

1. FORM FDA 2359L-STATUS OF MILK PLANTS (INCLUDING DRYING AND CONDENSING MILK PRODUCTS PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS) (~~STATUS OF MILK PLANTS~~ DRYING AND TRANSFER STATION)

(INCLUDING DRYING AND CONDENSING MILK PRODUCTS PLANTS, RECEIVING STATIONS and TRANSFER STATIONS)

Milk Plant Metro Dairy Company

Date of Rating October 30-31, 2016

Sanitation Compliance Rating¹ 91

NAME OF PLANT (MILK PRODUCT/ PASTEURIZATION/ FILLING AND CAPPING)	Pounds Processed Daily (100# Units) ³	ITEMS OF SANITATION																								Total Debits ²	Pounds Processed Daily (100# Units) ³ X Total Debits ²	REMARKS							
		Containers and Equipment												Pasteurization						Bottling Capping															
		Floors	Walls and Ceiling	Doors and Windows	Lighting	Ventilation	Separate Rooms	Toilet/Sewage Disposal Facilities	Water Supply	Hand Washing Facilities	Milk Plant Cleanliness	Sanitary Piping	Construction and Repair	Cleaning	Sanitation	Storage of Clean Equipment	Storage of Service Articles	Protected from Contamination	Indicating and Recording Thermometers	Time and Temperature Controls	Adulteration Controls	Regenerative Heating	Temperature Recording Charts	Cooling	Container Filling				Capping and Sealing	Personnel Cleanliness Protective Clothing	Vehicles	Surroundings	Bacterial Count*	Coliform Count*	
1	2	3	4a	4b	5	6	7	8	9	10	11	12ab	12c-e	13	14	15ac	15b	16ab (1)	16ab (2)	16b	16c	16d	17	18	19	20	21	22	5*	10*					
Metro Dairy Co.	1,000										3						5																8	8,000	100 - 8 = 92
Metro Receiving Station (680)		1		2						3																							9		Above 90, (Would not be Included in Plant Score)
White Milk Transfer Station (220)										3													5					1	2				11		100 - 11 = 89, (Below 90) Subtract Transfer Station Score From Plant Score).
TOTALS	1,000																															3	660	92 - 89 = 3 X 220 = 660	

Footnotes: ¹ Sanitation Compliance Rating = $100 - \frac{\text{Total Pounds Processed Daily (100\# Units)}^3 \times \text{Total Debits}^2}{\text{Total Pounds Processed Daily (100\# Units)}^3} = 100 - \frac{8,660}{1,000} = 8.7 = 91.3 = \mathbf{91}$

² Total Debits for each milk plant, receiving station or transfer station is the sum of the weights of the Items violated. (NOTE: Any Item or sub-item violated, indicate by placing the debit value (weight) of that Item or an X under that Item).

³ Total Pounds Processed Daily are calculated in 100# Units.

* Used only when not in compliance. Prorate by product.

2. FORM FDA 2359i-INTERSTATE MILK SHIPPER'S REPORT

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		INTERSTATE MILK SHIPPER'S REPORT (Submit an original and two (2) copies to the FDA Regional Office)										3-A. COUNTRY	
1. NAME OF SHIPPER Clean Milk Dairy				2. CITY Moosville				3. STATE State 00007					
4. STREET 2525 Milky Way			5. PLANT or BTU # 0 0 2 5 0				6. PRODUCT CODE #s 1 2 4 5 7 9 10 18 19 20						
7. SURVEY DATA													
		DAIRY FARMS TYPE OF RATING <input type="checkbox"/> AREA <input checked="" type="checkbox"/> INDIVIDUAL	RECEIVING OR TRANSFER STATION	MILK PLANT ¹				ENFORCEMENT					
RATING (%)		92	NA	91				90					
DATE OF RATING		8/5-7/2016	NA	8/3-4/2016				8/2/2016					
TOTAL NUMBER		120	NA	1				APPENDIX N. IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO					
NUMBER INSPECTED		34	NA	1									
VOLUME RECEIVE DAILY (Cwt)		NA	9,800										
RATING AGENCY <input checked="" type="checkbox"/> SHD <input type="checkbox"/> SDL <input type="checkbox"/> SDA <input type="checkbox"/> TPC <input type="checkbox"/> OTHER _____		CERTIFIED RATING OFFICER Mary Milkramer		OFFICER'S CERTIFICATION EXPIRATION DATE Sept. 19, 2017				EARLIEST RATING DATE					
								MONTH	DAY	YEAR			
								0	8	0	3	1	6
AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY State Department of Health						EXPIRATION RATING DATE ²							
						MONTH	DAY	YEAR					
						0	8	0	2	1	8		
8. LABORATORY CONTROL													
APPROVED LABORATORY NUMBER A. 00001 B. 00302		EXPIRATION DATE A. 02/2017 B. 09/2017	PROCESSED MILK TESTS APPROVED				RAW MILK TESTS APPROVED						
			SPC	COLI	PHOS	RBC	DRUG RESIDUE TESTS	VIABLE COUNTS	SOMATIC CELL COUNTS	DRUG RESIDUE TESTS			
			A. 2	A. 21	A. 28	A. 22	A. 9C28&9D3	A. 2	A. 12	A. 9C28&9D3			
			B. _____	B. _____	B. _____	B. _____	B. _____	B. 3	B. 16	B. _____			
DATE OF LAST TWO SPLIT SAMPLES A. 09/2015 B. 04/2014		APPROVED WATER LABORATORY AND DATE A. 04/2016 B. 09/2015		State Health Dept. Lab (State EPA) 10/2015				WATER TESTS APPROVED 24-MPN					
9. PUBLICATION (Written permission from a shipper shall be filed at a Regional Office of FDA prior to the publication of a rating/listing.)													
LETTER OF PERMISSION TO PUBLISH IS TRANSMITTED WITH THIS REPORT?						<input checked="" type="checkbox"/> YES			<input type="checkbox"/> NO				
10. SUBMISSION OF REPORT BY RATING AGENCY													
DATE OF REPORT 8/10/2016		SUBMITTED BY (Signature and Title) Mary Milkramer, Milk Sanitation Rating Officer											
FOR FDA REGIONAL OFFICE USE ONLY													
Written permission from shipper dated _____ on file and publication of rating/listing recommended.													
DATE		SIGNATURE (FDA Milk Specialist)											
¹ Submit separate Form for each milk plant. ² The expiration rating date is two (2) years after the earliest rating date, i.e., earliest rating date is 10/1/2015 with a corresponding expiration rating date of 9/30/2017, except if the Enforcement Rating is <90, then the expiration rating date is six (6) months after the earliest rating date, i.e., earliest rating date is 10/1/2015 with a corresponding expiration rating date of 3/31/2016.													

FORM FDA 2359i (10/13) FRONT (PREVIOUS EDITIONS ARE OBSOLETE)

11. **MILK PLANTS:** List below the Name and Address of all shippers of raw milk and milk products received during the thirty (30) days preceding the earliest rating date of the Rating; Sanitation Compliance Rating; and Expiration Rating Date. Plants receiving milk from an unlisted source(s), or source(s) with a Sanitation Compliance Rating below ninety (90), are not eligible for listing in the electronic publication, *IMS LIST – SANITATION COMPLIANCE AND ENFORCEMENT RATINGS OF INTERSTATE MILK SHIPPERS*

NAME OF SHIPPER (Include BTU or Plant #)	CITY AND STATE/COUNTRY	SANITATION COMPLIANCE RATING	EXPIRATION RATING DATE
ABC BTU	Bulls Role, State/Country	91	12/19/2017
Udderly Delightful BTU	Tootle Town, State/Country	92	06/21/2018
GMI Good Dairy	Paradise, State/Country	90	04/28/2018

INSTRUCTIONS:

Completed Forms shall be received by Milk Safety Branch (HFS-316) to be included in the *IMS List*.

Additional explanation is offered for the following Items:

Item 1: Name of Shipper - Limit shipper's name to not more than thirty-four (34) characters and spaces. If a receiving or transfer station is to be listed, please include "Receiving or Transfer Station" or "(RS)" or "(TR)" with the name of the shipper. Suggested abbreviations are published in the *IMS List*.

Item 5: Plant or BTU # - When the IMS Number is less than five (5) digits; leave the left-hand square(s) blank.

Item 6: Product Code #'s - Enter Product Code #'s starting in the first (left-hand) space. Product Codes # are listed below:

PRODUCT CODES:

- | | |
|--|--|
| 1. Raw Milk for Pasteurization (May Include Lowfat, Skim or Cream) | 26. Cream (Condensed or Dry) |
| 2. Pasteurized Milk, Reduced Fat, Lowfat, or Skim | 27. Blended Dry Products |
| 3. Heat-Treated (May Include Reduced Fat, Lowfat, Skim or Cream) | 28. Whey Cream |
| 4. Pasteurized Half & Half, Coffee Cream, Creams | 29. Whey Cream and Cream Blends |
| 5. Ultra-Pasteurized (UP) Milk and Milk Products | 30. Grade "A" Lactose |
| 6. Aseptic Milk and Milk Products (Including Flavored) | 31. Raw Goat Milk for Pasteurization |
| 7. Cottage Cheese (Including Lowfat, Nonfat or Dry Curd) | 32. Pasteurized Goat Milk and Milk Products |
| 8. Cultured or Acidified Milk and Milk Products | 33. Cultured Goat Milk and Milk Products |
| 9. Yogurt (Including Lowfat or Skim) | 34. Condensed or Dry Goat Milk and Milk Products |
| 10. Sour Cream Products (Acidified or Cultured) | 35. Ultra-Pasteurized (UP) Goat Milk and Milk Products |
| 11. Whey (Liquid) | 36. Aseptic Goat Milk and Milk Products |
| 12. Whey (Condensed) | 37. Raw Sheep Milk for Pasteurization |
| 13. Whey (Dry) | 38. Pasteurized Sheep Milk and Milk Products |
| 14. Modified Whey Products (Condensed or Dry) | 39. Cultured Sheep Milk and Milk Products |
| 15. Condensed Milk and Milk Products | 40. Concentrated Raw Milk Products for Pasteurization |
| 16. Nonfat Dry Milk | 41. Concentrated Pasteurized Milk Products |
| 17. Buttermilk (Condensed or Dry) | 42. Ultrafiltered Permeate from Milk |
| 18. Eggnog | 43. Ultrafiltered Permeate from Whey |
| 19. Lactose Reduced Milk and Milk Products | 44. Raw Water Buffalo Milk for Pasteurization |
| 20. Low-Sodium Milk and Milk Products | 45. Pasteurized Water Buffalo Milk and Milk Products |
| 21. Milk and Milk Products with Added Safe and Suitable Microbial Organisms
(Such as <i>Lactobacillus acidophilus</i>) | 46. Cultured Water Buffalo Milk and Milk Products |
| 22. Dry Milk and Milk Products | 47. Raw Camel Milk for Pasteurization |
| 23. Anhydrous Milk Fat | 48. Pasteurized Camel Milk and Milk Products |
| 24. Cholesterol Modified Anhydrous Milk Fat | 49. Cultured Camel Milk and Milk Products |
| 25. Cholesterol Modified Fluid Milk Products | |

