and infrequently encephalitis. These products are used to treat abscesses, wounds and to treat or prevent infections after surgery.

Antimicrobials are divided into classes. The following list provides these classes and examples of active ingredients in each class.

A. Sulfonamides

- Sulfathiazole
- Sulfamethazine
- Sulfamerazine
- Sulfadiazine
- Sulfabromomethazine
- Sulfaethoxypyridazine
- Sulfadimethoxine
- Sulfachloropyridazine
- Sulfanilamide

The sulfonamides, particularly sulfamethazine (SMZ), have received a great deal of attention in recent years. Sulfamethazine has been used in veterinary medicine in several animal species for more than 25 years. The sulfonamides have been widely used in human medicine for more than 40 years.

Studies conducted at the National Center for Toxicological Research (NCTR) have shown that SMZ at high doses causes thyroid tumors in rats and mice. Data showing tumor formation in laboratory animals always causes CVM to apply the 1 in 1,000,000 risk assessment techniques rather than the 100-fold or 1000-fold safety factor normally used (i.e. an ultra-conservative approach to food safety).

The Center for Veterinary Medicine is moving carefully and deliberately toward a position on SMZ. There are a number of scientific issues yet to be considered. If the drug must be removed from use in certain animal species, a notice of opportunity for hearing will be published providing interested persons an opportunity to present their views and justify a hearing.

B. Beta Lactams

Beta lactams are the most commonly used drugs for treating mastitis. Penicillin continues to be among the most important antibiotics available because of their remarkable antibacterial activity, relative safety and low cost. Their spectra are primarily gram-positive bacteria. The penicillin's share many characteristics with the cephalosporins group and these two classes are often referred to as beta-lactam drugs.

- Penicillin G (Procaine, Potassium, and Benzathine)
- Cloxacillin
- Ampicillin
- Hetacillin
- Amoxicillin
- Ticarcillin

C. Cephalosporin

Cephalosporin antibiotics are the most frequently prescribed class of antibiotics. They are related to the penicillin's and are a member of the beta lactam antibiotics. The name is derived from the fact they were first isolated from cultures of Cephalosporium acremonium from a sewer in Sardina. They are used to treat respiratory tract infections, skin infections, urinary tract infections and as a surgical prophylaxis before, during and after surgery they are classified by "generations" 1-4 with the earlier numbered classes predominantly effective on gram positive bacteria and the later classes or

generations having increased activity on gram negative bacteria often with reduced effect on gram + bacteria. Example of its generation is cephapirin, 2nd generation is cefaclor, 3rd generation is cefitraxone, and 4th generation example is cefpirome.

- Cephapirin
- Ceftiofur sodium
- Ceftiofur hydrochloride

D. Tetracycline

The tetracyclines are typically very broad spectrum drugs. Their spectra comprise gram-positive and gram-negative bacteria, including some anaerobes, Rickettsia, Chlamydia, Mycoplasma, Actinomyces, Spirochetes, Anaplasma and even some protozoa.

- Tetracycline
- Oxytetracycline
- Chlortetracycline

E. Chloramphenicol

Chloramphenicol is not approved for use in food-producing animals. The use of chloramphenicol in food-producing animals is a serious violation of the F,D,&C Act. Chloramphenicol has been demonstrated to cause fatal a plastic anemia in humans.

F. Florfenicol

Florfenicol was approved in 1996 for use in cattle. It is an effective, broad spectrum antibiotic active against many gram negative and gram positive bacteria. Florfenicol is chemically different from chloramphenicol and does not have the associated human food safety concerns.

G. Aminoglycosides

The aminoglycoside/aminocycitol antibiotics are compounds with a broad spectrum of activity against many bacterial species although chemical use in most cases is limited to gram-negative bacterial infections.

- Neomycin
- Streptomycin/Dihydrostreptomycin
- Gentamicin
- Kanamycin
- Amikacin

H. Spectinomycin

Spectinomycin is an aminocyclitol antibiotic, but its structure differs from that of the aminoglycosides.