3. FORM FDA 2359i-INTERSTATE MILK SHIPPER'S REPORT (ELECTRONIC SUBMISSION)

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICES FOOD AND DRUG ADMINISTRATION		INTERSTATE MILK SHIPPER'S REPORT		INTERNAL USE ONLY:AL27131									
1.NAME OF SHIPPER ABC MILK PLANT		2.CITY ANYWHERE		3.STATE / COUNTRY AL US									
4.STREET 92 BOONESBORO AVENUE		5.PLANT or BTU # PMO/FARMS 123		6. PRODUCT CODE #s									
				01	02	03	04	08	10				
7. SURVEY DATA													
		DAIRY FARMS TYPE OF RATING <input type="radio"/> AREA <input checked="" type="radio"/> INDIVIDUAL		RECEIVING OR TRANSFER STATIONS		MILK PLANT ¹		ENFORCEMENT					
RATING (%)		90				92		87					
DATE OF RATING		10 / 01 / 2014				10 / 03 / 2014		10 / 05 / 2014					
TOTAL NUMBER		10				1		APPENDIX N IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N ? <input checked="" type="radio"/> YES <input type="radio"/> NO					
NUMBER INSPECTED		10				1							
VOLUME RECEIVED DAILY (Cwt)						10000							
RATING AGENCY <input checked="" type="radio"/> SHD <input type="radio"/> SDA <input type="radio"/> SDL <input type="radio"/> TPC <input type="radio"/> OTHER		CERTIFIED RATING OFFICER ROGER RABBIT		OFFICER'S CERTIFICATION EXPIRATION DATE 09 / 2016		EARLIEST RATING DATE 10 / 01 / 2014							
AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY STATE DEPARTMENT OF PUBLIC HEALTH								EXPIRATION RATING DATE ² 03 / 31 / 2015					
8.LABORATORY CONTROL				PROCESSED MILK TESTS APPROVED				RAW MILK TESTS APPROVED					
APPROVED LABORATORY NUMBER	EXPIRATION DATE	DATE OF LAST TWO (2) SPLIT SAMPLES		SPC	COLI	PHOS	RBC	DRUG RESIDUE TESTS	VIABLE COUNTS	SOMATIC CELL COUNTS	DRUG RESIDUE TESTS		
A. 00012	02 / 2016	07 / 2015	08 / 2014	2	20	28	22	C3,C14,D3	2,3	12	C3,D3		
B.	/	/	/										
C.	/	/	/										
D.	/	/	/										
E.	/	/	/										
APPROVED WATER LABORATORY 00012				APPROVED WATER LABORATORY DATE 02 / 2014				WATER TESTS APPROVED 24					
9.PUBLICATION (Written permission from a shipper shall be filed at the Rating Agency prior to the publication of a rating/listing.)													
<input checked="" type="radio"/> YES <input type="radio"/> NO DATE: 10 / 09 / 2014													
10.SUBMISSION OF REPORT BY RATING AGENCY													
DATE OF REPORT 10 / 10 / 2014				SUBMITTED BY ROGER RABBIT				TITLE RATING OFFICER					
FOR FDA REGIONAL OFFICE USE ONLY													
DATE				FDA Regional Milk Specialist									
¹ Submit separate Form for each milk plant.													
² Expiration rating date is two (2) years after the earliest rating date, i.e., earliest rating date is 10/1/2011 with a corresponding expiration rating date of 9/30/2013, except if the Enforcement Rating is <90, then the expiration rating date is six (6) months after the earliest rating date, i.e., earliest rating date is 10/1/2011 with a corresponding expiration rating date of 3/31/2012.													
FORM FDA 2359i (10/11)													

4. FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM
AUDIT REPORT

Department of Health and Human Services Food and Drug Administration		MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT			
DATE January 23-25, 2016		TYPE OF AUDIT <input type="checkbox"/> REGULATORY* <input type="checkbox"/> REGULATORY FOLLOW-UP <input checked="" type="checkbox"/> LISTING <input type="checkbox"/> FDA AUDIT OF LISTING			
FIRM NAME My HACCP Dairy Plant		LICENSE/PERMIT NO. 123		IMS PLANT NO. 00-123	
ADDRESS (Line 1) 234 Milk Road					
ADDRESS (Line 2)			CITY My City	STATE/ COUNTRY MY	ZIP CODE 11111
IMS LISTED PRODUCT(S) MANUFACTURED AND REVIEWED Vitamin D Milk, Vitamin A & D Reduced Fat 2% Milk, Vitamin A&D Lowfat Nutrish 1%, Vitamin A & D Fat Free Milk, Chocolate Vitamin D Milk, Chocolate Vitamin A&D Reduced Fat 2% Milk, Chocolate Vitamin A&D Lowfat Nutrish 1%, and Chocolate Vitamin A & D Fat Free Milk (IMS Product Code 2)				Prerequisite Program(s) Issue Date(s) 3/15/2012	
Hazard Analysis Issue Date(s) <u>3/15/2014</u>		HACCP Plan Issue Date(s) <u>3/15/2014</u>			
ITEMS MARKED <u>DID NOT</u> MEET THE NCIMS HACCP PROGRAM CRITERIA DESCRIBED BELOW Starred ** Items are Critical Listing Elements					
*NOTE: This regulatory NCIMS System Audit Report of your plant, receiving station, or transfer station serves as a notification of the intent to suspend your permit if items marked on this audit report are not in compliance at the time of the next regulatory audit or within established timelines. (Refer to PMO Sections 3. and 6., and Appendix K. for details.)					
Section 1 HAZARD ANALYSIS <input type="checkbox"/> A. Flow Diagram and Hazard Analysis conducted and written for each kind or group of milk or milk product processed.** <input type="checkbox"/> B. Written Hazard Analysis identifies all potential milk or milk product safety hazards and determines those that are reasonably likely to occur (including hazards within and outside the processing plant environment). <input checked="" type="checkbox"/> C. Written Hazard Analysis reassessed after changes in raw materials, formulations, processing methods/systems, distribution, intended use or consumers. <input type="checkbox"/> D. Written Hazard Analysis signed and dated as required.			Section 6 HACCP PLAN CORRECTIVE ACTION <input type="checkbox"/> A. Corrective actions when defined in the HACCP Plan were followed when deviations occurred. <input type="checkbox"/> B. Predetermined corrective actions defined in the HACCP Plan ensure the cause of the deviation is corrected. <input type="checkbox"/> C. Corrective action taken for products produced during a deviation from CL(s) defined in the HACCP Plan.** <input type="checkbox"/> D. Affected milk or milk product produced during the deviation segregated and held, AND a review to determine product acceptability performed, AND corrective action taken to ensure that no adulterated milk and/or milk product that is injurious to health enters commerce. <input type="checkbox"/> E. Cause of deviation was corrected. <input type="checkbox"/> F. Reassessment of HACCP Plan performed and modified accordingly. <input type="checkbox"/> G. Corrective actions documented.		
Section 2 HACCP PLAN <input type="checkbox"/> A. Written HACCP Plan prepared for each kind or group of milk or milk product processed.** <input type="checkbox"/> B. Written HACCP Plan implemented. <input type="checkbox"/> C. Written HACCP Plan identifies all milk or milk product safety hazards that are reasonably likely to occur. <input type="checkbox"/> D. Written HACCP Plan signed and dated as required.			Section 7 HACCP PLAN VERIFICATION & VALIDATION <input type="checkbox"/> A. HACCP plan defines verification procedures, including frequency. <input type="checkbox"/> B. Verification activities are conducted and comply with HACCP Plan. <input type="checkbox"/> C. Reassessment of HACCP Plan conducted annually, OR <input type="checkbox"/> 1. After changes that could affect the hazard analysis, OR <input type="checkbox"/> 2. After significant changes in the operation including raw materials and/or source, product formulation, processing methods/systems, distribution intended use or intended consumer. <input type="checkbox"/> D. Calibration of CCP process monitoring instruments performed as required and at the frequency defined in the HACCP Plan.** <input type="checkbox"/> E. CCP monitoring records reviewed and document that values are within CL(s) as required. <input type="checkbox"/> F. Corrective action record reviewed as required. <input type="checkbox"/> G. Calibration records and end product or in-process testing results defined in HACCP Plan reviewed as required. <input type="checkbox"/> H. Records reviewed as required, including date and signature.		
Section 3 HACCP PLAN CRITICAL CONTROL POINTS (CCP) <input type="checkbox"/> A. HACCP Plan lists CCP(s) for each milk or milk product safety hazard identified as reasonably likely to occur. <input type="checkbox"/> B. CCP(s) identified are adequate control measures for the milk or milk product safety hazard(s) identified. <input type="checkbox"/> C. Control measures associated with CCP(s) listed are appropriate at the processing step identified.					
Section 4 HACCP PLAN CRITICAL LIMITS (CL) <input type="checkbox"/> A. HACCP Plan lists critical limits for each CCP. <input type="checkbox"/> B. CL(s) are adequate to control the hazard identified.** <input type="checkbox"/> C. CL(s) are achievable with existing monitoring instruments or procedures. <input type="checkbox"/> D. CL(s) are met.					
Section 5 HACCP PLAN MONITORING <input type="checkbox"/> A. HACCP Plan defines monitoring procedures for each CCP. (<i>what, how, frequency, whom, etc.</i>) <input type="checkbox"/> B. Monitoring procedures as defined in the HACCP Plan followed. <input type="checkbox"/> C. Monitoring procedures as defined in the HACCP Plan adequately measure CL(s) at each CCP. <input type="checkbox"/> D. Monitoring record data consistent with the actual value(s) observed during the audit.					

Milk Plant, Receiving Station or Transfer Station – NCIMS HACCP SYSTEM AUDIT REPORT

ITEMS MARKED *DID NOT* MEET THE NCIMS HACCP PROGRAM CRITERIA DESCRIBED BELOW

Starred ★★ Items are Critical Listing Elements

Section 8 HACCP SYSTEM RECORDS

- A. Required information included in the record, e.g., name/location of processor and/or date/time of activity and/or signature/initials of person performing operation and/or identity of product/product code.
- B. Processing/other information entered on record at time observed.
- C. Records retained as required, e.g., one year for refrigerated products and two years for preserved, shelf-stable or frozen products.
- D. Records relating to adequacy of equipment or processes retained for 2 years.
- E. HACCP records correct, complete and available for official review
- F. Information on HACCP records not falsified.**

Section 9 HACCP SYSTEM PREREQUISITE PROGRAMS (PPs)

- A. Required PP written, implemented, and in substantial compliance by firm.
 - 1. Safety of the water that comes into contact with milk or milk contact surfaces (including steam and ice);
 - 2. Condition and cleanliness of equipment milk contact surfaces.
 - 3. Prevention of cross contamination from unsanitary objects and/or practices to milk and milk products, packaging material and other milk contact surfaces, including utensils, gloves, outer garments, etc., and from raw product to processed product;
 - 4. Maintenance of hand washing, hand sanitizing, and toilet facilities;
 - 5. Protection of milk and milk product, milk packaging material, and milk contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical and biological contaminants;
 - 6. Proper labeling, storage, and use of toxic compounds.
 - 7. Control of employee health conditions that could result in the microbiological contamination of milk and milk products, milk packaging materials, and milk contact surfaces; and
- B. Additional PP's required or justified by the hazard analysis are written and implemented by firm.
- XX C. PP conditions and practices monitored as required
- D. PP monitoring performed at a frequency to ensure conformance.
- E. Corrections performed in a timely manner when PP monitoring records reflect deficiencies or non-conformities.
- XX F. PP audited by firm.
- G. PP monitoring records adequately reflect conditions observed.
- H. PP signed and dated as required.

Section 10 OTHER NCIMS REQUIREMENTS

- A. Incoming milk supply from NCIMS listed source(s) with sanitation scores of 90 or better or acceptable HACCP Listing.**
- B. Drug residue control program implemented.**
- C. Drug residue control program records complete.
- D. Labeling compliance as required.
- E. Prevention of adulteration of milk products.
- F. Regulatory samples comply with standards.
- G. Pasteurization Equipment design and construction.
- H. Approved Laboratory Utilized - (if not, Rating not conducted)
- I. Other items as noted.

Section 11 HACCP SYSTEM TRAINING (Individuals trained according to Appendix K. or alternatively have equivalent job experience.)

- A. PPs developed by trained personnel.
- B. Hazard Analysis developed by trained personnel.
- C. HACCP Plan developed by trained personnel.
- D. HACCP Plan validation, modification or reassessment performed by trained personnel.
- E. HACCP Plan records review performed by trained individual.
- F. Employees trained in monitoring operations.
- G. Employees trained in PP operations.

Section 12 HACCP SYSTEM AUDIT FOLLOW-UP ACTION

- A. Previous audit findings corrected.
- B. Previous audit findings remain corrected at time of this audit.
- C. A series of observations that lead to a finding of a potential HACCP System failure that is likely to result in a compromise to milk or milk product safety.**

Refer to attached Audit Discussion sheet(s) for details.