I. Macrolides

The macrolides are a large group of structurally related antibiotics but only a few have been found to be clinically useful. The macrolides' spectrum of activity is essentially against gram-positive organisms. Some strains of gram-negative bacteria as a well as Mycoplasma, Chlamydia, Rickettsia, and Actinomycetes may be susceptible.

- Erythromycin
- Tylosin
- Tilmicosin phosphate
- Pirlimycin

J. Lincosamides

Lincomycin has been employed in swine and cattle for systemic infections. This antibiotic is primarily bacteriostatic and possesses an antimicrobial spectrum that includes only gram-positive organisms, several anaerobes and some Mycoplasma species.

- Lincomycin
- Clindamycin

K. Polymyxins

Polymyxins have been used for the treatment of enteritis in young calves and pigs and of bovine mastitis as well as preputial irrigation of bulls. This class of polypeptide antibiotic is somewhat toxic and is rarely employed systemically injected.

L. Novobiocin

Novobiocin is a narrow-spectrum antibiotic with a bacteriostatic action against gram-negative organisms. Its principal use in food animal medicine is for the intramammary treatment of bovine mastitis.

M. Bacitracin

Bacitracin is a narrow-spectrum antibiotic against a range of bacteria similar to those affected by penicillin G.

N. Rifamycins

Rifamycins are extended-spectrum antibiotics. Two types of which (rifampin and rifanide) have enjoyed some clinical use in veterinary medicine.

O. Fluoroquinolines

Fluoroquinolines are derivatives of the class of quinolone acids. They have broad spectrum anti-bacterial activity. FDA issued an order on May 22, 1997 in the Federal Register prohibiting the extra-label use of these drugs and glycopeptides in food producing animals. Glycopeptides have only been approved for use in humans. On July 24, 1998, the FDA approved a new animal drug application for the use of enrofloxacin, which is a flouroquinolone, in cattle for the treatment of bovine respiratory disease associated with the Pasteurella haemolytica, Pasteurella multocida and Haemophilus sommus.

This product has a trade name of **Baytril® 100 Injectable Solution for the treatment of Bovine Respiratory Disease (BRD)**, is an Rx drug, and is administered by injection. This product is "**Not for use in dairy cattle greater than 20 months of age. Use of enrofloxacin in this class of cattle may cause milk residues."** Baytril® 100 is still prohibited for use in lactating dairy cows and should be segregated on the dairy farm from those drugs used for lactating animals. **Extra-label use of flouroquinolones in food animals has**

been prohibited by the FDA.

- Enrofloxacin
- Sarafloxacin
- Ciprofloxacin
- Orbafloxin

P. Nitrofurans

The nitrofuran derivatives are a group of relatively small antimicrobial drugs with activity principally against gram-negative bacteria, including Salmonella, though they are also often effective against some gram-positive organisms, fungi, and protozoa (coccidia). Nitrofuran drugs are illegal for use in food producing animals. Nitrofuran drugs are known carcinogens.

- Furazolidone
- Nitrofurazone

Q. Miscellaneous Antimicrobials

- Chlorhexidine
- Sodium Iodide

II. ANTHELMINTICS

Anthelmintics are a class of drugs intended for the treatment of internal parasites, including, nematodes (round worms), cestode (tapeworms) and trematodes (flukes).

- Benzimididazoles
- Thiabendazole
- Fenbendazole
- Albendazole
- Oxfendazole

A. Imidazothiazoles

- Levamisole

B. Avermectins

- Ivermectin
- Eprinomectin
- Moxidectin
- Duramectin

C. Tetrahydropyrimidine

- Pyrantel
- Morantel

D. Organophosphorus Compounds

- Coumaphos
- Dichlorvos
- Haloxon

E. Phenothiazine

F. Piperazine

G. Clorsulon

H. Anticoccidial Drugs

- Amprolium
- Decoquinate

I. Grubicides

- Famphur
- Fenthion

III. Hormones

The definition of a hormone is a chemical substance produced in the body by an organ or cells of an organ which has a specific regulatory effect on the activity of a certain organ. The term was originally applied to substances secreted by various endocrine glands and transported in the blood stream to the target organ on which their effect was produced. The term was later applied to various substances not produced by special glands but having similar action.