NAME OF AUDITOR(S) (Please Print)

I. M. A. Milkraater

SIGNATURE

I. M. A. Milkraater

DATE

January 23-25, 2016

NCIMS HACCP SYSTEM AUDIT REPORT DISCUSSION SHEET

FIRM NAME

My HACCP Dairy Plant

DATE OF AUDIT

January 23-25, 2016

**EXPLANATION OF DEVIATION/DEFICIENCIES/NON-CONFORMITIES THAT DID NOT MEET
THE NCIMS HACCP PROGRAM CRITERIA**

(Use additional sheets as necessary if entry field is non-expandable.)

NOTE: When Regulatory Audits are conducted, timelines for corrections of all identified deviations, deficiencies and non-conformities shall be established.

Section 1.C. - The firm has failed to reassess the hazard analysis after changes in raw materials, formulations, processing methods/systems, distribution, and intended use or consumer as evidenced by the lack of the hazard analysis being reviewed and re-dated after the 6/2015 addition of a new ingredient, chocolate slurry and again after the case washing area was relocated 7/31/2015. The current hazard analysis documented and signed is dated 3/15/2014.

Section 9.A.2. - The plant has failed to write and implement required prerequisite programs that are in substantial compliance with the HACCP requirements. Specifically, the plant has failed to monitor and comply with the HACCP requirement for the Condition and Cleanliness of Milk Contact Surfaces of Equipment as evidenced by the following: Product residues were observed in raw silos #1, #2 and #3, blending vat B and tank R7 following CIP; stabilizer residues were observed on the bottom of raw storage tank R16 after it had been cleaned; and there is no brief written description or checklist of monitoring the cleaning effectiveness after cleaning has occurred.

Based upon the equipment cleaning history at this milk plant, cleaning effectiveness checks shall be addressed in the written prerequisite program.

Section 9.C. & F. - The plant has failed to monitor or audit prerequisite program conditions, as required to ensure conformance. Specifically, the written procedures for CIP of raw silos #1, #2 and #3, blending vat B and tank R7 stipulated an alkali wash at 147°F for 20 minutes. An examination of the CIP charts for those circuits indicated that the temperature of the alkali wash ranged from 118°F to 128°F. There was no evidence that any of the CIP charts were monitored and signed by the operator or verified by the sanitation shift supervisor as required by the prerequisite program. The operator shall monitor, and the sanitation shift supervisor shall verify CIP charts as required by the written prerequisite program.

Section 11.D. - The plant failed to adequately train employees in their responsibilities related to the HACCP System. Specifically the employees operating the CIP systems and their supervisors evaluating the CIP recording charts. (Refer to Section 9. C. & F comments.)

I. M. A. Milkcrater

Department of Health and Human Services Food and Drug Administration		NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT (To be included with all NCIMS HACCP Listings and FDA Audits)	
STATE REGULATORY AGENCY State Department of Health		DATE OF EVALUATION January 23-25, 2016	
FIRM NAME My HACCP Dairy Plant	LICENSE/PERMIT NO. 123	IMS PLANT NO. 00-123	
ADDRESS 234 Milk Road, My City, MY 11111			
EXPLANATION OF CONCERNS NOTED REGARDING REGULATORY AGENCY OBLIGATIONS UNDER THE NCIMS HACCP SYSTEM (Use additional sheets if necessary.)			
A narrative description shall be provided as a part of all NCIMS HACCP Listings and FDA Audits, including aseptic and/or retort milk plants with NCIMS HACCP Listings. This report shall include an evaluation of the following requirements:			
1. Milk plant, receiving station or transfer station holds a valid permit. My HACCP Dairy Plant permit #123 is valid. It was issued January 1, 2016 and expires December 31, 2016.			
2. Milk plant, receiving station or transfer station audited by a HACCP trained Regulatory Agency auditor at the minimum required frequency and follow-ups conducted as required. The routine milk plant regulatory audits were conducted at the required frequencies. Follow up audits to verify correction of non-conformities from previous audits are not being conducted until the next routine audit. The last sweet water sample (January 5, 2016) was violative; therefore, the previous minimum frequency of once each six (6) months has been changed to once each four (4) months. (Note: The follow up sample taken January 11, 2016 was satisfactory.)			
3. Requirements interpreted in accordance with the <i>Grade "A" PMO</i> as indicated by past audits. The regulatory audit made August 3-5, 2015 did not note the need to re-evaluate the hazard analysis after the new chocolate slurry system was installed or after the case washer was moved. The October 26-28, 2015 regulatory audit did not question the equipment plant cleaning prerequisite program even though ongoing problems with equipment cleaning were observed in the plant records and by observation of the regulatory inspector. In the case of such repeated problems, in addition to assuring that the equipment is cleaned before being used again, the Regulatory Agency should be requiring the milk plant to investigate the cause of the problem and modify their HACCP system, if needed, to prevent reoccurrence.			
4. Pasteurization equipment tested at required frequency. (Not applicable to receiving stations, transfer stations, aseptic milk plants and retort milk plants.) All equipment tests were conducted at the required frequencies for HTST #1 and HTST #2.			
5. Individual and cooling water samples tested and reports on file as required. Sweet water and glycol samples were taken at the required frequency and, with the exception of the January 5, 2016 sample, all results were satisfactory.			
6. Samples of milk plant's milk and/or milk products collected at the required frequency and all necessary laboratory examinations made. (Not applicable to receiving and transfer stations.) Only three (3) samples of fat free chocolate milk were taken between March 2015 and September 2015.			
7. Sampling procedures approved by PHS/FDA evaluation methods. One (1) evening/weekend Industry Plant Sampler had not been evaluated in the last two (2) years.			
8. Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required. Two (2) of four (4) high Coliform counts for whole milk chocolate were observed (April 6, 2015 [Coliform 40] and June 21, 2015 [Coliform 26]; however a warning letter was not sent.			
9. Records systematically maintained and current. Overall, the records are generally up to date and accurate.			

FORM FDA 2359n (10/13)

6. FORM FDA 2359i-INTERSTATE MILK SHIPPER'S REPORT (EXAMPLE: NCIMS HACCP LISTING)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		INTERSTATE MILK SHIPPER'S REPORT <i>(Submit an original and two (2) copies to the FDA Regional Office)</i>					3-A. COUNTRY				
1. NAME OF SHIPPER My HACCP Milk Plant			2. CITY My City			3. STATE MY 11111					
4. STREET 234 Milk Road		5. PLANT or BTU # 0 0 1 2 3			6. PRODUCT CODE #s 2 4 5 7 8 9						
7. SURVEY DATA											
	DAIRY FARMS TYPE OF RATING <input type="checkbox"/> AREA <input checked="" type="checkbox"/> INDIVIDUAL	RECEIVING OR TRANSFER STATION	MILK PLANT ¹			ENFORCEMENT					
RATING (%)	90*	NA	HACCP Listing Acceptable			Acceptable					
DATE OF RATING		NA	1/23-25/2016								
TOTAL NUMBER		NA	1			APPENDIX N. IS THE SHIPPER IN COMPLIANCE WITH THE PROVISIONS OF APPENDIX N.? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO					
NUMBER INSPECTED		NA	1								
VOLUME RECEIVE DAILY (Cwt)		NA	9,800								
RATING AGENCY <input checked="" type="checkbox"/> SHD <input type="checkbox"/> SDL <input type="checkbox"/> SDA <input type="checkbox"/> TPC <input type="checkbox"/> OTHER _____	CERTIFIED RATING OFFICER I. M. A. Milkraater		OFFICER'S CERTIFICATION EXPIRATION DATE Oct 12, 2017			EARLIEST RATING DATE					
						MONTH	DAY	YEAR			
						0	1	2	3	1	6
AGENCY PROVIDING CONTINUOUS SUPERVISION OF SUPPLY State Department of Health						EXPIRATION RATING DATE ²					
						MONTH	DAY	YEAR			
						0	1	2	2	1	8
8. LABORATORY CONTROL											
APPROVED LABORATORY NUMBER		EXPIRATION DATE		PROCESSED MILK TESTS APPROVED				RAW MILK TESTS APPROVED			
A. 00001		A. 02/2017		SPC	COLI	PHOS	RBC	DRUG RESIDUE TESTS	VIABLE COUNTS	SOMATIC CELL COUNTS	DRUG RESIDUE TESTS
B. 00302		B. 09/2017		A. 2	A. 21	A. 28	A. 22	A. 9C28&9D3	A. 2	A. 12	A. 9C28&9D3
				B. _____	B. _____	B. _____	B. _____	B. _____	B. 3	B. 16	B. _____
DATE OF LAST TWO SPLIT SAMPLES		APPROVED WATER LABORATORY AND DATE				WATER TESTS APPROVED					
A. 09/2014 A. 09/2015		State Health Dept. Lab (State EPA) 10/2015				24-MPN					
B. 04/2014 B. 09/2015											
9. PUBLICATION <i>(Written permission from a shipper shall be filed at a Regional Office of FDA prior to the publication of a rating/listing.)</i>											
LETTER OF PERMISSION TO PUBLISH IS TRANSMITTED WITH THIS REPORT? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO											
10. SUBMISSION OF REPORT BY RATING AGENCY											
DATE OF REPORT 1/26/2016			SUBMITTED BY <i>(Signature and Title)</i> I. M. A. Milkraater, Milk Sanitation Rating Officer								
FOR FDA REGIONAL OFFICE USE ONLY											
Written permission from shipper _____ on file and publication of rating/listing recommended. dated _____											
DATE			SIGNATURE <i>(FDA Milk Specialist)</i>								
¹ Submit separate Form for each milk plant. ² The expiration rating date is two (2) years after the earliest rating date, i.e., earliest rating date is 10/1/2015 with a corresponding expiration rating date of 9/30/2017, except if the Enforcement Rating is <90, then the expiration rating date is six (6) months after the earliest rating date, i.e., earliest rating date is 10/1/2016 with a corresponding expiration rating date of 3/31/2016.											

11. **MILK PLANTS:** List below the Name and Address of all shippers of raw milk and milk products received during the thirty (30) days preceding the earliest rating date of the Rating; Sanitation Compliance Rating; and Expiration Rating Date. Plants receiving milk from an unlisted source(s), or source(s) with a Sanitation Compliance Rating below ninety (90), are not eligible for listing in the electronic publication, *IMS LIST – SANITATION COMPLIANCE AND ENFORCEMENT RATINGS OF INTERSTATE MILK SHIPPERS*

NAME OF SHIPPER (Include BTU or Plant #)	CITY AND STATE/COUNTRY	SANITATION COMPLIANCE RATING	EXPIRATION RATING DATE
Cows BTU #1	Milktown, State/Country	90	12/19/2017
Udderly Delightful BTU #2	Tootle Town, State/Country	92	06/02/2016
Moosville BTU	Cow Palace, State/Country	94	04/12/2016

INSTRUCTIONS:

Completed Forms shall be received by Milk Safety Branch (HFS-316) to be included in the *IMS List*.

Additional explanation is offered for the following items:

Item 1: Name of Shipper - Limit shipper's name to not more than thirty-four (34) characters and spaces. If a receiving or transfer station is to be listed, please include "Receiving or Transfer Station" or "(RS)" or "(TR)" with the name of the shipper. Suggested abbreviations are published in the *IMS List*.

Item 5: Plant or BTU # - When the IMS Number is less than five (5) digits; leave the left-hand square(s) blank.

Item 6: Product Code #'s - Enter Product Code #'s starting in the first (left-hand) space. Product Codes # are listed below:

PRODUCT CODES:

- | | |
|--|--|
| 1. Raw Milk for Pasteurization (May Include Lowfat, Skim or Cream) | 26. Cream (Condensed or Dry) |
| 2. Pasteurized Milk, Reduced Fat, Lowfat, or Skim | 27. Blended Dry Products |
| 3. Heat-Treated (May Include Reduced Fat, Lowfat, Skim or Cream) | 28. Whey Cream |
| 4. Pasteurized Half & Half, Coffee Cream, Creams | 29. Whey Cream and Cream Blends |
| 5. Ultra-Pasteurized (UP) Milk and Milk Products | 30. Grade "A" Lactose |
| 6. Aseptic Milk and Milk Products (Including Flavored) | 31. Raw Goat Milk for Pasteurization |
| 7. Cottage Cheese (Including Lowfat, Nonfat or Dry Curd) | 32. Pasteurized Goat Milk and Milk Products |
| 8. Cultured or Acidified Milk and Milk Products | 33. Cultured Goat Milk and Milk Products |
| 9. Yogurt (Including Lowfat or Skim) | 34. Condensed or Dry Goat Milk and Milk Products |
| 10. Sour Cream Products (Acidified or Cultured) | 35. Ultra-Pasteurized (UP) Goat Milk and Milk Products |
| 11. Whey (Liquid) | 36. Aseptic Goat Milk and Milk Products |
| 12. Whey (Condensed) | 37. Raw Sheep Milk for Pasteurization |
| 13. Whey (Dry) | 38. Pasteurized Sheep Milk and Milk Products |
| 14. Modified Whey Products (Condensed or Dry) | 39. Cultured Sheep Milk and Milk Products |
| 15. Condensed Milk and Milk Products | 40. Concentrated Raw Milk Products for Pasteurization |
| 16. Nonfat Dry Milk | 41. Concentrated Pasteurized Milk Products |
| 17. Buttermilk (Condensed or Dry) | 42. Ultrafiltered Permeate from Milk |
| 18. Eggnog | 43. Ultrafiltered Permeate from Whey |
| 19. Lactose Reduced Milk and Milk Products | 44. Raw Water Buffalo Milk for Pasteurization |
| 20. Low-Sodium Milk and Milk Products | 45. Pasteurized Water Buffalo Milk and Milk Products |
| 21. Milk and Milk Products with Added Safe and Suitable Microbial Organisms
(Such as <i>Lactobacillus acidophilus</i>) | 46. Cultured Water Buffalo Milk and Milk Products |
| 22. Dry Milk and Milk Products | 47. Raw Camel Milk for Pasteurization |
| 23. Anhydrous Milk Fat | 48. Pasteurized Camel Milk and Milk Products |
| 24. Cholesterol Modified Anhydrous Milk Fat | 49. Cultured Camel Milk and Milk Products |
| 25. Cholesterol Modified Fluid Milk Products | |

PERMISSION FOR PUBLICATION
Interstate Milk Shipper's Listing

SHIPPER'S NAME

My HACCP Milk Plant

ADDRESS

234 Milk Road, My City, MY 11111

You are hereby advised that on (date[s]) January 23-25, 2016 a Rating or
HACCP Listing Audit was conducted with the following results:

Producer Supply (BTU) 90* Transfer Station NA

Receiving Station NA Milk Plant Acceptable HACCP Listing

Enforcement Rating (For all Ratings and for attached farm supplies of HACCP listings) Acceptable

The results will be transmitted to the U.S. Food and Drug Administration. They will publish the information in the "IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers". The official Rating or HACCP Listing is valid for a period not to exceed two (2) years from the earliest rating/listing date, except if the Enforcement Rating is less than 90 percent (<90%), then the official Rating is valid for a period not to exceed six (6) months from the earliest rating date, subject to the rules of the National Conference on Interstate Milk Shipments.

Publication Permission Section

Permission is hereby granted to release and publish the above-stated Rating or HACCP Listing for use by Regulatory Agencies and prospective purchasers.

It is understood and agreed by the undersigned that the official Rating or HACCP Listing Agency may review this supply at any time during the two (2)-year or six (6) month period, respectively, referred to above. *It is further understood* that we will notify the Rating or HACCP Listing Agency if any significant change should occur, which affects our raw milk supply, milk plant, receiving station or transfer station status, including products listed.

It is understood and agreed that the failure to maintain the Rating or HACCP System at a level, which is acceptable for listing, may result in immediate removal of this listing.

It is further agreed that plants, receiving stations or transfer stations, which receive milk or milk products for processing into milk or milk products for which that milk plant, receiving station or transfer station is listed, are from a non-listed source or a source having a Milk Sanitation Compliance Rating of less than ninety percent (90%), shall be immediately withdrawn from the Interstate Milk Shipper's List.

SIGN AND RETURN TO MY State Department of Health WITHIN FIVE (5)
DAYS OF RECEIPT. (Name of Agency)

NAME OF SHIPPER

My HACCP Dairy Plant

SIGNATURE OF REPRESENTATIVE

I. Havepride

TITLE

Chief Operating Officer

DATE

January 29, 2016

PERMISSION FOR PUBLICATION
Interstate Milk Shipper's Listing

SHIPPER'S NAME

Clean Milk Dairy

ADDRESS

2525 Milky Way, Moosville, State 00007

You are hereby advised that on (date[s]) August 3-7, 2016 a Rating
or HACCP Listing Audit was conducted with the following results:

Producer Supply (BTU) 92% Transfer Station NA

Receiving Station NA Milk Plant 91%

Enforcement Rating (For all Ratings and for attached farm supplies of HACCP listings) 90%

The results will be transmitted to the U.S. Food and Drug Administration. They will publish the information in the "IMS List-Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers". The official Rating or HACCP Listing is valid for a period not to exceed two (2) years from the earliest rating/listing date, except if the Enforcement Rating is less than 90 percent (<90%), then the official Rating is valid for a period not to exceed six (6) months from the earliest rating date, subject to the rules of the National Conference on Interstate Milk Shipments.

Publication Permission Section

Permission is hereby granted to release and publish the above-stated Rating or HACCP Listing for use by Regulatory Agencies and prospective purchasers.

It is understood and agreed by the undersigned that the official Rating or HACCP Listing Agency may review this supply at any time during the two (2)-year or six (6) month period, respectively, referred to above. *It is further understood* that we will notify the Rating or HACCP Listing Agency if any significant change should occur, which affects our raw milk supply, milk plant, receiving station or transfer station status, including products listed.

It is understood and agreed that the failure to maintain the Rating or HACCP System at a level, which is acceptable for listing, may result in immediate removal of this listing.

It is further agreed that plants, receiving stations or transfer stations, which receive milk or milk products for processing into milk or milk products for which that milk plant, receiving station or transfer station is listed, are from a non-listed source or a source having a Milk Sanitation Compliance Rating of less than ninety percent (90%), shall be immediately withdrawn from the Interstate Milk Shipper's List.

SIGN AND RETURN TO State Department of Health WITHIN FIVE (5)
DAYS OF RECEIPT. (Name of Agency)

NAME OF SHIPPER

Clean Milk Dairy

SIGNATURE OF REPRESENTATIVE

J. M. Bosse

TITLE

Chief Operating Officer

DATE

August 12, 2016

9. FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products)

Department of Health and Human Services Food and Drug Administration	NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products)
<i>(To be included with all NCIMS Aseptic Processing and Packaging Program and Retort Processed after Packaging Program Ratings/HACCP Listings and FDA Check Ratings/HACCP Audits.)</i>	
MILK PLANT ASEPTIC DAIRY	DATE OF RATING 10/8-9-2016
ADDRESS 100 PLANT DRIVE MOTOPIA, USA 00000	LICENSE/PERMIT NO. 80-001
RATING AGENCY USA MILK CONTROL AGENCY	
EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS UNDER THE NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM <i>(Use additional sheets as necessary.)</i>	
A narrative description shall be provided as a part of all NCIMS Aseptic Processing and Packaging Program and Retort Processed after Packaging Program Ratings/ HACCP Listings and FDA Check Ratings/HACCP Audits. This report shall include an evaluation of the following requirements:	
1. Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic and/or retort processed after packaging Grade "A" milk and/or milk products covered by a filing with the FDA LACF using Form FDA 2541c, or Form FDA 2341a, respectively, or equivalent electronic filing? Yes – FCE number 000000; Grade "A" Products: White Milks (Whole, 2%, 1% and Skim), Flavored Milk, including chocolate (Whole, 2% and Skim). SID 2005-01-12/001 indirect UHT processor. SUP SID 2005-01-12/2003 Tetra Pak A3/Flex. (Or refer to attached list of additional SIDs and SUP SIDs.)	
2. Are the milk plant's filed scheduled processes for all of its low-acid aseptic and/or retort processed after packaging Grade "A" milk and/or milk products developed by a recognized Process Authority qualified as having expert knowledge of thermal processing requirements? YES-Sterilization Processing System #1 and 2: Processing Authorities, Inc., 400 SE 1 st , Aseptic, State 00000 (George reviewer); Aseptic Fillers #3 and 4: Good Packaging, LLC, 1111 Filler Lane, Bottle, State 00000 (Johnny B. Sterile).	
3. Are the operators of the milk plant's aseptic processing and packaging systems and/or retort processed after packaging systems under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)? YES-Supervisors on site are: Jeff Plant-Better Processing Control School-Purdue University (10/2011); Robert Fixer-Better Processing Control School-WA State University (6/2005); and Jamie Boss-Better Processing Control School-University of Arkansas (8/2010).	
4. Is the milk plant currently under an "Order of Determination of Need" for an Emergency Permit? No.	

MILK SANITATION RATING REPORT

SECTION B. REPORT OF ENFORCEMENT METHODS

(Example: Aseptic or Retort Milk Plant)

SHIPPER ASEPTIC OR RETORT DAIRY
DATE OF RATING 10/8-10-2016

ENFORCEMENT RATING 91

DAIRY FARMS PART I						MILK PLANT PART II						INDIVIDUAL SHIPPER RATING PART III											
Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All dairy farmers hold a valid permit				5		1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5	5	1		Enter Total Credit from Part I under Percent Complying			NA	47	NA
2	5	All dairy farms inspected once every six (6) months or as required in Appendix "P"				15		2	5	Milk plant and receiving station(s) inspected once every three (3) months; aseptic and retort milk plant and transfer station(s) once every six (6) months	4	3	75	11.25		2		Enter Total Credit from Part II under Percent Complying			92.06	47/94	86.54
3	5	Inspection sheet posted or available				5		3	5	Inspection sheet posted or available				5	5	3	4	All milk and milk products properly labeled	5	4	80	6	4.80
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10		4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	1	.90	90	10	9	TOTAL CREDIT, PART III						91.34	
5	8	T B & Brucellosis certification on file as required				10		5	7 App I	Pasteurization equipment tested at required frequency (Not required for aseptic and retort milk plants.)	NA	NA	NA	NA	NA	INDIVIDUAL SHIPPER ENFORCEMENT RATINGS							
6	7	Water samples tested and reports on file as required				5		6	7	Individual and cooling water samples tested and reports on file as required	6	6	100	5	5	Individual Shipper of Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging:							
7	5	Milking time inspection program established				5		7	6	Samples of each milk plant's milk and milk products collected at required frequency and all necessary laboratory examinations made	5	4	80	8.00	<ul style="list-style-type: none"> Without Milk Plant, Receiving Station or Transfer Station: <ul style="list-style-type: none"> Evaluate all Items Part I and record. With Receiving Station(s) or Transfer Station(s): <ul style="list-style-type: none"> Evaluate all Items Part I. Evaluate all Items Part II., except Numbers 5 and 7. Divide by 75. Evaluate all Items Part III. 								
8	6	At least four (4) samples collected from each dairy farm's milk supply every six (6) months and all necessary laboratory examinations made				10		8	6 App B	Sampling procedures approved by PHS/FDA evaluation methods	1	1	100	10	Individual Shipper of Pasteurized Milk and Milk Products:								
9	6 App B	Sampling procedures approved by PHS/FDA evaluation methods				10		9	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	1	100	15	<ul style="list-style-type: none"> Aseptic and Retort Milk Plants: <ul style="list-style-type: none"> Evaluate all Items Part II., except Number 5. Divide by 85. With Attached Raw Supply: <ul style="list-style-type: none"> Evaluate all Items Part I. Evaluate all Items Part II., use 47 Weight. Evaluate all Items Part III. With Unattached Raw Supplies: <ul style="list-style-type: none"> Evaluate all Items Part II., use 94 Weight. Evaluate all Items Part III., except Number 1. Evaluate all Items Part III, except Number 1. 								
10	3,5, 6,16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15		10		Records systematically maintained and current	1	1	100	10	REMARKS								
11		Records systematically maintained and current				10		TOTAL CREDIT, Part II						92.06									
TOTAL CREDIT, Part I						Remarks																	
REMARKS						Room was in very poor condition. All existed but were not debited on the last inspection.						#3-Aseptic (or Retort) nonfat milk was not labeled as Grade "A" and "Keep Refrigerated After Opening".											
#2-One (1) of the required six (6) month inspections was missed (12/2015)						#7-Aseptic (or Retort) 2% chocolate milk, vitamins A & D fortified, did not have a vitamin assay conducted during 2015.																	
#4-Violation of Item 7(b) (4 pts)-Submerged water inlet in the CIP make-up tank. Item 15b(c) (5 pts)-Cross connection between the raw milk storage silo #2 and the CIP system in the receiving area: and Item 1(a) (1 pt)-The flooring in the APPS (or RPPS)						78.25/85 = 92.06																	