A. Recombinantly derived products:

- Sometribone zinc-recombinant DNA derived bovine somatotropin (rBST)

B. Pituitary Hormones

- Follicle Stimulating Hormones (FSH)
- Luteinizing Hormones (LH)
- Gonadorelin (GnRH)
- Chorionic Gonadotropin (CG, HCG)
- Oxytocin
- Corticotropin (ACTH)

C. Adrenocorticosteroids

This class of drugs has many complex effects in the animal. More of the reactions associated with inflammation are suppressed by the corticosteroids than by any other class of anti-inflammatory drugs. Because of their effects on glucose metabolism, these drugs are also used in the treatment of ketosis.

- Dexamethasone
- Isoflupredone
- Prednisone
- Prednisolone
- Flumethasone
- Triamcinolone

D. Prostaglandins

- Cloprostenol
- Dinoprost
- Fenprostalene

E. Estrogens

- Estradiol

F. Testosterone

IV. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

These drugs inhibit the conversion of arachidonic acid to prostaglandins and thromboxanes. This inhibition results in decreased formation of some, but by no means all mediators of inflammation. These drugs also have some analgesic, antipyretic effects.

- Aspirin
- Phenylbutazone
- Flunixin
- Dipyrone
- Meclofenamic Acid
- Naproxen
- Ketoprofen
- Carprofen

A. Antihistamines

Antihistamines are administered to counter some of the signs associated with allergic and anaphylactic reactions. Empirically, the antihistaminic agents seem to be of value in the treatment of various forms of dermatitis , laminitis, asthma, bloat, mastitis, and metritis. However, there are no well-controlled clinical studies to support these proposed indications

- Pyrilamine
- Tripelenamine
- Diphenhydramine

B. Diuretics

Diuretics, except water and osmotic diuretics, exert their action by interfering with the normal kidney transport mechanisms which principally move sodium back into the system from the provisional urine. The sodium draws additional water into the urine and a diuresis results. Many edematous conditions such as udder edema, are associated with a positive-sodium balance. Thus use of diuretics that interfere with sodium transport mechanisms are the most effective in the treatment of this class of edema.

- Chlorothiazide
- Furosemide and Hydrochlorothiazide

V. Anesthetics

Are a class of drugs / substances that reduces sensitivity to pain and may cause unconsciousness, specifically these are pain killers used in animal medicine. Pain management drugs are made up of the true anesthetics (lidocaine, xylazine etc), the sedatives (acepromazine, atomidine) etc, and the non steroidal anti-inflammatory drugs (NSAIDs) such as aspirin, flunixin meglumine and carprofin.

A. Tranquilizers

- Acepromazine
- Promazine
- Propiopromazine
- Diazepam

B. Sedatives

- Torbutol
- Xylazine

C. General Anesthetics

- Chloral Hydrate
- Pentobarbitol
- Thiopental
- Thiamylal
- Ketamine

D. Local Anesthetics

- Lidocaine

VI. Autonomic Nervous System Drugs (ANS)

These drugs are designed to influence the functions of the autonomic nervous system or involuntary nervous system. The autonomic nervous system functions to sustain homeostatic mechanisms within an organism just as importantly assists in internal bodily reactions to stressful conditions. The autonomic nervous system regulates such functions as respiration, heart rate, blood pressure, gastrointestinal motility and secretion, urinary output as well as many other body functions.

- Epinephrine
- Atropine
- Neostigmine

VII. Digestive System Drugs

Digestive system drugs and/or substances are used to treat digestive disorders, just as the name implies. They are made up of stomachic (which are drugs or substances which are beneficial to digestion in the rumen of a cow), ruminators which basically do the same thing, carminatives which control flatulence, antizymotics which arrest fermentation, antacids such as sodium bicarbonate and magnesium hydrochloride which counteract stomach acid, laxatives which induce movement in the intestine and loosens the stool, and purgatives which cause cleansing of the digestive tract and colon. The chart below shows some very common digestive system drugs.

STOMACHICS AND RUMINATORICS	CARMINATIVES AND ANTIZYMOTICS	ANTACIDS	LAXATIVES AND PURGATIVES
Neostigmine	**Poloxalene** **Polyoxyethylene**	**Sodium Bicarbonate** **Magnesium Oxide** **Magnesium Hydroxide**	**Neostigmine** **Carbachol** **Arecoline** **Mineral Oil** **Dioctyl Sodium Sulfosuccinate**

NEW ANIMAL DRUG LISTS are available from:

CODE OF FEDERAL REGULATIONS

Parts 500 to 599 Subchapter E
Animal Drugs, Feeds, and Related Products
U.S. Government Printing Office
Washington, D.C. 20402

REVIEW QUESTIONS

To illustrate the investigative process, following are several scenarios which are similar to those encountered by FDA. Facts have been left out to demonstrate how alternative facts affect our compliance decisions.

1. A farmer visits a local veterinarian and describes an illness that he is seeing in his dairy cattle. The veterinarian asks a few probing questions and determines his cattle have pneumonia. The veterinarian prescribes a drug and labels the drug in accordance with the PMO guidelines. Does a proper VCPR exist?

2. A dairy inspector visits the farms and finds a properly labeled prescription drug from a veterinarian not licensed in that state. Does a proper VCPR exist?

3. The vet last visited the farm a year ago. He provides properly labeled drugs to the farmer and well written informational brochures describing the diseases for which these drugs should be used. Does a proper VCPR exist?

4. The local mobile peddler hires a veterinarian to make rounds with him. When the peddler sells prescription drugs, the veterinarian labels them in accordance with the PMO. Does a proper V-C-P exist?

5. The farmer's veterinarian has left a prescription for a drug with the farmer. The farmer purchases the drug from the mobile peddler. The peddler labels the drug in accordance with the PMO. Does a proper VCPR exist? What if the prescription was for 5 drugs? What about 25?

6. A farmer visits his consultant veterinarian and purchases a drug from the receptionist. The receptionist identifies the farmer as a client of the doctor. The receptionist labels the drug in accordance with the PMO. Does a proper VCPR exist?

7. The veterinarian prescribed gentamicin for extra-label use in a lactating dairy cow within a valid VCPR. The gentamicin product was labeled in accordance with the PMO requirements. The veterinarian assigned a slaughter withdrawal time of 10 days. The farmer held the cow for 12 days after treatment, then shipped it for slaughter. A gentamicin residue was detected by USDA. Is this situation within the provisions of the extra-label use regulations?

8. A veterinarian prescribed a prescription drug for treatment of mastitis. The drug was purchased on several occasions from a mobile peddler and labeled in accordance with the PMO for mastitis use. The veterinarian did not assign an expiration date to the prescription or the drug. The farmer used the drug on a cow with pneumonia. Is the veterinarian responsible?

NOTES:

COURSE REVIEW

INSTRUCTIONS: Read each situation carefully and determine whether it is a PMO violation. If you determine it is a violation, record the violation item in the space provided. Be prepared to defend your interpretation.

OBSERVED CONDITION	VIOLATION (X)	ITEM
1. Broken windows and torn screens in the milking area (parlor).		
2. The milkhouse well (600 ft deep) is located in a corn field. The farmer sprays twice a year with herbicides and pesticides. The well seal is tight fitting and in tact.		
3. Filter socks are in a closed filter box which is located in the milking area.		
4. The milk receiver is located in the parlor in a pit that is not provided with a floor drain.		
5. You observe nitrofurazone ointment in the milking barn.		
6. PVC piping is used for the CIP return solution line into the utensil wash sink.		
7. Numerous calf buckets and feeding bottles, etc. are stored in the milkhouse utensil wash sink and on the floor.		
8. The producer is housing his calves in the stanchions in the milking area causing overcrowding.		
9. An intermittent pyrethrin pesticide dispenser located in the milkhouse is programmed to operate during periods between milking. You observe the dispenser activating during CIP.		
10. The door between the milkhouse and milking parlor is not self-closing.		
11. Large piles of manure are stored accessible to the dry cow housing area. There is no evidence of fly breeding, however excessive numbers of insects are observed in the milking parlor.		