11. FORM FDA 2359e-STATUS OF MANUFACTURING PLANTS (Single-Service Containers and/or Closures for Milk and/or Milk Products)

STATUS OF MANUFACTURING PLANTS
(SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS)

Plant **Blow Mold Plastics**

Date of Certification **June 21, 2016**

Sanitation Compliance Rating¹ **85**

NAME OF PLANT	ITEMS OF SANITATION																				REMARKS								
	Floors	Walls and Ceilings	Doors and Windows	Lighting and Ventilation	Separate Rooms	Toilet/Facilities- Sewage Disposal	Water Supply	Handwashing Facilities	Plant Cleanliness	Lockers and Lunchrooms	Disposal of Wastes	Personnel - Practices	Protection From Contamination	Storage of Materials and Finished Product	Fabrication Equipment	Materials for Construction of Containers and/or Closures	Waxes, Adhesives, Sealants, Coating and Inks	Handling of Containers, Closures and Equipment	Wrapping and Shipping	Identification and Records		Surroundings	Bacterial Count*	Coliform Count*	Total Debits ²				
ITEM	1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c, f,g,i,k	13 d,e,h,j	14	15	16 a	16 b,c	17 a,b, d,e	17 c	18	19	20 a,b,f	20 c,d,e	21				
WEIGHT	1	1	2	2	3	3	4	2	3	2	2	3	3	11	3	5	11	3	3	11	2	4	3	11	2	5	10		
Blow Mold Plastics	1														3														15
																													SCR = 100-15 = 85
TOTALS	1														1										1				15

Footnotes:
¹ Sanitation Compliance Rating = 100 – Total Debits
² Total Debits for each manufacturing plant are the sum of the weights of the Items violated. (NOTE: Any Item or sub-item violated, indicate by placing the debit value (weight) of that Item or an “X” under that Item.)
 *Used only when not in compliance.

12. FORM FDA 2359d-REPORT OF CERTIFICATION (Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		REPORT OF CERTIFICATION <i>(Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)</i>			FOR FDA USE ONLY																						
					1	2	3	4	5																		
IDENTIFICATION																											
1. NAME OF SINGLE-SERVICE FABRICATING PLANT Blow Mold Plastics			2. CITY Container			3. STATE/COUNTRY Country																					
4. STREET 4200 Injection Point				5. MFG. CODE NO			6. CODE																				
							PRODUCT CODE		MATERIAL CODE																		
7. AGENCY OR SSC, AS APPLICABLE, PROVIDING ROUTINE INSPECTION Resin Single-Service Consultants 2100 Injection Point Nozzle, State 00000				56 XX	57 XX	58 0	59 1	60 1	61 -	62 3																	
7.a. RATING/ CERTIFICATION PERSONNEL <input type="checkbox"/> SHD <input type="checkbox"/> Other <input type="checkbox"/> SDA <input type="checkbox"/> TPC <input type="checkbox"/> SDL <input checked="" type="checkbox"/> SSC				7.b. DATE OF PLANT CERTIFICATION 6/21/2018			7.d. EXPIRATION DATE*			PRODUCT CODE (60) MATERIAL CODE (62) 1. Containers 1. Metal 2. Closures 2. Paper (Includes laminates) 3. Other products 3. Plastic 4. Containers and closures 4. Metal and paper 5. Containers and other 5. Metal and plastic products 6. Paper and plastic 6. Closures and other 7. Metal, paper and plastic products 8. Glass 7. Containers, closures and 9. Rubber other products 10. Paper, metal, plastic and glass 11. Ceramic																	
												7.c. SANITATION COMPLIANCE RATING 85		MONTH 0	DAY 6	YEAR 2	67	68	69	70	72	72					
*EXPIRATION DATE Certification of single-service manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest certification date. The expiration date is one (1) or two (2) years from the earliest certification date. NOTE: Certifications conducted by SSCs shall only be valid for a period not to exceed one (1) year from the earliest certification date.				8. SRO OR SSC Hammer Down, SSC			9. CERTIFICATION RECOMMENDED <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO		9a. LISTING TYPE <input checked="" type="checkbox"/> FULL <input type="checkbox"/> PARTIAL																		
LABORATORY CONTROL																											
10. NAME AND ADDRESS (OR CODE) OF APPROVED LABORATORY XX-XX-100																											
11. INSPECTION RESULTS (Place an "X" under Items debited)																											
1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c,f, g,i,k	13 d,e, h,j	14	15	16 a	16 b,c	17 a,b, d,e	17 c	18	19	20 a,b,f,	20 c,d,e	21	BACTI	COLI	
X														X										E			
12. PERMISSION TO PUBLISH																											
Permission is hereby granted to release and publish the above-stated certification for use by Regulatory/Rating Agencies and prospective purchasers. It is understood and agreed by the undersigned that the official Rating Agency or SSC, as applicable, may review and appraise the single-service fabricating plant at any time during the period of time the above certification is in effect. It is further understood that failure to maintain the above certification will subject this plant to withdrawal from the IMS Listing. We will notify the Rating Agency or SSC, as applicable, of any significant changes made in the operation of this plant.																											
12.a. NAME OF PLANT Blow Mold Plastics																											
12.b. OFFICER AUTHORIZING RELEASE Single Service					12.c. TITLE Owner																						
13. SUBMISSION OF REPORT BY MILK SANITATION RATING AGENCY OR SSC, AS APPLICABLE																											
13.a. DATE OF REPORT 6/22/2018			13.b. RECOMMENDED CLASSIFICATION ACCEPTED <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO				13.c. SUBMITTED BY (Signature and Title) Hammer Down, SSC																				
FOR FDA USE ONLY																											
14. DATE RECEIVED			15. PUBLICATION OF RATING RECOMMENDED <input type="checkbox"/> YES <input type="checkbox"/> NO <i>(If "NO", indicate why.)</i>																								
16. DATE TRANSMITTED			17. SIGNATURE (FDA Milk Specialist)																								

TABLE FOR COMPUTING PERCENT VIOLATION

Number of Dairy Farms or Milk Plants in Sample

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	50	1																																																																																	
100	50	33	25	20	17	14	13	11	10	9	8	8	7	7	6	6	6	5	5	5	5	5	4	4	4	4	3	3	3	3	3	3	3	3	3	3	3	3	3	2	2	2	2	2	2	1																																																																																
	100	67	50	40	33	29	25	22	20	18	17	15	14	13	13	12	11	11	10	10	9	9	8	8	8	7	7	7	7	6	6	6	6	5	5	5	5	5	5	5	5	5	5	4	4	4	3	2	2	2	2	2	1																																																																									
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APPENDIX A.

GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS (FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2))

PART I. DAIRY FARMS

Enforcement evaluation is based on NCIMS requirements, not on individual State's and/or Country's laws or regulations.

The term "permit", whenever it appears in this document shall also mean a MC operating under the ICP possessing a valid MOA with a TPC.

1. All dairy farm operators hold valid permits (*Grade "A" PMO*, Section 3. PERMITS). Prorate by the number of dairy farms in compliance.

- a. Every dairy farm operator, in compliance, holds a valid permit.
- b. Permits not transferable with respect to person and/or location.

2. All dairy farms inspected at least once every six (6) months or as required under Appendix P. (*Grade "A" PMO*, Section 5. INSPECTION OF DAIRY FARMS and APPENDIX P. PERFORMANCE-BASED DAIRY FARM INSPECTION SYSTEM). Prorate by the number of dairy farms in compliance.

NOTE: A single dairy farm BTU shall be prorated by the number of inspections in compliance with the required frequency.

Every dairy farm inspected at least once every six (6) months or as required by Appendix P.

NOTE: Use *MMSR*, Section D., 1., e. and D., 2., e. as a guide: "The interval shall include the designated period, plus the remaining days of the month in which the inspection is due."

3. Inspection sheets posted or available (*Grade "A" PMO*, Section 5. INSPECTION OF DAIRY FARMS). Prorate by the number of dairy farms in compliance.

A copy of the most recent inspection report shall be available at the dairy farm.

4. Requirements interpreted in accordance with the *Grade "A" PMO* as indicated by past inspections (*Grade "A" PMO*, Section 7. STANDARDS FOR MILK AND MILK PRODUCTS). Prorate by the number of dairy farms in compliance.

NOTE: A single dairy farm BTU shall be prorated by significant interpretation violation(s) not noted on previous inspection reports. For each Item that is identified as being misinterpreted, the value to be taken off from a possible 100 points corresponds to the weight value identified per Item on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-

PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING.

- a. Sanitarian's criterion is neither too lenient nor too stringent.
- b. Significant violations, including construction, debited by the sanitarian on the most recent inspection.
- c. Sanitarian recognizes violations and debits as appropriate on the previous inspection reports.

5. Tuberculosis and Brucellosis Certification on file as required (*Grade "A" PMO*, Section 8. ANIMAL HEALTH and APPENDIX A. ANIMAL DISEASE CONTROL). All or nothing Item based on record verification.

- a. Located in a Certified Brucellosis - Free Area as defined by USDA and enrolled in the testing program for such areas; or
 - 1.) Meet USDA requirements for an individually certified herd; or
 - 2.) Participate in an approved milk ring testing program; or
 - 3.) Have individual blood agglutination testing done annually; or
 - 4.) For goat, sheep, water buffalo, or any other hooved mammal herds/flocks, excluding cattle and bison, they are included in an official annual written certification from the State Veterinarian documenting their brucellosis-free status.
- b. Located in an Area, which has a Modified Accredited Advanced Tuberculosis status or greater as determined by USDA. Other Areas or herds shall have passed an annual tuberculosis test or the Area has established a tuberculosis testing protocol that assures tuberculosis protection and surveillance of the dairy industry and is approved by FDA, USDA and the State Regulatory Agency.
- c. Tuberculosis and/or Brucellosis certificates on file as required by the Regulatory Agency.
- d. Notice of status changes readily available to the Regulatory Agency.
- e. Milk from Brucellosis reactor animals withheld as required.

NOTE: For the ICP, references to USDA and/or State within 5. above, shall mean the Government Agency responsible for animal disease control in the Country or region of that Country. The term "State Veterinarian" shall mean an individual veterinarian authorized for those activities in said Country or region of that Country.

6. Water samples tested and reports on file as required (*Grade "A" PMO*, Section 7. STANDARDS FOR MILK AND MILK PRODUCTS, APPENDIX D. STANDARDS FOR WATER SOURCES and APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS). Prorate by the number of dairy farms in compliance. A dairy farm missing one (1) water sample during a required time period shall not receive any credit for this Item.

NOTE: A single dairy farm BTU shall be prorated by the number of water samples tested during the required time period vs. the total number of water tests due per water system.

- a. Samples of private water supplies and recirculated cooling water systems taken upon initial construction/installation and within thirty (30) days after extensive repairs or alterations.
- b. Private water supplies sampled every three (3) years.
- c. Hauled water (cisterns) sampled in at least four (4) months out of six (6), at the point of use.
- d. Recirculated water sampled every six (6) months.
- e. Water supplies with buried well seals sampled every six (6) months.

NOTE: Use *Grade "A" PMO*, Section 7., Item 8r, ADMINISTRATIVE PROCEDURES #7, as a guide: "To determine if water samples have been taken at the frequency established in this Section, the interval shall include the designated period plus the remaining days of the month in which the sample is due."

- f. Sampling is not required for public, community, or rural water system(s), which are under EPA/applicable Government Water Control Authority and in compliance with their requirements.
- g. Appropriate follow-up investigation and re-sampling of the supply/system following a positive bacteriological result. (Within thirty (30) days.)
- h. Heterotrophic count performed when required by APPENDIX G. of the *Grade "A" PMO*.
- i. Samples submitted to a laboratory acceptable to the Regulatory Agency.
- j. Current record of sample results on file at the Regulatory Agency, back to the last rating.

NOTE: Applicable Government Water Control Authority requirements, which are less stringent than the *Grade "A" PMO*, shall be superseded by the *Grade "A" PMO*. Applicable Government Water Control Authority requirements, which are stricter than the *Grade "A" PMO*, shall not be considered in determining the acceptability of water supplies during ratings, check ratings, single-service listing evaluations and audits.

For Example: If the applicable Government Water Control Authority's law required more frequent individual water supply samples to be taken, a SRO conducting a rating, which includes that dairy farm, shall give that dairy farm full credit for water sample frequency, if the *Grade "A" PMO* minimum sampling frequency requirement is met, even though, the applicable Government Water Control Authority's frequency is not met.

Supplies other than individual water supplies, which have been approved as safe by the applicable Government Water Control Authority, shall be considered to be acceptable sources, as provided in Section 7. of the *Grade "A" PMO*, for Grade "A" inspections, as well as for all other IMS purposes, without further inspection of the spring, well or reservoir treatment facility(ies), testing records, etc.

7. Milking Time Inspection Program established (*Grade "A" PMO*, Section 5. INSPECTION OF DAIRY FARMS and Section 6. EXAMINATION OF MILK AND MILK PRODUCTS). All or nothing Item.

NOTE: Until FDA guidance is developed for a Milking Time Inspection Program; full credit is given for this Item.

8. At least four (4) samples collected in at least four (4) separate months from each dairy farm's milk supply, during any consecutive six (6) months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, and all necessary laboratory examinations made (*Grade "A" PMO*, Section 6. EXAMINATION OF MILK AND MILK PRODUCTS). Prorate by the number of dairy farms in compliance.

a. Four (4) samples taken from each dairy farm during any consecutive six (6) month period. However, if the production of Grade "A" raw milk is not on a continuous monthly basis and; therefore, cannot meet PMO sampling frequency as cited, then a sample of the Grade "A" raw milk shall be collected during each month of production for any consecutive six (6) month period. (Use *MMSR*, Page 10 as a guide.)

NOTE: Use *MMSR*, Section B., 2., e.2.), as a guide for frequency determination.

b. Required bacterial counts, somatic cell counts, drug residue and cooling temperature checks performed on each sample in an Official or Officially Designated Laboratory.

9. Sampling procedures approved by PHS/FDA evaluation methods (*Grade "A" PMO*, Section 6. EXAMINATION OF MILK AND MILK PRODUCTS; *EML*; and *STANDARD METHODS FOR THE EXAMINATION OF DAIRY PRODUCTS (SMEDP)*).

NOTE: Use *MMSR*, "GUIDANCE FOR COMPUTING ENFORCEMENT CREDIT FOR PART I, ITEM 9 AND/OR PART II, ITEM 8 OF FORM FDA 2359j-MILK SANITATION RATING REPORT, SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2)".

10. Permit issuance, suspension, revocation, reinstatement, hearings and/or court action taken as required (*Grade "A" PMO*, Section 3. PERMITS, Section 5. INSPECTION OF DAIRY FARMS, Section 6. EXAMINATION OF MILK AND MILK PRODUCTS and Section 16. PENALTY). The BTU shall be prorated by enforcement action(s) in compliance per dairy farm. Five (5) Categories (a-e) shall be utilized for determining compliance with this Item and each shall possess a value of twenty percent (20%) compliance. The Categories are as follows:

- a. Category I: Permit Issuance;
- b. Category II: Permit Suspension;
- c. Category III: Permit Revocation;
- d. Category IV: Permit Reinstatement; and
- e. Category V: Hearing/Court Action.

The Categories relate to the following Sanitation Requirements and Product Compliance. Compliance shall be prorated based on **full** compliance with each of the five (5) Categories.

NOTE: Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section J. #4 for an example of the Form.)

SANITATION REQUIREMENTS

Category I: Permit Issuance

- a. Inspected prior to the issuance of a permit.
- b. Permit issuance based on compliance.

Category II: Permit Suspension

- a. Notice issued for intent to suspend permit if an inspection(s) discloses a violation of a *Grade "A" PMO* requirement(s). Reinspection(s) made as required.
- b. Permit suspension upon violation of:
 - 1.) Section 3. for a serious health hazard or interference by the permit holder in the performance of the Regulatory Agency's duties; or
 - 2.) Section 5. for consecutive violation(s) of the same requirements of Section 7.
- c. Milk produced during suspension or while a monetary penalty is imposed for repeated inspection violations is not eligible for sale as *Grade "A"*.

NOTE: *Grade "A" PMO*, Section 3. states: "The Regulatory Agency may forego suspension of the permit, provided the milk and/or milk product in violation is not sold or offered for sale as a *Grade "A"* milk and/or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk and/or milk product in violation is not sold or offered for sale as a *Grade "A"* milk and/or milk product. Except, that a milk producer may be assessed a monetary penalty in lieu of permit suspension for violative counts provided"

The option to issue a monetary penalty in lieu of a permit suspension as cited above shall not be applicable to a TPC authorized under the ICP.

Category III: Permit Revocation

Action to revoke a permit taken upon multiple suspensions.

Category IV: Permit Reinstatement

Reinstatement procedures followed.

NOTE: *Grade "A" PMO*, Section 3. states: "Within one (1) week of the receipt of such notification {of correction}, the Regulatory Agency shall make an inspection/audit of the applicant's facility and as many additional inspections/audits thereafter as are deemed necessary to determine that the applicant's facility is complying with the requirements."

Category V: Hearing/Court Action

Hearings provided for as required.

PRODUCT COMPLIANCE

Category II: Permit Suspension

- a. All milk produced during suspension or while a monetary penalty is imposed for bacterial, somatic cell, cooling temperature or drug residue violation is not eligible for sale as Grade “A”.
- b. When two (2) out of the last four (4) samples exceed the standards, a written notice is sent, and an additional sample is taken within twenty-one (21) days of the date of the notice, but not before three (3) days.
- c. Permit suspension; stop sale; or imposition of a monetary penalty upon violation of:
 - 1.) Section 3. for serious health hazard; or
 - 2.) Section 6. for:
 - i. Three (3) out of the last five (5) samples exceeding the bacterial, somatic cell, or cooling temperature standards; or
 - ii. “Four (4) in six (6) months” positive antibiotic (not of Appendix N. origin); or
 - iii. If pesticide contaminated milk is not withheld from sale.

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above shall not be applicable to a TPC authorized under the ICP.

Category IV: Permit Reinstatement

- a. Temporary permit issued as required on reinstatement(s) following somatic cell count resampling, which indicates the milk supply to be within acceptable limits; or reinspection (bacterial or cooling temperature standards violation) made within one (1) week following proper notification, except after reinstatement for a drug residue or with resampling for somatic cell standard.
- b. “Reinstating accelerated sample(s)” for bacterial, cooling temperature, or somatic cell counts taken at a rate of not more than two (2) per week on separate days within a three (3) week period.

For Example: FORM FDA 2359j-PART I, Item 10 Calculation (Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section J. #4 for an example of the Form.)

	Number Inspected	Number Complying	Percent Complying	Weight	Credit
Category I	25	25	100	20	20
Category II	25	22	88	20	17.6
Category III	25	25	100	20	20
Category IV	25	25	100	20	20
Category V	25	25	100	20	20

TOTAL CREDIT ► 97.6 = 98

TOTAL CREDIT to be entered into PART I, Item 10 “Percent Complying” column of FORM FDA 2359j. (Refer to Section K. #s 5, 9 and 11 for examples.)

11. Records systematically maintained and current (*Grade “A” PMO*, Section 3. PERMITS, Section 5. INSPECTION OF DAIRY FARMS, Section 6. EXAMINATION OF MILK AND MILK PRODUCTS, and Section 7. STANDARDS FOR MILK AND MILK PRODUCTS). Make use of both general record-keeping deficiencies and record keeping by dairy farm to determine the value. The BTU shall be prorated by the number of identified record-keeping deficiencies per dairy farm. The four (4) Categories (a-d) listed below shall be utilized for determining compliance with this Item and each shall possess a value of twenty-five percent (25%) compliance. Compliance shall be prorated based on **full** compliance with each of the four (4) Categories.

NOTE: Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section J. #4 for an example of the Form.)

a. Category I: Permit records available, accurate and current, including permit suspension, impositions of a monetary penalty, notices, reinstatement, etc. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used.

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above shall not be applicable to a TPC authorized under the ICP.

b. Category II: Inspection reports on file as directed by the Regulatory Agency and retained at least twenty-four (24) months. The results are entered on a milk ledger form or computer.

c. Category III: Bacterial counts, somatic cell counts, cooling temperatures, drug residues, pesticide results, and water analysis results promptly recorded on a milk ledger form or a computer program for each individual dairy farm. (Use the arithmetic average for bacterial counts, somatic cell counts and cooling temperature determinations when samples are collected from the same dairy farm on the same day from multiple storage tanks.)

d. Category IV: Within the Rating Period: Plan review file in order and written approval given for construction during the rating period.

For Example: FORM FDA 2359j-PART I, Item 11 Calculation (Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION D. DAIRY FARM ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 4). (Refer to Section J. #4 for an example of the Form.)

	Number Inspected	Number Complying	Percent Complying	Weight	Credit
Category I	25	25	100	25	25
Category II	25	25	100	25	25
Category III	25	23	92	25	23
Category IV	25	25	100	25	25

TOTAL CREDIT ► 98

TOTAL CREDIT to be entered into PART I, Item 11 “Percent Complying” column of FORM FDA 2359j. (Refer to Section K. #s 5, 9 and 11 for examples.)

PART II. MILK PLANTS

Enforcement evaluation is based on NCIMS requirements, not on individual State’s and/or Country’s laws or regulations.

The term “permit”, whenever it appears in this document shall also mean a MC operating under the ICP possessing a valid MOA with a TPC.

1. All milk plants, receiving stations and transfer stations operators hold valid permits (*Grade “A” PMO*, Section 3. PERMITS). All or nothing Item.
 - a. All milk plants, receiving and transfer stations hold a valid permit.
 - b. Permits retained only by those in compliance with the *Grade “A” PMO* requirements.
 - c. Permits not transferable with respect to persons and/or locations.

2. Milk plants and receiving stations inspected at least once every three (3) months (transfer stations, aseptic milk plants and retort milk plants once every six (6) months) (*Grade “A” PMO*, Section 5. INSPECTION OF MILK PLANTS). Prorate by the number of inspections in compliance with the required frequency.

For Example:

$$= \frac{\text{\# of three (3) or six (6) month periods with an inspection conducted}}{\text{Total \# of three (3) or six (6) month periods in rating period}}$$

- a. Milk plants and receiving stations inspected at least once every three (3) months.
- b. Transfer stations, aseptic milk plants and retort milk plants inspected at least once every six (6) months.

NOTE: Use *MMSR*, Section D., 1., e. as a guide: "...the interval shall include the designated period plus the remaining days of the month in which the inspection is due."

3. Inspection sheets posted or available (*Grade "A" PMO*, Section 5. INSPECTION OF MILK PLANTS). All or nothing Item.

A copy of the most recent inspection report shall be available at the milk plant, receiving station or transfer station.

4. Requirements interpreted in accordance with the *Grade "A" PMO* as indicated by past inspections (*Grade "A" PMO*, Section 7. STANDARDS FOR MILK AND MILK PRODUCTS.) Prorate by significant interpretation violation(s) not noted on previous inspection reports.

NOTE: For each Item that is identified as being misinterpreted, the value to be taken off from a possible 100 points corresponds to the weight value identified per Item on FORM FDA 2359L-STATUS OF MILK PLANTS.

- a. Sanitarian's criterion is neither too lenient nor too stringent.
- b. Significant violations, including construction, debited by the sanitarian on the most recent inspection.
- c. Sanitarian recognizes violations and debits as appropriate on the previous inspection reports.

5. Pasteurization equipment tested at required frequency (*Grade "A" PMO*, Section 7. STANDARDS FOR MILK AND MILK PRODUCTS and APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS-TESTS). Prorate by the number of units per quarter that were correctly tested within the required testing frequency vs. the total number of units.

NOTE: Not required for aseptic and retort milk plants, except when the APPS is utilized to produce aseptically processed and packaged Grade "A" milk and/or milk products and pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products. The APPS shall then be tested by the Regulatory Agency in accordance with the requirements cited in Section 7. of the *Grade "A" PMO*.

- a. Total required tests performed based on pasteurization system(s) equals the #-number of Vat Pasteurizers, plus the number of HTST Pasteurizers, plus the number of HHST Pasteurizers, plus the number of APPSs, if applicable as cited above, at the milk plant.

For Example:

$$* = \frac{\# \text{ of three (3) month periods} \times \# \text{ of pasteurizers properly checked within each period}}{\# \text{ of three (3) month periods} \times \text{Total \# of pasteurizers}}$$

***NOTE:** No credit for a period is given for a pasteurization unit unless all required tests for that unit have been correctly completed and recorded.

b. Test performed at required frequency, including semi-annual and quarterly tests conducted by the Regulatory Agency and daily tests conducted by an operator.

NOTE: Use *MMSR*, Section D., 4., a.1.) as a guide: "...the interval shall include the designated period plus the remaining days of the month in which the test(s) is due."

c. All tests made and properly recorded (required calculations available). The results shall be entered on appropriate ledger forms. A computer or other information retrieval system may be used.

6. Individual and cooling water samples tested and reports on file as required (*Grade "A" PMO*, Section 7. STANDARDS FOR MILK AND MILK PRODUCTS, APPENDIX D. STANDARDS FOR WATER SOURCES, and APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS). Prorate by the number of water samples tested during the required time period vs. the total number of water tests due per water system.

a. Total required water tests performed based on each water system requiring testing at the milk plant, receiving or transfer station.

For Example:

$$= \frac{\text{\# of test(s) performed at the required frequency per water system X \# of water systems}}{\text{\# of test(s) due at the required frequency per water system X \# of water systems}}$$

b. Samples of private water supplies and recirculated cooling water, including sweet water and glycol systems, taken upon initial construction/installation; within thirty (30) days after extensive repairs or alterations; and every six (6) months thereafter.

c. Sampling is not required for public, community, or rural water system(s), which are under EPA/applicable Government Water Control Authority and in compliance with their requirements.

d. Condensing water for milk evaporators and water reclaimed from milk or milk products complying with APPENDIX D. requirements.

e. Hauled water (cisterns) sampled in at least four (4) months out of six (6) months, at the point of use.

f. Water supplies with buried well seals sampled every six (6) months.

NOTE: Use *Grade "A" PMO*, Section 7., Item 7p, ADMINISTRATIVE PROCEDURES #7 as a guide: "To determine if water samples have been taken at the frequency established in this Section, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due."

g. Appropriate follow-up investigation and re-sampling of the supply/system following a positive bacteriological result. (Within thirty (30) days.)

h. Heterotrophic count performed when required by APPENDIX G. of the *Grade "A" PMO*.

i. Samples submitted to a laboratory acceptable to the Regulatory Agency.

j. Current record of sample results on file at the Regulatory Agency, back to the last rating.

NOTE: Applicable Government Water Control Authority requirements, which are less stringent than the *Grade "A" PMO*, shall be superseded by the *Grade "A" PMO*. Applicable Government Water Control Authority requirements, which are more strict than the *Grade "A" PMO*, shall not be considered in determining the acceptability of water supplies during ratings, check ratings, single-service listing evaluations and audits.

For Example: If the applicable Government Water Control Authority's law required more frequent individual water supply samples to be taken, a SRO conducting a rating, which includes that milk plant, shall give that milk plant full credit for water sample frequency, if the *Grade "A" PMO* minimum sampling frequency requirement is met, even though, the applicable Government Water Control Authority's frequency is not met.

Supplies other than individual water supplies, which have been approved as safe by the applicable Government Water Control Authority, shall be considered to be acceptable sources, as provided in Section 7. of the *Grade "A" PMO*, for Grade "A" inspections, as well as for all other IMS purposes, without further inspection of the spring, well or reservoir treatment facility(ies), testing records, etc.

7. Samples of each milk plant's milk and/or milk products collected at the required frequency and all necessary laboratory examinations made (*Grade "A" PMO*, Section 6. THE EXAMINATION OF MILK AND/OR MILK PRODUCTS). Prorate by the number of milk and/or milk products in compliance. (Refer to M-a-98, latest revision, for the FDA validated and NCIMS accepted test methods for the specific milk and/or milk products.)

a. During any consecutive six (6) months, at least four (4) samples of raw milk, after receipt by the milk plant, including aseptic and retort milk plants, shall be collected, prior to pasteurization, ultra-pasteurization, aseptic processing and packaging, or retort processed after packaging, in four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days.

b. During any consecutive six (6) months, at least four (4) samples of each Grade "A" milk and/or milk product processed, as defined in Sections 1. and 6. of the *Grade "A" PMO* shall be collected in four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. However, if the production of any Grade "A" milk or milk product, as defined in the *Grade "A" PMO*, is not on a continuous monthly basis and; therefore, cannot meet the PMO sampling frequency requirement as cited, then a sample of the Grade "A" milk or milk product shall be collected during each month of production.

c. All required examinations performed on each sample (bacterial, coliform, drug residue, phosphatase, and cooling temperature) in an Official or Officially Designated Laboratory.

NOTE: All pasteurized and ultra-pasteurized milk and/or milk products required sampling and testing is to be conducted only when there are test methods available that are validated by FDA and accepted by the NCIMS. Milk and/or milk products that do not have validated and accepted methods are not required to be tested. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.)

d. Assays of Vitamin A, D, and/or A and D fortified milk and/or milk products, including aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaging low-acid milk and/or milk products, conducted at least annually in an IMS Listed Laboratory. Credit for vitamin-fortified milk and/or milk products is not given unless vitamin analysis is completed and records are available. Each vitamin fortified product is evaluated separately. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods for vitamins.)

8. Sampling procedures approved by PHS/FDA evaluation methods (*Grade "A" PMO*, Section 6. EXAMINATION OF MILK AND MILK PRODUCTS; *EML*; and *SMEDP*).

NOTE: Use *MMSR*, "GUIDANCE FOR COMPUTING ENFORCEMENT CREDIT FOR PART 1, ITEM 9 AND/OR PART II, ITEM 8 OF FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2).

Items 4 and 7 on FORM FDA 2359j-MILK SANITATION RATING REPORT- SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) are not applicable for milk plants, receiving and transfer stations when calculating enforcement scores for FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), Part II, Item 8.

NOTE: Divide by seventy-five (75) instead of 100 when making the calculations.

9. Permit issuance, suspension, revocation, reinstatement, hearings and/or court action taken as required (*Grade "A" PMO*, Section 3. PERMITS, Section 5. INSPECTION OF MILK PLANTS, Section 6. EXAMINATION OF MILK AND MILK PRODUCTS and Section 16. PENALTIES). Prorate by enforcement action(s) in compliance.

NOTE: A milk plant shall be prorated by enforcement action(s) in compliance. Five (5) Categories shall be utilized for determining compliance with this Item and each shall possess a value of twenty percent (20%) compliance. The Categories are as follows:

- a. Category I: Permit Issuance;
- b. Category II: Permit Suspension;
- c. Category III: Permit Revocation;
- d. Category IV: Permit Reinstatement; and
- e. Category V: Hearing/Court Action.

The Categories relate to the following Sanitation Requirements and Product Compliance. Compliance shall be prorated based on **full** compliance with each of the five (5) Categories.

NOTE: Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5). (Refer to Section J. #5 for an example of the Form.)

SANITATION REQUIREMENTS

Category I: Permit Issuance

- a. Inspected prior to the issuance of a permit.
- b. Permit issuance based on compliance.

Category II: Permit Suspension

- a. Notice issued for intent to suspend permit if an inspection(s) discloses a violation of a *Grade "A" PMO* requirement(s). Reinspection(s) made as required.
- b. Permit suspension upon violation of:
 - 1.) Section 3. for a serious health hazard or interference by the permit holder in the performance of the Regulatory Agency's duties; or
 - 2.) Section 5. for sanitation and/or uncorrected critical processing elements; or
 - 3.) Section 5. for consecutive violation(s) of the same requirements of Section 7.
- c. Milk products processed during suspension or while a monetary penalty is imposed for repeated inspection violations is not eligible for sale as Grade "A".

NOTE: *Grade "A" PMO*, Section 3. states: "The Regulatory Agency may forego suspension of the permit, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade "A" milk and/or milk product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided the milk and/or milk product in violation is not sold or offered for sale as a Grade "A" milk and/or milk product. The option to issue a monetary penalty in lieu of a permit suspension as cited above shall not be applicable to a TPC authorized under the ICP.

Category III: Permit Revocation

Action to revoke a permit taken upon multiple suspensions.

Category IV: Permit Reinstatement

Reinstatement procedures followed.

NOTE: *Grade "A" PMO*, Section 3. states: "Within one (1) week of the receipt of such notification {of correction}, the Regulatory Agency shall make an inspection/audit of the applicant's facility and as many additional inspections/audits thereafter as are deemed necessary, to determine that the applicant's facility is complying with the requirements."

Category V: Hearing/Court Action

Hearings provided for as required.

PRODUCT COMPLIANCE

Category II: Permit Suspension

a. All milk and/or milk products produced during a permit suspension or while a monetary penalty is imposed for bacterial count, coliform count, cooling temperature or drug residue violations are not eligible for sale as Grade "A".

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above shall not be applicable to a TPC authorized under the ICP.

b. When two (2) out of the last four (4) samples exceed the limits, a written notice is sent, and an additional sample is taken within twenty-one (21) days of the date of the notice, but not before three (3) days.

c. When three (3) out of the last five (5) samples exceed the standards; or a positive drug residue or pesticide residue, the permit is immediately suspended.

d. Violation of Vitamin Fortification Levels (Refer to Appendix O. of the *Grade "A" PMO*): Determine the cause and re-sample or withhold product from the market.

e. Positive Phosphatase: Determine the probable cause and if the cause is improper pasteurization it shall be corrected before further sale of milk is allowed.

f. Positive Drug Residues or Pesticide Test: Investigate, determine the probable cause and correct before further sale of milk is allowed.

g. Permit suspension upon violation of:

1.) Section 3. for serious health hazard; or

2.) Section 6. for bacterial counts, coliform counts and cooling temperature violations if the product is not otherwise withheld.

h. All permits suspended as required by the *Grade "A" PMO*.

Category IV: Permit Reinstatement

a. All milk and/or milk product violations followed promptly by an inspection to determine the cause(s).

b. Temporary permit issued as required on reinstatement(s) and reinspection made within one (1) week following proper notification (except for drug residues).

c. "Reinstating accelerated samples" for bacterial, cooling temperature, or coliform counts taken at a rate of not more than two (2) per week, on separate days, within a three (3) week period.

d. All permits reinstated as required by the *Grade "A" PMO*.

10. Records systematically maintained and current (*Grade "A" PMO*, Section 3. PERMITS, Section 4. LABELING, Section 5. INSPECTION OF MILK PLANTS, Section 6. EXAMINATION OF MILK AND MILK PRODUCTS, and Section 7. STANDARDS FOR MILK AND MILK PRODUCTS.) Make use of both general and specific record-keeping deficiencies to determine the value. The four (4) Categories (I-IV) listed below shall be utilized

for determining compliance with this Item and each shall possess a value of twenty-five percent (25%) compliance. Compliance shall be prorated based on **full** compliance with each of the four (4) Categories.

NOTE: Use FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION E. MILK PLANT ENFORCEMENT ACTION AND RECORDS EVALUATIONS (PAGE 5). (Refer to Section J. #5 for an example of the Form.)

a. Category I: Permit records available, accurate and current, including permit suspension, imposition of a monetary penalty, notices, reinstatement, etc. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used.

NOTE: The option to issue a monetary penalty in lieu of a permit suspension as cited above shall not be applicable to a TPC authorized under the ICP.

b. Category II: Inspection reports and equipment tests filed as directed by the Regulatory Agency and retained for at least twenty-four (24) months. The results are entered on a milk ledger form or computer.

c. Category III: All test results for bacterial, coliform, cooling temperature, phosphatase, drug residues, pesticide, if available, and vitamin assay promptly recorded on an appropriate ledger or computer for each individual milk and milk product. (Use the arithmetic average for bacterial counts, coliform counts, and cooling temperature determinations when samples are collected of the same milk or milk product from the same milk plant on the same day from multiple storage tanks or silos.)

d. Category III: Records maintained on bacteriological examination of milk containers, if required.

e. Category III: Vitamin volume control records complete and on file at the milk plant as required.

f. Category IV: Within the Rating Period: Plan review file in order and written approval given for construction during the rating period.

PART III. INDIVIDUAL SHIPPER RATING

1. Refer to the "Total Credit", Part I value and multiply by "47", if an attached raw supply (dairy farms) is included with the milk plant listing. (Refer to the instructions below Part III on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2).) If an attached raw supply (dairy farms) is not included with the milk plant listing, leave this Item blank.

2. Refer to the "Total Credit", Part II value and multiply by "47", if an attached raw supply (dairy farms) is included with the milk plant listing; or by "94", if only an unattached raw supply(ies) (dairy farms) is utilized. (Refer to the instructions below Part III on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2).)

3. All milk and/or milk products properly labeled (*Grade "A" PMO*, Section 4. LABELING).
 - a. Prorate by Milk and/or Milk Product: Number of different milk and/or milk products correctly labeled vs. total number of milk and/or milk products, including raw.
 - b. Include in Label Review:
 - 1.) A representative label(s) for all milk and/or milk products produced, including raw. Milk and/or milk products are labeled according to the *Grade "A" PMO* definition(s) and requirements and applicable CFRs.
 - 2.) Vehicles hauling milk shall be properly identified with the name and address of the milk plant or hauler. (Include under raw milk.)
 - 3.) Milk cans from dairy farms properly identified. (Include under raw milk.)
 - 4.) Bills-of-lading and dairy farm weight tickets contain all the required information, including BTU #. (Include under raw milk where applicable.)

NOTE: All records shall be summarized in ledger form. Computer ledgers are acceptable. Records include:

- a. Inspections of dairy farms, milk plants, receiving and transfer stations, samplers, milk tank trucks, etc.;
- b. Laboratory information, i.e., raw milk, finished milk and/or milk products, vitamin assays, water, cooling media, etc.; and
- c. Equipment tests.

**GUIDANCE FOR COMPUTING ENFORCEMENT CREDIT FOR PART
I, ITEM 9 AND/OR PART II, ITEM 8 OF FORM FDA 2359j-MILK
SANITATION RATING REPORT-SECTION B. REPORT OF
ENFORCEMENT METHODS (PAGE 2)**

FORM FDA 2359j-MILK SANITATION RATING REPORT- SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) shall be used to determine enforcement credit for Part I, Item 9, FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (Dairy Farms), and Part II, Item 8, FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (Milk Plant). Items 4 and 7 on FORM FDA 2359j-MILK SANITATION RATING REPORT- SECTION C. EVALUATION OF SAMPLING PROCEDURES (PAGE 3) do not apply when calculating Enforcement Ratings for milk plants, receiving and transfer stations for FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), Part II, Item 8.

Item 1. Sampling Surveillance Officers (SSOs) Properly Certified

- a. All SSOs are certified by FDA.
- b. Certification is currently valid (three years).
- c. SSOs shall be a certified SRO, LEO or Regulatory Supervisor per "*Procedures*" Section V., F.

Item 2. Adequate Training Program Provided

- a. Reference material available to samplers.
- b. Training program conforms to established procedures.
- c. Training program implemented.
- d. Copies of training materials and other related information are on file for review.

Item 3. Sampling Surveillance Authority Properly Delegated

- a. Proper delegation procedures have been conducted.
- b. Only those eligible receive delegated authority.
- c. Initial Delegation: Comparison evaluations shall be performed on at least five (5) bulk milk hauler/samplers during a routine milk pick-up at a dairy farm; one (1) plant sampler that collects raw and finished milk and/or milk product samples and single-service container/closures at one (1) milk plant, if applicable; and one (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) milk plant, if applicable, with at least eighty percent (80%) agreement on each listed Item.
- d. Re-delegation conducted at least each three (3) years. Comparison evaluations shall be performed on at least two (2) bulk milk hauler/samplers during a routine milk pick-up at a dairy farm; one (1) plant sampler that collects raw and finished milk and/or milk product samples and single-service containers/closures at one (1) milk plant, if applicable; and one (1) industry plant sampler that collects a raw milk sample from a milk tank truck at one (1) milk plant, if applicable, with at least eighty percent (80%) agreement on each listed Item.

- e. Proper certification of industry field personnel when applicable.

Item 4. Permit Issuance (Applies to Part I-DAIRY FARMS Only)

- a. All bulk milk hauler/samplers have a valid permit.
- b. Inspected prior to the issuance of a permit.
- c. Only bulk milk hauler/samplers who comply with *Ordinance* requirements shall be entitled to receive a permit.
- d. Permits not transferable with respect to persons.

Item 5. Sampler (Including Dairy Plant and Industry Plant Samplers at the Receiving Site) Evaluated Every Two (2) Years and Reports Properly Filed

- a. Samplers shall have their sampling collection procedures evaluated by a certified SSO or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO) every two (2) years. SSOs or dSSOs are not required to be evaluated for sampling collection procedures.

NOTE: Use *Grade "A"* PMO, Section 5., **ADMINISTRATIVE PROCEDURES, INSPECTION FREQUENCY** as a guide: "For the purposes of determining the inspection frequency for bulk milk hauler/samplers, industry plant samplers and dairy plant samplers, the interval shall include the designated twenty-four (24) month period plus the remaining days of the month in which the inspection is due."

- b. Proper Agencies are advised of all samplers and of all evaluations annually in accordance with procedures.

Item 6. Sampling Procedures in Substantial Compliance

- a. Appraisal of each sampler's compliance done by record review.
- b. Appraisal of sampler's compliance.
- c. Evaluation criteria neither too stringent nor too lenient.

Item 7. Permit Suspension, Revocation, Reinstatement, Hearings and/or Court Actions Taken as Required (Applies to Part I- DAIRY FARMS Only)

- a. Action taken on repeat violations of sampling requirements.
- b. Re-evaluations made as required.

Item 8. Records Systematically Maintained and Current

- a. Records of the delegation of sampling evaluation authority to other Regulatory Agency or industry individuals on file and available for review with the dairy farm or milk plant records.
- b. Records of each sampler evaluation on file and available for review with the dairy farm or milk plant records.

- c. Records for each sampler evaluation entered on individual history cards or computer ledgers.
- d. Records of permit issuance, suspension, reinstatement, revocation and hearings on file and available for review.
- e. Records of bulk milk hauler/sampler, dairy plant sampler and industry plant sampler inspections on file.

APPENDIX B.

TABLE OF DAIRY FARM WATER SUPPLY VIOLATIONS

The following Table was accepted by the NCIMS Executive Board for use as guidance in evaluating dairy farm water supplies. The Table provides guidance, which may be used to differentiate between two (2) point (minor) and five (5) point (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 (5 point)	Minor (2 point)
<p><u>1. Any openings that allow direct contamination of the well water, such as:</u></p> <ul style="list-style-type: none"> 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. 	<p><u>1. Any openings that allow indirect contamination of the well water:</u></p> <ul style="list-style-type: none"> 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.
<p><u>2. Large hole/depression, indication of erosion around well casing or standing water around well casing.</u></p>	<p><u>2. Slight depression around well with no evidence of standing water.</u></p>

Major (5 point)	Minor (2 point)
<p>3. <u>Well pit does not meet the following requirements:</u></p> <ul style="list-style-type: none"> 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. 	<p>3. <u>Well pit does not meet the following requirements:</u></p> <ul style="list-style-type: none"> 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.
<p>4. <u>Spring box not properly constructed or protected:</u></p> <ul style="list-style-type: none"> 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. 	<p>4. <u>Spring box not properly constructed or protected:</u></p> <ul style="list-style-type: none"> a. Overflow piping not screened; b. Spring box cover not overlapping; and c. Minor construction deficiencies.
<p>5. <u>Water reservoir/cistern/tank construction and use:</u></p> <ul style="list-style-type: none"> 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. 	<p>5. <u>Water reservoir/cistern/tank construction:</u></p> <p>Minor construction problems.</p>
<p>6. <u>Buried well seal:</u> With a bad water sample not brought into compliance.</p>	<p>6. <u>Inaccessibility:</u> Except for seasonal conditions like snow and insulation wrap during winter months, the following water sources/supplies shall be accessible for routine inspection and rating evaluation:</p> <ul style="list-style-type: none"> a. Above ground wells and well pits; b. Cisterns, reservoirs and springs; and c. Stock waterers.

Major (5 point)	Minor (2 point)
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.).	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. Well casing terminating below or at ground level. (Does not include well pits or buried well seals complying with Item 8r of the <i>Grade "A" PMO</i> .)	8. Any pit not meeting the construction standards of the <i>Grade "A" PMO</i> , which is located within 10 feet (3 meters) of the well.
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.	

* If there is not any 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 (5 point)	Minor (2 point)
1. Last water sample unsatisfactory.	1. Last sample on record tested safe, but the next sample was not collected/analyzed within the required time frames: <ul style="list-style-type: none">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; andd. After Any Well Repair: Within thirty (30) days.
2. No record of an initial bacteriological sample on file prior to the issuance of a permit for new dairy 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 dairy 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 shall be sampled at the required frequency (M-I-86-9).	

CROSS-CONNECTIONS AND SUBMERGED INLETS:

(Items B and C)

Major (5 point)	Minor (2 point)
<p>1. <u>Submerged inlets: Into non-potable water, (i.e.):</u></p> <ul style="list-style-type: none"> 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. Water inlet to a CIP/wash vat is submerged in water or solution in the vat; and g. Chill water tank (sweet water, glycol, etc.). 	<p>1. <u>Potential submerged inlets:</u></p> <ul style="list-style-type: none"> a. Single-cased pipe in a stock tank or fountain; b. Properly working stock tank float located below the overflow rim of the tank; and c. Water inlet (equipped with an automatic shut-off) to a CIP/wash vat terminates below the rim of the vat, but is not submerged in water or solution. <p>(NOTE: If the float has stuck and it is submerged at the time of the inspection it is a five (5) point debit.)</p>
<p>2. <u>Permanent in-line high pressure pump (power washer): Without acceptable protection, such as:</u></p> <ul style="list-style-type: none"> 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. 	<p>2. <u>Portable high pressure water pump (power washer): Without acceptable protection, such as:</u></p> <ul style="list-style-type: none"> 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 applicable Government Water Control Authority. <p>(NOTE: Lack of a valve or improperly located valve, used to test the low-pressure cut-off switch is a two (2) point debit.)</p>
<p>3. <u>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.</u></p>	

Major (5 point)	Minor (2 point)
4. Anti-siphon vent-type backflow preventer with vent plugged.	
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 (5 point)

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.