OBSERVED CONDITION	VIOLATION (X)	ITEM
12. The agitator shaft of a bulk headed milk tank, which is adequately protected, is located in a room without finished walls.		
13. One of the compartments of the utensil wash sink is marked "hand wash". It has been provided with dispenser soap and single service towels.		
14. The milkhouse has a door which opens directly into a calf housing area. The door is solid and self closing. The calf area is not clean and is poorly ventilated and these odors are detected in the milkhouse.		
15. Well water, which is used to pre-cool milk in a plate cooler, is discharged into the cow washer reservoir. The discharge pipe is located below the overflow level of the reservoir.		
16. The overhead hay storage loft door in the milking area of a stanchion barn is left open during non-milking times.		
17. The holding pen (catch pen) has manure buildup from only the morning milking operation.		
18. The milkhouse is provided with 20 foot-candles of natural lighting. All light fixtures either have missing or broken bulbs.		
19. Boxes of Dri-Clox (RX dry cow drug) are properly labeled with the prescribing DVM's name and address and are stored with the lactating drugs.		
20. A portable high pressure water pump is equipped with a pressure type vacuum breaker to protect the water system.		
21. The Mueller "wand" tank washer is stored above the floor in the breezeway.		
22. The air injector for the CIP system is located in an unclean area of the compressor room and the filter is excessively dirty.		
23. Manure packs are not solid to the footing. There is no evidence of fly breeding.		
24. The water used for washing the parlor is from an old irrigation well which, during dry seasons, draws water from a small		

OBSERVED CONDITION	VIOLATION (X)	ITEM
surface pond.		
25. The producer is using a third compartment of the milkhouse utensil sink to prepare mastitis treatment medicines.		
26. The milkhouse wall has four 24 inch square screen vents which open directly into the breezeway. The doors on both ends of the breezeway are closed.		
27. The automatic stock watering tank has a submerged inlet, however there is only an approved vacuum breaker installed on the main line of the community water system which serves the farm.		
28. A Nitrofuran derivative drug is found in the dry cow cabinet. It has a complete Extra Label.		
29. Kopertox and Udderbalm are stored in the hand wash sink.		
30. The tanker driver is smoking in the milkhouse while collecting the "Universal Sample".		
31. Drug administration equipment is being stored in the handwash sink.		

FARM INSPECTION CASE STUDIES

Assumption:

You are the State Grade "A" dairy farm inspector. You have chosen today to do your south route farms since the north route roads are a mess due to the rain yesterday. You have loaded everything you hopefully need into the state vehicle including your farm boot covers, flashlight with fresh batteries, sanitizer test kits, ledgers and map book, inspection forms and inspection clip board, boot sanitizer, camera, and an optimistic attitude. You have chosen a few of your best farms to visit. Upon arrival at each farm you observe the following conditions, respectively.

Farm #1:

You enter the milk room and find that the morning milking has been completed. It's around 11:00 a.m. and the milker usually gets finished at around 9:00 a.m. every morning. There is no one around and you observe that the equipment has been rinsed out and water is visible in the receiver and weigh jars. Out in the milk barn (stanchion type operation), there are several small birds skittering about. There is some manure on the walls, you can tell it's probably from the morning milking activities. As you re-enter the milk house you take the stored milk temperature and find it to be exactly 57^{o} F.

What are your actions?

Farm #2:

The dairy farmer meets you as you get out of your vehicle and says he's expecting the herd tester today and would appreciate you not inspecting his barn today. This producer has a record of good cooperation with the regulatory agency but you have been waiting a long time to take a look at the "testers" equipment.

What are your actions?

Farm #3:

This facility milk 1500 head 3x daily. You arrive shortly after lunch and upon entering the milkroom notice the tank thermometer is reading 60^{o} F. Milking begins at approximately 4 a.m. every day and they finish up at around 10 p.m. at night at which time the equipment is cleaned and sanitized. Both the owner and the herdsman have gone to town to an all day co-op meeting and the milkers are hesitant to let you into the office where all of the drugs are stored. You look out in the corral and notice several pools of water in the area where the milking herd is loose-housed. On the way out, you notice the hauler has arrived and is looking at his thermometer.

What are your actions?

Farm #4:

It's your first farm of the day and as you approach the milkhouse you can see that there are no walls. The milkhouse consists of concrete slab graded to drain, a roof and since it has no walls, adequate lighting is available. As you enter the milkhouse you notice that there is a hose attached to a water line, which terminates below the flood rim of the 2 compartment wash vat. You also notice that there is a plug in the wash vat but the vat is not holding any water. As you make your way through your inspection you go outside to inspect the well. You notice that the well-head terminates only 8 inches above the ground and there is a frost-free hydrant mounted directly on top of the well-head.

What are your actions?

Farm #5:

While in the parlor you can see that the cows are stepping through a footbath. You inquire as to what is in the footbath and the farmer tells you that he is using chlorine dioxide. As cows come into the parlor you notice that the person milking the cows is not stripping the foremilk and checking for abnormalities prior to milking. You are also curious as to how they milk their fresh cows, because you observe abnormal milking buckets in the milking area. The person doing the milking explains to you that they do not segregate the fresh cows from the lactating herd and they milk them as they come into the parlor with the other cows.

What are your actions?

FARM #6:

Upon entering the milk-house you find a note on the roll of paper towels over the hand sink – “Do Not Use for Inspectional Purposes Only”. You also notice that the small parts basket for the upright CIP tank is firmly attached to the wall and used for tool storage. As you enter the parlor you notice that the glass pipeline has been painted white, including the connectors.

What are your actions?

Farm # 7:

It's your last farm, it's been a long day and as you drive up to the farm you notice the milk-house door is open. Upon entering the milkroom, you immediately notice that the agitator motor on the milk tank is a Makita hand drill attached to the agitator shaft, properly suspended so as not to cause any scoring on the interior of the milk tank. The milk line is attached to the milk tank, and the CIP supply line to the milk tank has not been disconnected from the wash unit. As you continue your inspection, you notice the drain in the milking pit from the milkroom is not screened. While in the milking parlor observing the milking procedures, you are greeted by Ruby (the farmer's daughters pet chicken) who proceeds to follow you everywhere you go.

What are your actions?

COMMON DAIRY TERMS

Common Dairy Terms

AREA RATING - An area rating, if used, shall apply to raw milk for pasteurization only. An area rating consists of more than one producer group operating under the supervision of a single regulatory agency and which is rated as a single entity.

BLOWN QUARTER - A hard inflamed portion of the udder indicative of severe mastitis.

BOB CALF - A calf usually less than one week old, but may be up to 3 weeks old. Most are bulls and are also referred to as "drop" or slaughter calves.

BOLUS - A large medicated tablet or pill.

BOVINE MENSTRUAL CYCLE - 21 days or estrous cycle of a cow or heifer

BREED BACK - To re-inseminate a cow 50-60 days after last calving (this is usually done several times to one animal)

BULK TANK UNIT(BTU) - A group of dairy farms from which raw milk for pasteurization is collected by bulk tank pickup tankers, under the routine supervision of one regulatory agency and rated as a single entity and given a raw milk and enforcement rating.

CERTIFIED RATING OFFICER - A state employee who has been standardized by the FDA, has a current valid certificate, and does not have direct responsibility for the routine inspection and enforcement of the supply to be rated. A certificate is issued only after the applicant has completed the field joint inspection exercise (for dairy farms and/or milk pasteurization plants, receiving stations, or transfer stations) with a Regional Milk Specialist and is within 80% agreement on each item of the inspection form.

CLEANING OUT - The removal of the retained placenta after calving.

COLOSTRUM - First quantities of milk from a fresh cow which is rich in immunization factors which is very beneficial to the newborn calf.

COME FRESH - (OR TO FRESHEN) - The beginning of milk production by a cow upon giving birth to a calf.

CONDITIONING - Refers to the amount of body fat of the animal during the various stages of lactation and/or non-lactation.

COW - A post heifer, female bovine which has been bred and produces milk.

CHECK RATING - (Federal Spot Check) - A rating conducted on a group of IMS listed Grade A farms based on a random sampling

CLAW - The sanitary manifold that spaces and connects the four teat cup assemblies into a milking unit.

CULL ANIMALS - Animals removed or separated from the rest of the herd because of some undesirable defect/illness.

DAIRY REPLACEMENT - A heifer being raised for milk production.

DOWNER COW - A cow physically unable to stand.

DRY COW - A cow not producing milk (in the nonlactating stage). The cow is "dried off" approximately 50-60 days prior to estimated calving date.

DRY TREATMENT - Mastitis drug prevention (IV, IM or orally) begun when lactation has ceased, and is usually about 60 days prior to calving.

FIRST CALF HEIFER - The first lactation period as a cow.

FREE MARTIN - The sterile female twin bovine of a male calf which because of hormonal exchange shows male tendencies. Often used as heat detectors within the breeding female herd.

HEIFER - A female bovine between calf and puberty (approximately 15 months old)

KETOSIS - A metabolic disease of lactating cows resulting in low blood sugar.

MASTITIS - A bacterial infection of the udder.

MECHANICAL CLEANING - Cleaning by circulation and/or flowing chemical detergent and water rinses onto and over the surfaces by mechanical means.

MILK FEVER - An imbalance in the calcium/phosphorus ratio in a bovine dairy animal, immediately after calving.

MILK HOSE - A hose that connects the claw or milker to a bucket or a milking pipeline or a milk conveying line.

MILK INLET - A nipple on the milking pipeline or milk conveying line for the attaching the milk hose.

MILK LETDOWN - A response by the cow to stimulus causing milk to flow into the udder. Initiated by the hormone Oxytocin.

MILK PRODUCTION PERIOD - For bovines, the 10 month period (approximate) after calving.

MILK REPLACER - A substitute for the mothers' natural milk. May contain medications.

MILK TUBE - A tube that connects the liner to the milk nipple.

MILKING VACUUM - The vacuum recommended by the manufacturer for the inside of the inflation or liner.

NIPPLE - Usually a short pipe projection from the claw, pulsator, milking machine lid or other part of the milking apparatus.

OXYTOCIN - A hormonal Rx non-withdrawal drug used to stimulate milk let down in bovines. The drug is also sometimes used to expedite the removal of placental materials (clean-out).

PMO - Pasteurized Milk Ordinance, current edition. Minimum requirements and standards for Grade A milk supplies. The standards used by the National Conference of Interstate Milk Shippers (NCIMS).

PRODUCT CONTACT SURFACES - Shall mean all surfaces which are exposed to the product and surfaces from which liquids may drain, drop or be drawn into the product.

PULSATOR - The device that provides a set amount of timed vacuum to each of the individual milking units.

RATING - A sanitation and enforcement evaluation of a randomly selected group of IMS listed Grade A dairy farms conducted in accordance with NCIMS Methods and Procedures. Ratings are made on a maximum 24 month period of time and are conducted only by Certified State Milk Rating Officers.

RECEIVER (milk) - A device that receives milk from the milk piping, and is the source of vacuum for the milk pipe.

RELEASER - A device that releases milk from under vacuum and discharges it to atmospheric pressure.

RUMINANT - A four stomached animal.

SANITARY TRAP - A flow vessel that separates the milk side of a milking machine system from the vacuum supply side to keep milk and fluids out of the vacuum system and to prevent back-flow of moisture.

SCOURS - Severe diarrhea, usually in younger livestock. Can result in death caused by dehydration of the animal.

SHIPPING FEVER - A respiratory disease frequently found in cattle shipped long distances. Often used as a catch-all phase for pneumonia.

STALL COCK - The valve device on the vacuum line to which the air hose is attached.

STEER - A castrated bull animal that is grown for beef and is slaughtered at approximately two years of age and weights 1100 - 1400 pounds.

SURCINGLE - A strapping device used to stabilize or suspend the milking bucket unit underneath the cow during milking.

UDDER INFUSION - Administration of a substance through the orifice of the udder teat.

NOTES: