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SOUTH CAROLINA

STATE REGISTER

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of the

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***South Carolina State Register***

An official state publication, the *South Carolina State Register* is a temporary update to South Carolina’s official compilation of agency regulationsthe *South Carolina Code of Regulations*. Changes in regulations, whether by adoption, amendment, repeal or emergency action must be published in the *State Register* pursuant to the provisions of the Administrative Procedures Act. The *State Register* also publishes the Governor’s Executive Orders, notices or public hearings and meetings, and other documents issued by state agencies considered to be in the public interest. All documents published in the *State Register* are drafted by state agencies and are published as submitted. Publication of any material in the *State Register* is the official notice of such information.

**Style and Format**

Documents are arranged within each issue of the *State Register* according to the type of document filed:

**Notices** are documents considered by the agency to have general public interest.

**Notices of Drafting Regulations** give interested persons the opportunity to comment during the initial drafting period before regulations are submitted as proposed.

**Proposed Regulations** are those regulations pending permanent adoption by an agency.

**Pending Regulations Submitted to the General Assembly** are regulations adopted by the agency pending approval by the General Assembly.

**Final Regulations** have been permanently adopted by the agency and approved by the General Assembly.

**Emergency Regulations** have been adopted on an emergency basis by the agency.

**Executive Orders** are actions issued and taken by the Governor.

**2005 Publication Schedule**

Documents will be accepted for filing on any normal business day from 8:30 A.M. until 5:00 P.M. All documents must be submitted in the format prescribed in the *Standards Manual for Drafting and Filing Regulations.*

To be included for publication in the next issue of the *State Register*, documents will be accepted no later than 5:00 P.M. on any closing date. The modification or withdrawal of documents filed for publication must be made **by 5:00 P.M.** on the closing date for that issue.

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After the date of hearing, the regulation must be submitted to the General Assembly for approval. The General Assembly has one hundred twenty days to consider the regulation. If no legislation is introduced to disapprove or enacted to approve before the expiration of the onehundredtwentyday review period, the regulation is approved on the one hundred twentieth day and is effective upon publication in the *State Register*.

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**2005-10**

**WHEREAS,** on April 20, 2005, I received a Decision of the South Carolina State Election Commission, in its capacity as the State Board of Canvassers, upholding the Order of the Charleston County Election Commission (Charleston County Board of Elections and Voter Registration) to overturn the January 11, 2005, special election for Charleston County Council District 7 due to voting irregularities that could have changed the outcome of the election; and

**WHEREAS,** on April 11, 2005, the South Carolina Supreme Court denied a writ of certiorari to hear a challenge to the Decision of the South Carolina State Election Commission thereby upholding its Decision to overturn the January 11, 2005, special election; and

**WHEREAS,** the Charleston County Board of Elections and Voter Registration (“Board”) has requested that a new election be held on Tuesday, July 19, 2005; and

**WHEREAS,** the Board has stated that, in requesting this date, it has complied with the notice provisions in the South Carolina Code of Laws and the pre-clearance requirements of Section 5 of the Voting Rights Act of 1965; and

**WHEREAS,** Section 7-13-1170 of the South Carolina Code of Laws (1976), as amended, provides “when any election official of any political subdivision of this State charged with ordering, providing for, or holding an election has neglected, failed, or refused to order, provide for, or hold the election at the time appointed, or if for any reason the election is declared void by competent authority, and these facts are made to appear to the satisfaction of the Governor, he shall, should the law not otherwise provide for this contingency, order an election or a new election to be held at the time and place, and upon the notice being given which to him appears adequate to insure the will of the electorate being fairly expressed. To that end, he may designate the existing election official or other person as he may appoint to perform the necessary official duties pertaining to the election and to declare the result.”

**NOW, THEREFORE,** pursuant to the authority vested in me by the Constitution and Statutes of the State of South Carolina, I hereby (a) order that a new election be held for Charleston County Council District 7 on July 19, 2005, subject to pre-clearance approval by the United States Department of Justice, or at the earliest possible date and time after July 19, 2005, as is permitted by the United States Department of Justice; and (b) designate the Charleston County Board of Elections Voter Registration to perform the necessary official duties pertaining to the election to declare the result.

**GIVEN UNDER MY HAND AND THE GREAT SEAL OF THE STATE OF SOUTH CAROLINA, THIS 29th DAY OF APRIL, 2005.**

**MARK SANFORD**

**Governor**

**2005-11**

**WHEREAS**, by Executive Order 1989-10, a Conservation, Education and Communications Advisory Board was created upon the request of the Wildlife and Marine Resources Commission and in furtherance of the objectives of that Commission; and

**WHEREAS**, conditions now exist which justify the rescission of the order creating such Commission.

**NOW**, **THEREFORE**, by virtue of the power and authority vested in me as Governor, pursuant to the Constitution and Statutes of the State of South Carolina, I hereby declare that Executive Order 1989-10 is cancelled, rescinded, and from this date declared null and void.

**GIVEN UNDER MY HAND AND THE GREAT SEAL OF THE STATE OF SOUTH CAROLINA, THIS 6th DAY OF MAY 2005.**

**MARK SANFORD**

**Governor**

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

Notice of General Public Interest

Public Notice #05-522-GP-N

May 27, 2005

The South Carolina Department of Health and Environmental Control (DHEC), Bureau of Air Quality, does hereby give notice of authorization being granted to the following source who has requested coverage under General Conditional Major Operating Permit (GCMP-04) “Concrete Batch Plants.” This general permit was previously open for a thirty (30) day public comment period on March 28, 2001, with final issuance on November 1, 2001. Pursuant to South Carolina Regulation 61-62.1, Section II G(7)(a)&(b), DHEC may now grant coverage to any qualified sources seeking to operate under the terms and conditions of this general permit. The authorization of each facility’s coverage shall be a final permit action for purposes of administrative review.

In accordance with the provisions of the Pollution Control Act, Sections 48-1-50(5) and 48-1-110(a), the 1976 Code of Laws of South Carolina, as amended, and Regulation 61-62.1 “Air Pollution Control Regulations and Standards,” this sources is hereby granted permission to discharge air contaminants into the ambient air. The Bureau of Air Quality authorizes the operation of this source in accordance with the plans, specifications, and other information submitted by the facility in the General Conditional Major Permit application. Any facility operating under this permit seeks to limit its potential to emit to below the thresholds which define a major source by complying with the federally enforceable conditions contained in the permit. Permit coverage is subject to and conditioned upon the terms, limitations, standards, and schedules contained in or specified on said permit.

Interested persons may review the final general permit, materials submitted by the applicant, and any written comments received, during normal business hours, at the following location: SC DHEC, Bureau of Air Quality, 2600 Bull Street, Columbia, South Carolina, 29201 at (803) 898-4123.

This notice is given pursuant to the requirements of South Carolina Regulation 61-62.1, Section II G(7)(c). Comments and questions concerning the following facility’s coverage under this permit should be directed to: Mr. Carl W. Richardson, P.E., Director, Engineering Services Division, Bureau of Air Quality, SC DHEC, 2600 Bull Street, Columbia, South Carolina, 29201 at (803) 898-4123.

**DEPARTMENT OF HEALTH AND ENVIRONMENAL CONTROL**

**NOTICE OF PROPOSED REVISION TO THE**

**SOUTH CAROLINA STATE IMPLEMENTATION PLAN**

**AND NOTICE OF PUBLIC HEARING**

**Synopsis:**

The South Carolina Department of Health and Environmental Control (Department) is proposing to revise the South Carolina State Implementation Plan also referred to as the SIP. The proposed revision is being conducted in accordance with our commitments under the Early Action Compact (EAC) process. The EAC process is an alternative to traditional nonattainment planning that allows local areas flexibility to control air emissions from their sources and offers a means to achieve cleaner air sooner than the Clean Air Act requires. In December 2002, the Department entered in compacts with the Environmental Protection Agency (EPA) and local governments for the purpose of developing ozone reduction strategies as part of the EAC process. The compacts require EAC areas to attain the 8-hour ozone standard by December 31, 2007, a date that is sooner than would otherwise be required through the traditional nonattainment designation process. The compacts include all necessary elements of a comprehensive air quality plan, but are tailored to local needs. As a result of an area’s participation, the EAC process calls for EPA to recognize the area’s commitment to early action by provisionally deferring the effective date of the nonattainment designation.

The EAC process sets forth a series of rolling deferrals that are contingent upon the participating area’s meeting all terms and milestones of the compact. On April 30, 2004 (69 FR 23857), following the completion of the first set of milestones, EPA promulgated the first deferrals of the effective date of the nonattainment designations for eligible EAC areas. In accordance with the EAC process, the Department submitted a final EAC SIP on December 29, 2004, consisting of local plans, including all adopted control measures, and a demonstration that the areas will attain the 8-hour ozone standard by December 31, 2007. After several discussions with the EPA, the Department has made some modifications to this final EAC SIP to include maintenance plan action triggers. Therefore, the Department is proposing to amend the SIP and allow opportunity to comment on these modifications as noticed below.

**Public Hearing**:

Staff of the Department will conduct a public hearing to receive public comments on the proposed revision of the SIP on June 30, 2005, at 10:00 a.m. in Room 2380 of the Aycock Building, South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC. Interested members of the public are invited to attend and comment on the proposed revisions. Interested persons may also submit comments in writing to Heather Preston at the South Carolina Department of Health and Environmental Control, Bureau of Air Quality, 2600 Bull Street, Columbia, SC 29201. To be considered, comments must be received by June 30 2005, the close of the comment period.

Copies of the proposed SIP revision for public notice and comment will be available at the public hearing. Copies may also be obtained by contacting Heather Preston at the South Carolina Department of Health and Environmental Control, Bureau of Air Quality, 2600 Bull Street, Columbia, SC 29201, or by calling (803) 898-4287.

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

In accordance with Section 44-7-200(C), Code of Laws of South Carolina, the public is hereby notified that a Certificate of Need application has been accepted for filing and publication May 27, 2005, for the following project(s). After the application is deemed complete, affected persons will be notified that the review cycle has begun. For further information, please contact Mr. Albert N. Whiteside, Director, Division of Planning and Certification of Need, 2600 Bull St., Columbia, SC 29201 at (803) 545-4200.

Affecting Charleston County

Addition of one (1) fixed four (4) slice Computed Tomography (CT) scanner.

Charleston Cancer Center, LLC

Charleston, South Carolina

Project Cost: $848,140

Construction of a replacement hospital with the addition of 40 general acute care beds and four Level II Neonatal Intensive Care bassinets to include replacement of a mobile Magnetic Resonance Imaging (MRI) service with a fixed MRI unit and replacement of an existing Computed Tomography (CT) Scanner with a multi-slice CT Scanner.

East Cooper Regional Medical Center

Mt. Pleasant, South Carolina

Project Cost: $159,612,353

Replacement of a linear accelerator and retention of the old existing linear accelerator for the pediatric population and time intensive treatments.

Medical University of South Carolina Medical Center

Charleston, South Carolina

Project Cost: $1,498,721

Affecting Chesterfield County

Construction to replace one (1) single-slice Computed Tomography (CT) scanner with a multi-slice CT scanner.

Chesterfield General Hospital

Cheraw, South Carolina

Project Cost: $744,879

Affecting Clarendon County

Construction of an addition to Clarendon Memorial Hospital to house the replacement of the existing mobile 1.0T Magnetic Resonance Imaging (MRI) unit with a fixed 1.5 MRI unit and replacement of the existing fixed Single Slice Computerized Tomography (CT) scanner with a fixed Sixteen (16) slice CT scanner.

Clarendon Memorial Hospital

Manning, South Carolina

Project Cost: $4,527,197

Affecting Greenville County

Construction for the addition of seven (7) psychiatric beds, to include renovation of the lobby and administrative areas for a total of seventy-six (76) licensed psychiatric beds and 13 substance abuse beds.

UHS of Greenville, Inc.

d/b/a The Carolina Center for Behavioral Health

Greer, South Carolina

Project Cost: $1,924,970

Affecting Horry County

Purchase and installation of a linear accelerator and the development of a freestanding radiation oncology facility in an existing building adjacent to Conway Medical Center in Conway, South Carolina.

South Carolina Radiation Oncology center, LLC

Conway, South Carolina

Project Cost: $2,810,406

Affecting Lexington County

Construction for an addition of fifty-six (56) nursing home beds, that do not participate in the Medicaid (Title XIX) program, for a total of 100 licensed nursing home beds.

Agape Nursing & Rehab, Inc.

West Columbia, South Carolina

Project Cost: $3,500,000

Affecting Richland County

Addition of sixty (60) nursing home beds that do not participate in the Medicaid (Title XIX) Program for a total of one hundred eighty (180) nursing home beds.

NHC HealthCare/Parklane, LLC

Columbia, South Carolina

Project Cost: $5,027,000

Affecting York County

Renovations and replacement of equipment for the interventional angiography suite.

Piedmont Medical Center

Rock Hill, South Carolina

Project Cost: $1,632,601

Renovations and replacement of the existing four (4) Slice Computerized Tomography (CT) scanner with a sixty-four (64) Slice CT scanner.

Piedmont Medical Center

Rock Hill, South Carolina

Project Cost: $1,957,980

In accordance with S.C. DHEC Regulation 61-15, the public and affected persons are hereby notified that the review cycle has begun for the following project(s) and a proposed decision will be made within 60 days beginning May 27, 2005. "Affected persons" have 30 days from the above date to submit comments or requests for a public hearing to Mr. Albert N. Whiteside, Director, Division of Planning and Certification of Need, 2600 Bull Street, Columbia, S.C. 29201. For further information call (803) 545-4200.

Affecting Aiken County

Establish an outpatient narcotic treatment program (Methadone Treatment Center) to be located at 1740 Jefferson Davis Highway, Graniteville, SC 29829.

Aiken Treatment Associates

Graniteville, South Carolina

Project Cost: $275,258

Affecting Charleston County

Replacement of a linear accelerator and retention of the old existing linear accelerator for the pediatric population and time intensive treatments.

Medical University of South Carolina Medical Center

Charleston, South Carolina

Project Cost: $1,498,721

Affecting Clarendon County

Construction of an addition to Clarendon Memorial Hospital to house the replacement of the existing mobile 1.0T Magnetic Resonance Imaging (MRI) unit with a fixed 1.5 MRI and replacement of the existing fixed Single Slice Computerized Tomography (CT) scanner with a fixed Sixteen (16) Slice CT scanner.

Clarendon Memorial Hospital

Manning, South Carolina

Project Cost: $4,527,197

Affecting Greenville County

Construction of a new replacement hospital to include the existing fifty-eight (58) general acute care beds and the conversion of the existing ten (10) hospital based nursing home beds to acute care beds for a total of sixty-eight (68) licensed general acute care beds.

Allen Bennett Memorial Hospital

Greer, South Carolina

Project Cost: $48,500,000

Change in licensure of five (5) long-term adult psychiatric beds to short-term adult psychiatric beds

for a total of 20 psychiatric beds and 68 Residential Treatment Facility (RTF) bed for children and adolescents.

SpringBrook Behavioral Health System

Travelers Rest, South Carolina

Project Cost: $-0-

Affecting Greenville County

Construction for the addition of seven (7) psychiatric beds to include renovation of the lobby and administrative areas for a total of seventy-six (76) licensed psychiatric beds and 13 substance abuse beds.

UHS of Greenville, Inc.

d/b/a The Carolina Center for Behavioral Health

Greenville, South Carolina

Project Cost: $1,924,970

Construction of a new nursing home to replace the existing 44 bed nursing home with the addition of 16 nursing home beds, which do not participate in the Medicaid (Title XIX) program, resulting in a total licensed capacity of 60 nursing home beds.

Fountain Inn Nursing Home

Fountain Inn, South Carolina

Project Cost: $3,922,205

Affecting Laurens County

Establish an outpatient narcotic treatment program (Methadone Treatment center) to be located at Lot 5, Professional Park Road, Clinton, South Carolina 29325.

Laurens Treatment Associates

Clinton, South Carolina

Project Cost: $262,000

Construction to establish an Ambulatory Surgical Facility (ASF) with two (2) operating rooms (ORs).

The Surgery & Laser Center at Professional Park, LLC

Clinton, South Carolina

Project Cost: $3,741,258

Affecting Richland County

Construction of an Ambulatory Surgery Facility (ASF) with two (2) licensed endoscopy rooms restricted to gastroenterology procedures only.

Berkeley Endoscopy Center, LLC

Columbia, South Carolina

Project Cost: $5,428,644

Addition of sixty (60) nursing home beds that do not participate in the Medicaid (Title XIX) Program for a total of one hundred eighty (180) nursing home beds.

NHC HealthCare/Parklane, LLC

Columbia, South Carolina

Project Cost: $5,027,000

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

Bureau of Land and Waste Management

Former Pontiac Bombing Range, Richland County

**NOTICE OF SETTLEMENT**

PLEASE TAKE NOTICE that the South Carolina Department of Health and Environmental Control ("SCDHEC") intends to enter into a Settlement Agreement with The United States Department of Defense, the United States Army (f/k/a The United States War Department), and The United States Army Corps of Engineers (referred to collectively as “the US” or “the United States”). Prior to final execution by SCDHEC, the Settlement Agreement is subject to a 30-day public comment period, consistent with the Comprehensive Environmental Response, Compensation, and Liability Act (“CERCLA”) Section 122, 42 U.S.C. Section 9622 and the South Carolina Hazardous Waste Management Act ("SCHWMA") S.C. Code Ann. Section 44-56-200 (2002).

The Settlement Agreement relates to the alleged release, and threatened release, of hazardous substances, pollutants, or contaminants at the Former Pontiac Bombing Range Site (the “Site”), located in Richland County, South Carolina, in and around the vicinity of 216 Cherry Stone Drive, 200 cherry Stone Drive and 107 Cherry Stone Drive. The Settlement Agreement provides for recovery of response costs from the US in the amount of $160,000.00 for the SCDHEC’s past response actions at the Site. In consideration of the foregoing, the Settlement Agreement provides for a release of the US from further liability related to the matters addressed by the Settlement Agreement and confers contribution protection upon the US pursuant to CERCLA Section 113, 42 U.S.C. Section 9613.

Notice of the proposed Settlement Agreement has been provided to all identified potentially responsible parties.

Copies of the Settlement Agreement may be obtained by providing a written Freedom of Information request to the South Carolina Department of Health and Environmental Control at:

Mr. Jody Hamm

Freedom of Information Office

South Carolina Department of Health and Environmental Control

2600 Bull Street

Columbia, SC 29201-1708

Any comments must be submitted in writing, postmarked no later than June 27, 2005, and addressed to:

Ms. Pat Vincent

Bureau of Land & Waste Management

South Carolina Department of Health and Environmental Control

2600 Bull Street

Columbia, SC 29201

UPON FINAL EXECUTION OF THE SETTLEMENT AGREEMENT, ANY AND ALL CLAIMS BY ANY AND ALL PERSONS AGAINST THE UNITED STATES SEEKING CONTRIBUTION FOR MATTERS ENCOMPASSED BY THE SETTLEMENT AGREEMENT SHALL BE FORECLOSED.

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

Bureau of Land and Waste Management

Philip Services Corporation Site, York County

**NOTICE OF SETTLEMENT**

PLEASE TAKE NOTICE that the South Carolina Department of Health and Environmental Control ("SCDHEC") intends to enter into a Cost Recovery Settlement Agreement with Caraustar Industrial and Consumer Products Group, Inc., the successor of Star Paper Tube, Inc. and its affiliate Rock Hill Paper Tube Plant #414 (jointly referred to as “Caraustar”). Prior to final execution by SCDHEC, the Cost Recovery Settlement Agreement is subject to a 30-day public comment period, consistent with the Comprehensive Environmental Response, Compensation, and Liability Act (“CERCLA”) Section 122, 42 U.S.C. Section 9622 and the South Carolina Hazardous Waste Management Act ("SCHWMA") S.C. Code Ann. Section 44-56-200 (2002).

The Cost Recovery Settlement Agreement relates to the release, and threatened release, of hazardous substances, pollutants, or contaminants at the Philip Services Corporation Site (the “Site”), located at 2324 Vernsdale Road, Rock Hill, South Carolina. The Cost Recovery Settlement Agreement provides for recovery of response costs from Caraustar in the amount of $5,000.00. In consideration of the foregoing, the Cost Recovery Settlement Agreement provides for a release of Caraustar from further liability related to the matters covered by the Cost Recovery Settlement Agreement and confers contribution protection upon Caraustar pursuant to CERCLA Section 113, 42 U.S.C. Section 9613.

Copies of the Cost Recovery Settlement Agreement may be obtained by providing a written Freedom of Information request to the South Carolina Department of Health and Environmental Control at:

Mr. Jody Hamm

Freedom of Information Office

South Carolina Department of Health and Environmental Control

2600 Bull Street

Columbia, SC 29201-1708

Any comments must be submitted in writing, postmarked no later than June 27, 2005, and addressed to:

Ms. Pat Vincent

Bureau of Land & Waste Management

South Carolina Department of Health and Environmental Control

2600 Bull Street

Columbia, SC 29201

UPON FINAL EXECUTION OF THE COST RECOVERY SETTLEMENT AGREEMENT, ANY AND ALL CLAIMS BY ANY AND ALL PERSONS AGAINST CARAUSTAR SEEKING CONTRIBUTION FOR MATTERS ENCOMPASSED BY THE COST RECOVERY SETTLEMENT AGREEMENT SHALL BE FORECLOSED.

**DEPARTMENT OF LABOR, LICENSING AND REGULATION**

**BUILDING CODES COUNCIL**

**NOTICE OF GENERAL PUBLIC INTEREST**

Notice is hereby given that, in accordance with Section 6-9-40 of the 1976 Code of Laws of South Carolina, as amended, the South Carolina Building Codes Council intends to update the National Electrical Code, 2002 Edition to the National Electrical Code, 2005 Edition.

The Council specifically requests comments concerning sections of this edition, which may be unsuitable for enforcement in South Carolina. Written comments may be submitted to Gary F. Wiggins, Board Administrator, at 110 Centerview Drive, 1st Floor, Columbia, SC, 29211-1329, (803) 896-4620, on or before October 20, 2005.

The South Carolina Building Codes Council will accept comments for 180 days and, if appropriate, convene a study committee pursuant to Section 6-9-40 for the consideration of the comments regarding the 2005 Edition of the National Electrical Code.

**CLEMSON UNIVERSITY**

CHAPTER 27

Statutory Authority S. C. Code Section 47-4-30

**Notice of Drafting:**

The State Livestock-Poultry Health Commission is considering amending Regulations 27-1010, 27-1013, 27-1015 and proposing new regulations regarding required official identification of sheep and goats moving both interstate and intrastate. Interested persons should submit their views in writing to Dr. Parr, Clemson LPHD, P.O. Box 102406, Columbia, SC 29224-2406. To be considered comments should be received no later than June 27, 2005, the close of the drafting comment period.

**Synopsis:**

The proposed amendments and new regulations will change the requirements for official identification of sheep and goats moving interstate and intrastate to make them consistent with federal requirements for Scrapie Consistent State Status.

The amendments and regulation will require legislative action.

**DEPARTMENT OF NATURAL RESOURCES**

CHAPTER 123

Statutory Authority: 1976 Code Sections 50-15-30, 50-15-40, 50-15-50 and 50-15-70

**Notice of Drafting:**

The South Carolina Department of Natural Resources is proposing to amend the existing regulations that list endangered species and non-game species in need of management in South Carolina. The Department will also amend the existing regulation for management of non-game wildlife in South Carolina.

Any person interested may submit written comments to D. Breck Carmichael, Jr., Deputy Director, Wildlife & Freshwater Fisheries Division, S.C. Department of Natural Resources, Post Office Box 167, Columbia, SC 29202.

**Synopsis:**

The proposed amendments will change the composition of both the list of species in need of management and the endangered species list for South Carolina. The Department proposes to remove the indigo snake from the list of endangered species, and add the southern hognose snake to the list of species in need of management. The Department will amend the Spotted Turtle Program regulation to change the reporting time for permits from annual reports to reporting every five (5) years. In addition the Department will correct several names of currently listed species to reflect recent changes in their taxonomy.

**Department of Revenue**

CHAPTER 117

Statutory Authority: 1976 Code Section 12-4-320

**Notice of Drafting:**

The South Carolina Department of Revenue is considering amending SC Regulation 117-335 concerning the sales and use tax and manufactured and modular homes to address a change in the law in 2004 as to how modular homes are taxed and to address the issue of furniture and appliances sold with manufactured and modular homes. The portion of the proposal concerning the taxation of furniture and appliances sold with manufactured and modular homes is consistent with present Department of Revenue policy.

Interested persons may submit written comments to Meredith F. Cleland, South Carolina Department of Revenue, Legislative Services, P. O. Box 125, Columbia, SC 29214. To be considered, comments must be received no later than 5:00 p.m. on June 28, 2005.

**Synopsis:**

The South Carolina Department of Revenue is considering amending SC Regulation 117-335 concerning the sales and use tax and manufactured and modular homes to address a change in the law in 2004 as to how modular homes are taxed and to address the issue of furniture and appliances sold with manufactured and modular homes. The portion of the proposal concerning the taxation of furniture and appliances sold with manufactured and modular homes is consistent with present Department of Revenue policy.

Document No. 2980

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: S.C. Code Section 48-1-10 *et seq.*

**Regulation 61-62, *Air Pollution Control Regulations and Standards,* and the South Carolina State Implementation Plan**

**Preamble:**

The United States Environmental Protection Agency (EPA) promulgates amendments to 40 CFR Parts 60, 61 and 63 throughout each calendar year. Recent Federal amendments include clarification, guidance and technical amendments regarding New Source Performance Standards (NSPS), National Emission Standards For Hazardous Air Pollutants (NESHAP) and National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories. The Department proposes to amend Regulations 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards;* 61-62.61, *National Emission Standards For Hazardous Air Pollutants (NESHAP)* and 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories* to incorporate recent Federal amendments promulgated during the period from January 1, 2004, through December 31, 2004. The Department also proposes to amend R. 61-62.1, *Definitions and General Requirements*, to incorporate amendments to the definition of Volatile Organic Compounds (VOCs) promulgated by the EPA on November 29, 2004.

The proposed amendments to Regulation 61-62, *Air Pollution Control Regulations and Standards,* are necessary to maintain consistency with Federal rules and will not require legislative review.

A Notice of Drafting for these proposed changes was published in the *State Register* on January 28, 2005. Since this amendment is consistent with Federal law, neither a preliminary fiscal impact statement nor a preliminary assessment report is required.

**Discussion of Proposed Revisions:**

SECTION CITATION:EXPLANATION OF CHANGE:

R. 61-62.1Amend Section I - Definition of VOC.

R. 61-62.60Tables in Subparts A, Cb, and GG are amended.

R. 61-62.60Subparts B, C and BBBB are added.

R. 61-62.61Subpart A is added.

R. 61-62.61Tables in Subpart M and Appendix B to Part 61 are amended.

R.61-62.63Subparts C, D, E, DDDD, EEEE, IIII, MMMM, PPPP, YYYY, ZZZZ, AAAAA, DDDDD, and EEEEE are added.

R. 61-62.63Tables in Subparts A, N, Q, LL, MM, EEE, JJJ, PPP, RRR, UUU, GGGG, HHHH, OOOO, and CCCCC are amended.

R. 61-62.63 (Subpart UUU)Add “and as subsequently amended upon publication in the *Federal Register*” to introductory paragraph.

R. 61-62.63 (Subpart HHHH)Add “and as subsequently amended upon publication in the *Federal Register*” to introductory paragraph.

**Notice of Staff Informational Forum:**

Staff of the Department of Health and Environmental Control invites interested members of the public to attend a staff-conducted informational forum to be held on June 27, 2005 at 10:00 a.m. in room 2280 at the Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC. The purpose of the forum is to receive comments from interested persons on the proposed amendments to Regulation 6162, *Air Pollution Control Regulations and Standards*.

Interested persons are also provided an opportunity to submit written comments to Anthony T. Lofton at the South Carolina Department of Health and Environmental Control, Bureau of Air Quality, 2600 Bull Street, Columbia, SC 29201. To be considered, comments must be received no later than 5:00 p.m. on June 27, 2005. Comments received shall be submitted to the Board in a Summary of Public Comments and Department Responses.

Copies of the proposed regulation for public notice and comment may be obtained by contacting Anthony T. Lofton at the South Carolina Department of Health and Environmental Control, Bureau of Air Quality, 2600 Bull Street, Columbia, SC 29201, or by calling (803) 898-7217.

**Notice of Public Hearing and Opportunity for Public Comment Pursuant to S.C. Code Sections 1-23-110 and 1-23-111:**

Interested members of the public and regulated community are invited to comment on the proposed amendments to Regulation 6162, *Air Pollution Control Regulations and Standards* at a public hearing to be conducted by the Board of Health and Environmental Control at its regularly-scheduled meeting on August 11, 2005. The public hearing is to be held in room 3420 (Board Room) of the Commissioner’s Suite, third floor, Aycock Building of the Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC. The Board meeting commences at 10:00 a.m. at which time the Board will consider items on its agenda in the order presented. The order of presentation for public hearings will be noted in the Board’s agenda to be published by the Department twenty-four hours in advance of the meeting. Persons desiring to make oral comments at the hearing are asked to limit their statements to five minutes or less, and as a courtesy are asked to provide written copies of their presentation for the record.

Interested persons are also provided an opportunity to submit comments on the proposed amendments to Anthony T. Lofton at the South Carolina Department of Health and Environmental Control, Bureau of Air Quality, Regulatory Development Section, 2600 Bull Street, Columbia, SC 29201, or by calling (803) 898-7217. To be considered, comments must be received no later than 5:00 p.m. on June 27, 2005. Comments received shall be considered by the staff in formulating the final proposed regulation for public hearing on August 11, 2005, as noticed above. Comments received shall be submitted to the Board in a Summary of Public comments and Department Responses.

**Statement of Need and Reasonableness:**

This statement of need and reasonableness was determined by staff analysis pursuant to S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION: Amendments to Regulation 61-62, *Air Pollution Control Regulations and Standards,* and the South Carolina State Implementation Plan*.*

*Purpose of Regulation:* These amendments and corrections will maintain conformity with Federal requirements and ensure compliance with Federal standards.

*Legal Authority*: The legal authority for Regulation 61-62, *Air Pollution Control Regulations and Standards*, and the South Carolina State Implementation Plan is S.C. Code Section 48-1-10 *et seq.*

*Plan for Implementation:* The proposed amendments will take effect upon approval and adoption by the South Carolina Board of Health and Environmental Control and publication in the *State Register.*

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATIONS BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The United States Environmental Protection Agency (EPA) promulgates amendments to 40 CFR Parts 60, 61 and 63 throughout each calendar year. Recent Federal amendments include clarification, guidance and technical amendments regarding New Source Performance Standards (NSPS), National Emission Standards For Hazardous Air Pollutants (NESHAP)and National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories. The Department proposes to amend Regulations 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*; *R.* 61-62.61, *National Emission Standards For Hazardous Air Pollutants (NESHAP)*; and 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories* to incorporate recent Federal amendments promulgated during the period from January 1, 2004, through December 31, 2004. The Department also proposes to amend R. 61-62.1, *Definitions and General Requirements*, to incorporate amendments to the definition of Volatile Organic Compounds (VOCs) promulgated by the EPA on November 29, 2004.

DETERMINATION OF COSTS AND BENEFITS:

There will be no increased cost to the State or its political subdivisions as a result of these amendments. The standards to be adopted are already effective and applicable to the regulated community as a matter of Federal law. The proposed amendments will benefit the regulated community by clarifying the regulations and increasing their ease of use.

UNCERTAINTIES OF ESTIMATES:

EPA has provided the estimated costs and benefits for these standards in the *Federal Register* notices that are cited within this document.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

Adoption of the recent changes in Federal law through the proposed amendments to Regulation 61-62, *Air Pollution Control Regulations and Standards*, and the South Carolina State Implementation Plan will provide continued protection of the environment and public health.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATIONS ARE NOT IMPLEMENTED:

While there is no specific detrimental effect on the environment and public health, the State’s authority to implement Federal requirements, which are believed to be beneficial to the public health and environment, would be compromised if these amendments are not adopted in South Carolina.

**Text:**

The full text of this regulation is available on the South Carolina General Assembly Home Page: **http://www.scstatehouse.net/regnsrch.htm.** Full text may also be obtained from the promulgating agency.

Document No. 2930

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: S.C. Code Sections 44-1-140(1); 1-23-10; -110

R. 61-41. Hotel – Motel Sanitation.

**Synopsis:**

R.61-41 was last revised in 1984. The requirements and need for R.61-41 are outdated and obsolete. Due to dwindling resources and prioritization of programs, the Department has not routinely inspected hotels and motels under this regulation in over 10 years; the Department continues to investigate complaints in hotels and motels. Furthermore, the hotel – motel industry has become largely self-regulating; the business is very customer-driven and competition dictates that facilities be maintained and operated properly. The public health concerns that the R.61-41 was intended to address can be addressed through other department regulations, such as R.61-56, Individual Sewage Treatment and Disposal Systems, and R.61-46, Nuisances. Since this regulation is no longer needed, and in the interest of good government and efficiency, the Department proposes repeal of R.61-41.

See Statement of Need and Reasonableness herein.

**Instructions:** Delete R.61-41 in its entirety.

**Text of Repeal:**

R.61-41**.** Hotel-Motel Sanitation.

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Section I. Definitions

A. APPROVED--means acceptable to the Health Authority based on relevant regulations, standards, and good public health practices.

B. DURABLE AND EASILY CLEANABLE--means material of sound construction, readily accessible and of such finish and so fabricated that residue may be completely removed by normal cleaning methods.

C. EXISTING FACILITY--means any facility which has been operated as a hotel-motel for any part of the year immediately prior to the adoption of this Regulation, or a facility upon which construction was commenced prior to the adoption of this Regulation and has progressed to a stage where modification is impracticable.

D. HEALTH AUTHORITY--means the authorized representative of the South Carolina Department of Health and Environmental Control.

E. HOTEL-MOTEL--means any building, part of a building, or group of buildings, containing rooms or units where overnight sleeping accommodations are available; provided, that the term shall not apply to private clubs, or to apartments, boarding homes, rooming houses, or portions thereof, where single night accommodations are not available.

F. NEW FACILITY--means any facility not encompassed in the definition of an existing facility.

G. PERMIT--means the document issued by the Health Authority indicating that a hotel-motel complies with this Regulation.

H. PERMIT HOLDER--means the owner or authorized agent.

I. SINGLE-SERVICE ITEMS--mean cups, containers, plastic liners, utensils and similar products constructed of paper, plastic foil, or similar materials, which are intended by the manufacturer and generally recognized as items to be used only once and then discarded.

Section II. Purpose

The purpose of this Regulation is to ensure that every hotel-motel permitted in this State shall be operated in a sanitary manner, free of any conditions which constitute a substantial hazard to the public's health.

Section III. Employees

HEALTH AND DISEASE CONTROL--All employees engaged in cleaning services, porterage, or other customer-contact services, shall wear clean outer garments and keep their hands clean. No person who is afflicted with boils, infected wounds, sores or any acute respiratory infection accompanied by fever, shall be engaged in the services described above.

Section IV. Conditions of Building

A. ROOMS AND UNITS--All rooms and units, furnishings and equipment therein shall be constructed of a durable and easily cleanable material, and be maintained in a sanitary condition.

B. TOILETS, LAVATORIES AND BATHING FACILITIES:

1. All new facilities shall provide toilets, lavatories and bathing facilities in each room or unit.

2. Toilets, lavatories, showers, and tubs shall be constructed of durable and easily cleanable material, shall be maintained in good repair, and shall be cleaned and disinfected daily.

3. The floors and walls of all toilets and bathrooms shall be of a durable and easily cleanable material and shall be kept clean.

4. Hot and cold water under pressure shall be provided to each lavatory. New facilities shall provide mixing faucets at each lavatory.

C. SERVICE SINK AND HOSE BIBBS--New facilities shall provide a service sink in each work room or janitor's closet. Back flow preventers shall be provided on all hose bibb faucets.

D. DRINKING FOUNTAINS--Drinking fountains shall be constructed of impervious material with an angle-jet nozzle protected by a non-oxidizing guard above the overflow rim of the bowl. Drinking fountains shall be equipped with a pressure regulating valve and be maintained in a sanitary manner.

E. VENTILATION:

1. Toilets and bathrooms shall be ventilated. Where the bathroom is mechanically vented into a pipe raceway, the raceway shall be ventilated to the exterior of the building.

2. Rooms or units shall have an operable window or transom area for ventilation or a mechanical system capable of exhausting 20 cfm of air, not including the bathroom vent.

3. Laundry rooms and other employee work areas shall be adequately ventilated.

4. Heating systems using combustion-type fuels shall be vented to the exterior of the building.

F. KITCHENETTES:

1. Kitchenettes and efficiency cooking equipment shall be constructed of durable and easily cleanable material, and maintained in a sanitary condition.

2. No enamelware, or cracked or chipped utensils shall be provided for use in kitchenettes.

3. The walls within the food preparation and service area of a kitchenette shall be constructed of a durable and easily cleanable material, washable up to the level of splash.

4. Garbage containers and single-service liners shall be provided.

G. LIGHTING: Adequate lighting shall be provided as follows:

1. At beds and/or other general areas, a minimum of ten foot candles, 30"' from the floor.

2. In laundry rooms, linen rooms, glass washing areas, kitchenettes or other work areas, a minimum of twenty foot candles, 30"' from the floor.

Section V. Linen, Bedding, and Toilet Supplies

1. Blankets, sheets, pillows, pillow cases, towels, wash cloths and bath mats shall be provided, and laundered, stored, and distributed in a sanitary manner. All body-contact linen shall be changed at least twice weekly and with every new occupant. Blankets shall be maintained in a clean condition.

2. Mattresses shall be covered with a washable mattress pad or water-proof material. Rubber sheets or water-proof backing on mattresses are acceptable for use under the mattress pad. All mattresses and covers or mattress pads shall be kept clean and maintained in good repair.

3. Non-washable pillows shall have an easily removable inner case between the pillow case and the pillow ticking. The inner case and/or washable pillow shall be kept clean and maintained in good repair.

4. Baskets or bins used to collect dirty lien shall not be used to redistribute clean linens to the rooms unless protected by single-service liner which is utilized only once and then discarded.

5. Toilet Supplies--Adequate toilet tissue and soap shall be provided for each occupant.

Section VI. Glasses, Ice Storage and Dispensing

A. GLASSES:

1. Multi-use glasses shall be collected daily, washed, rinsed, sanitized, and wrapped in a sanitary manner before being replaced in the room. Single-service drinking containers are acceptable for use, provided used containers are discarded daily and replaced with a new supply. All drinking containers shall be stored so as to prevent contamination.

2. Drinking glasses shall be cleaned in a manner acceptable to the Health Authority, such as:

Washing in a properly operating commercial dish machine with a 180°F. or chemical bactericide rinse

cycle, or

Washing, rinsing and sanitizing in a three compartment sink (lavatories, mop sinks, plastic buckets, or

similar compartments are not acceptable for washing glasses).

B. ICE:

1. All ice shall be purchased from a source permitted by the Health Authority or produced and stored at the hotel-motel in a clean and sanitary manner.

2. Ice Buckets:

Plastic, plastic lined or glass ice containers shall be collected from the rooms and washed, rinsed and

sanitized for each new guest.

b. Single-service ice buckets, such as wax-coated paper ice buckets, unless lined with single-service liners, shall be maintained in a sanitary condition or discarded and replaced for each new guest.

Section VII. Refuse and Vermin Control

A. REFUSE--Refuse shall be stored, collected and disposed of in a manner which prevents the breeding of flies and other vermin.

B. VERMIN CONTROL--All hotels-motels shall be free of vermin. Number sixteen mesh screens shall be installed and properly maintained on all operable windows.

Section VIII. Water and Sewage

A. WATER--Water shall be provided from a source permitted by the Health Authority, or otherwise meet all relevant Health Authority regulations.

B. SEWAGE--Sewage shall be disposed of in a manner permitted by the Health Authority, or otherwise meet all relevant Health Authority regulations.

Section IX. Food Service and Swimming Pools

All food services and swimming pools operated in conjunction with a hotel-motel must obtain applicable permits from the Health Authority.

Section X. Permitting and Enforcement Provisions

A. PERMITS

1. It shall be unlawful to operate a hotel-motel within the State of South Carolina without a valid permit issued to the operating entity by the Health Authority. Only a hotel-motel which complies with the requirements of this Regulation and is operated in a sanitary manner, free of any conditions which constitute a substantial hazard to the public's health, shall be permitted. Permits shall not be transferable from one operating entity to another operating entity. A valid permit shall be posted in every hotel-motel at a place designated by the Health Authority.

2. Any entity desiring to operate a hotel-motel shall make written application to the Health Authority for a permit.

3. Upon receipt of an application, the Health Authority shall make an inspection of the hotel-motel to determine compliance with this Regulation. When inspection reveals that the requirements of this Regulation have been met and that the hotel-motel is sanitary and free of any conditions which constitute a substantial hazard to the public's health, a permit shall be issued to the entity by the Health Authority.

B. INSPECTIONS AND NOTICES

1. The Health Authority shall inspect each hotel-motel located in the State of South Carolina prior to the issuance of a permit, and shall make inspections thereafter as necessary for the enforcement of this Regulation.

2. The Health Authority, after proper identification, shall be allowed to enter, at any reasonable time, any hotel-motel for the purpose of making inspections to determine compliance with this Regulation.

3. Whenever the Health Authority makes an inspection of a hotel-motel, it shall record the findings on an inspection report form and shall furnish a copy of such inspection report form to the permit holder.

4. Notice shall be deemed to have been properly served when a copy of the inspection form or other notice has been delivered personally to the permit holder, a responsible agent, or such notice has been sent by certified mail to the last known address of the permit holder. A copy of such notice shall be filed with the Health Authority.

C. SUSPENSION AND REVOCATION

1. The Health Authority may suspend or revoke a permit for repeated violation of any of the requirements of this Regulation, for the continuing existence of unsanitary conditions or other conditions which constitute a substantial hazard to the public's health, or for interference with the Health Authority in the performance of its duties under this Regulation. Prior to such action, the Health Authority shall notify the permit holder, in writing, stating the basis for suspension or revocation and advising that the permit shall be suspended or revoked on the fifteenth day following the mailing of the written notification, unless a request for a hearing is filed with the Health Authority by the permit holder within the fifteen day period.

2. A permit may be summarily suspended by the Commissioner of the Department of Health and Environmental Control or his designee, pending a hearing as herein provided if conditions exist which pose an immediate and serious threat to the public's health. In the case of a summary suspension, the permit holder shall be given a hearing, if requested, as soon as possible.

3. All hearings shall be conducted in accordance with the South Carolina Administrative Procedures Act.

D. ENFORCEMENT INTERPRETATION

This Regulation is issued under the authority of Section 44-1-140, Code of Laws of South Carolina, 1976, and subsequent legislation. It shall be enforced by the Health Authority in accordance with the best practices of public health as determined by the Board of Health and Environmental Control, and any conditions which have not been covered in this Regulation shall be handled in a like manner.

E. PENALTIES

Violation of this Regulation shall be a misdemeanor punishable under Section 44-1-150, Code of Laws of South Carolina, 1976, by fine not exceeding One Hundred Dollars or imprisonment not exceeding Thirty Days; and each day of continued violation after notice shall be a separate offense.

F. CONSTITUTIONALITY

If any part or provisions of this Regulation is declared unconstitutional or invalid for any reason, the remainder of the Regulation shall not be affected thereby.

G. REPEAL/AMENDMENT

The regulation dealing with this subject matter and filed in the Office of the Secretary of State on February 17, 1944, was repealed in its entirety by the regulation approved by the Legislature on April 22, 1979. The amendments to the April 22, 1979, regulation were approved by the Legislature on July 27, 1984.

H. PERMIT FEES

1. If a fee system is hereafter established by the Health Authority, proof of payment of the fee shall accompany each initial application and shall be furnished to the county health department within 30 days after the renewal date. If such proof is not so presented, the permit shall be immediately suspended until such proof is received, notwithstanding the sanitary conditions of the establishment.

2. Upon receipt of an application for a permit to operate a hotel-motel, accompanied by the required fee receipt, the local health department shall issue a permit if the establishment meets the requirements of this Regulation.

I. EFFECTIVE DATE

This Regulation shall become effective as provided by Section 1-23-120, Code of Laws of South Carolina, 1976.

**Fiscal Impact Statement:**

The Department estimates there will be no costs imposed on the State or its political subdivisions by this regulation repeal.

**Statement of Need and Reasonableness and Rationale:**

The Statement of Need and Reasonableness was determined by staff analysis pursuant to S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION:

Purpose:The purpose of this action is to repeal in entirety R.61-41, Hotel-Motel Sanitation.

Legal Authority:The legal authority for R.61-41 is Section 44-1-140(4) et seq., S.C. Code of Laws.

Plan for Implementation:None.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION REPEAL BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The requirements and need for R.61-41 are outdated and obsolete. Due to dwindling resources and prioritization of programs, the Department has not routinely inspected hotels and motels under this regulation in over 10 years. The public health concerns that the R.61-41 was intended to address can be addressed through other department regulations, such as R.61-56, Individual Sewage Treatment and Disposal Systems, and R.61-46, Nuisances. Since this regulation is no longer needed, and in the interest of good government and efficiency, the Department proposes repeal of R.61-41.

DETERMINATION OF COSTS AND BENEFITS:There are no anticipated costs or benefits associated with the repeal of this regulation. The hotel – motel industry has become largely self-regulating; the business is very customer-driven and competition dictates that facilities be maintained and operated properly.

UNCERTAINTIES OF ESTIMATES:None.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:There will be no effect on the environment or public health.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:There will be no detrimental effect on the environment or public health by the repeal of R.61-41.

**Statement of Rationale:**

This regulation is no longer needed, and in the interest of good government and efficiency, the Department proposes repeal of R.61-41.

Document No. 2926

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: S.C. Code Sections 44-1-140(3); 1-23-10; -110

R. 61-34.1. Pasteurized Milk And Milk Products

**Synopsis:**

R.61-34.1 ensures that consumers are receiving safe, high quality Grade “A” milk and milk products. The Regulation was amended last in 1993. These amendments will bring the Regulation into compliance with the latest guidelines of the Interstate Milk Shipments Conference Pasteurized Milk Ordinance and assure consumers that the latest sanitation requirements are being met by the dairy industry. Also, the United States Public Health Service, Food and Drug Administration (FDA) requires that South Carolina’s dairy regulation be at least as stringent as the Pasteurized Milk Ordinance in order for South Carolina milk producers to ship their products in interstate commerce and market their product as Grade “A” milk products; the FDA has previously cited the South Carolina program for not meeting this requirement. Amendments will also insure that the regulation complies with the requirements of the federal Nutrition Labeling and Education Act, the federal Food, Drug and Cosmetic Act, and the South Carolina Administrative Procedures Act, and is compatible with R.61-36, *Frozen Desserts*. Other related editorial and stylistic changes were included to improve the overall quality of the regulation.

See Summary of Revisions below and Statement of Need and Reasonableness herein.

**Summary of Revisions:**

SECTION / REVISION

Contents Table of Contents revised

61-34.1 I.A. Twenty definitions added, nomenclature of one definition changed and thirteen definitions revised to be consistent with the current Pasteurized Milk Ordinance (PMO).

61-34.1 I. B. All specific product standards being deleted due to new federal regulations allowing for extensive flexibility in labeling. Product standards are now covered by reference to 21 Code of Federal Regulations, Chapter 1 - Parts 130-131 and Appendix L. of the current PMO. Standards added for whey products to be consistent with the current PMO.

61-34.1 II.A.6. Drug residue adulteration violations revised, reconditioning of adulterated milk added, and drug avoidance control measures revised to be consistent with the current PMO.

61-34.1 III.A.2. Language added to grant exemption to agents, brokers, etc.

61-34.1 III.A.3. Language added to require separate permits for non-Grade “A” condensed or dry milk products.

61-34.1 III.A.4. Language changed to clarify reasons for permit suspension.

61-34.1 III.B.1. Permit requirement added for milk tank truck cleaning facilities to be consistent with the current PMO.

61-34.1 III.B.2.a. The term “growth inhibitors (drugs)” changed to “drug residue standards”.

61-34.1 III.B.2.b. Added specific requirement to stop all manufacturing operations immediately upon permit suspension added to be consistent with the current PMO.

61-34.1 III.B.2.c. Language changed to clarify hearing process.

61-34.1 III.B.3.a. Language added to clarify process for permit reinstatement.

61-34.1 III.B.3.c. Additional sentence added for compliance with somatic cell violations to be consistent with the current PMO.

61-34.1 III.B.4. Language added to allow DHEC to deny an application for a new permit based on past history.

61-34.1 IV.A.1. Labeling references changed to be consistent with the current PMO.

61-34.1 IV.A.2.a. Labeling requirements changed to be consistent with the current PMO.

61.34.1. IV.A.2.b. The words “condensed and/or dried” added to be consistent with the current PMO.

61-34.1 IV.A.2.d. Requirements for reconstituting or recombining of condensed and dry milk products added to the consistent with the current PMO.

61-34.1 IV.A.2.f. The term “UHT” deleted to be consistent with the current PMO.

61-34.1 IV.A.2.g. Changed from “goat” or “sheep” to “hooved mammal” to be consistent with the current PMO.

61-34.1 IV.A.4. Changed to be consistent with the current PMO - proper identification and sealing of tank trucks.

61-34.1 IV.A.4.a. Additional requirements for proper tanker identification added to be consistent with the current PMO.

61-34.1 IV.A.4.h. Specific temperature requirement added to be consistent with the current PMO.

61-34.1 IV.A.4.j. Wording added to be consistent with the current PMO.

61-34.1 IV.A.4.l. Sealing requirement added to be consistent with the current PMO.

61-34.1 IV.A.5. Milk tank truck identification information changed to be consistent with the current PMO.

61-34.1 IV.A.6. Unnecessary milk shipping required information deleted to be consistent with the current PMO.

61-34.1 IV.B.2. Condensing and/or drying” added to be consistent with the current PMO.

61-34.1 IV.B.2.a. Additional plant product identification added to be consistent with the current PMO.

61-34.1 IV.B.3. Dry milk product labeling requirements and the objection to using descriptive labeling terms added to be consistent with the current PMO.

61-34.1 V.A.1.Requirement added for a DHEC inspection of a milk tank truck cleaning facility to be consistent with the current PMO.

61-34.1 V.A.1.a. Name change to be consistent with the current PMO.

61-34.1 V.A.1.b. Name change and requirement added for an inspection of dairy plant and industry plant samplers to be consistent with the current PMO.

61-34.1 V.A.1.c. Deleted current inspection criteria of a transfer station to be in compliance with the current PMO.

61-34.1 V.A.1.d. Hazard Analysis Critical Control Point (HACCP) based regulatory inspections added to be consistent with the current PMO.

61-34.1 V.A.1.e. Inspection requirements added for milk tank truck cleaning facilities and transfer stations to be consistent with the current PMO.

61-34.1. V.A.2. Penalties revised on second inspections/audits to be consistent with the current PMO.

61-34.1 V.A.3. This section moved to 61-34.1 V.A.2. to correct punctuation and to be consistent with the current PMO.

61-34.1 V.A.4. This section moved to 61-34.1 V.A.2. to be consistent with the current PMO.

61-34.1 V.A.4.(new) This section added to be consistent with the current PMO regarding inspections and investigations.

61-34.1 V.A.5. This was previously 61.34.1 V.A.6. and reworded to be consistent with the PMO.

61-34.1 V.B.1. Nomenclature changed, inspection frequencies added, and audit frequencies added to be consistent with the current PMO.

61-34.1 V.B.2. Title of section added.

61-34.1. V.B.3. Terminology changed and additional facilities subject to permit suspensions and/or court actions added for repeated violations to be consistent with the current PMO.

61-34.1 V.B.3.a. Terminology changed and additional permit holders subject to penalty actions added to be consistent with the current PMO.

61-34.1 V.B.3.b. Terminology changed, additional permit holders subject to penalty actions added and a time period added before regulatory actions can be taken to be consistent with the current PMO.

61-34.1 V.B.5. Terminology changed and new criteria added for certified industry inspections to be consistent with the current PMO.

61-34.1 V.B.6. Criteria for audit reports to be filed added and report retention time increased from 12 to 24 months to be consistent with the current PMO.

61-34.1 VI.A.1. Terminology changed to consistent with the current PMO.

61-34.1 VI.A.2. Revised sampling criteria to be consistent with the current PMO.

61-34.1. VI.A.3. Revised sampling criteria, including drug testing, to be consistent with the current PMO.

61-34.1 VI.A.4. Terminology changed and criteria added for averaging samples to be consistent with the current PMO.

61-34.1 VI.A.7. Criteria added for drug residue testing to be consistent with the current PMO.

61-34.1 VI.A.9. Terminology changed, allowances made for the use of in-line samplers, HACCP requirements added, additional criteria added and a requirement for vitamin testing laboratories to be certified added to be consistent with the current PMO.

61-34.1 VI.B.2. Terminology changed to be consistent with the current PMO.

61-34.1 VI.B.3. Laboratory testing procedures, standards and methods revised to be consistent with the current PMO.

61-34.1 VI.B.4. Laboratory reference made to the “Standard Methods for the Examination of Dairy Products” to be consistent with the current PMO.

61-34.1 VI.B.5. Reference made to App. B of the current PMO for milk hauling program requirements.

61-34.1 VII.A.2. Terminology and standards revised and/or added to be consistent with the current PMO. Specific requirements added for processing heat-treated cream, whey and buttermilk products.

61-34.1 VII.B.1.a. Abnormal milk terminology changed to be consistent with the current PMO. Reference made to Appendix Q of the current PMO for automatic milking installations.

61-34.1 VII.B.1.b. Terminology changed and requirement to properly maintain milking equipment used on animals with abnormalities added to be consistent with the current PMO.

61-34.1 VII.B.2.a.(1) Specific requirements added for convalescent pens to be consistent with the current PMO.

61-34.1 VII.B.2.b.(8) Feed storage requirements moved to 61-34.1 VII.B.3.a. to be consistent with the current PMO.

61-34.1. VII.B.3.a. Feed storage requirements moved from 61-34.1 VII.B.2.b.(8) to this section to be consistent with the current PMO.

61-34.1. VII.B.3.b.(8) Requirements moved from 61-34.1 VII.B.15 to be consistent with the current PMO.

61-34.1 VII.B.4. Terminology changed, cooling ponds allowed, and explanation of cow yard sanitation criteria added to be consistent with the current PMO.

61-34.1 VII.B.5.a.(5) Parlor added as an area that cannot connect directly to an area used for domestic purposes; allowances made for a single or double acting door; and additional allowances for screen vents added to be consistent with the current PMO.

61-34.1 VII.B.5.a.(8) Terminology changed and criteria added for the use of transportation tanks for cooling and storage of milk on a dairy farm.

61-34.1 VII.B.5.b.(6) 220 lux added to be consistent with the current PMO.

61-34.1 VII.B.5.b.(11) Parlor added as an area that cannot connect directly to an area used for domestic purposes; allowances made for a simple or double acting door; and additional allowances for screen vents added to be consistent with the current PMO.

61-34.1 VII.B.5.b.(13) Criteria added for allowing milk to be transferred from a bulk milk tank to a bulk milk pickup tanker by stubbing the milk transfer and associated mechanically cleaned lines outside the milk house wall to be consistent with the current PMO.

61-34.1 VII.B.5.b.(16) Requirement for a second wash vat made optional with DHEC approval to be consistent with the current PMO.

61-34.1 VII.B.5.b.(17) Requirement for a shelter over a transportation tank made optional and criteria added for the use of a milk tank truck for cooling and storage of milk on a dairy farm.

61-34.1 VII.B.7. “Flies” changed to “insects” to be consistent with the current PMO.

61-34.1 VII.B.8.b.(7) Sampling criteria for hauled water changed to be consistent with the current PMO.

61-34.1 VII.B.9.b.(6) Terminology changed to be consistent with the current PMO.

61-34.1 VII.B.9.b.(7) Terminology changed to be consistent with the current PMO.

61-34.1 VII.B.9.b.(10) Specific criteria not allowed in product contact surface areas added to be consistent with the current PMO.

61-34.1 VII.B.9.b.(13) Specific criteria for use of flexible, plastic hoses added to be consistent with the current PMO.

61-34.1 VII.B.9.b.(14) Specific criteria for use of transparent flexible plastic tubing added to be consistent with the current PMO.

61-34.1 VII.B.9.b.(15) Requirements for Automatic Milking Installations (AMIs) added to be consistent with the current PMO. Association name change in “Note” to be consistent with the current PMO.

61-34.1 VII.B.10 Additional criteria added for cleaning utensils and equipment to be consistent with the current PMO.

61-34.1 VII.B.11.(2) Sanitization criteria revised to be consistent with the current PMO.

61-34.1 VII.B.12.a. “Meters” added as equipment allowed to be stored in parlor to be consistent with the current PMO.

61-34.1 VII.B.12.b.(1) Additional criteria added for allowing seasonally enclosed holding areas to be consistent with the current PMO.

61-34.1 VII.B.13(old) Section deleted to be consistent with the numbering in current PMO and corresponding inspection report. Items previously in this Section covered under other “utensils and equipment” sections.

61-34.1 VII.B.13(new) Renumbered to be consistent with the current PMO and corresponding inspection report.

61-34.1 VII.B.13.a. “Cows” changed to “lactating animals” to be consistent with the current PMO. This change consistent throughout the revised regulation.

61-34.1 VII.B.13.b.(4) Udder and teat preparation revised to be consistent with the current PMO.

61-34.1 VII.B.15(old) Section deleted to be consistent with the current PMO. Criteria for sursingle milk stools and anti-kickers covered under other sections.

61-34.1 VII.B.16(old) Renumbered to be consistent with the current PMO.

61-34.1 VII.B.14.a.(new) Renumbered to be consistent with the current PMO and corresponding inspection report. Product contact surface and vehicle protection from contamination criteria moved to this section for consistency with the current PMO.

61-34.1 VII.B.14.b.(4) Wording changed to be consistent with the current PMO.

61-34.1 VII.B.14.b.(5) “Stable or parlor” added for clarification purposes to be consistent with the current PMO.

61-34.1 VII.B.14.b.(8) Reference to Appendix H. of the current PMO added for air criteria specifications.

61-34.1 VII.B.14.b.(9-11)(Old) Moved to VII.B.15 to be consistent with the current PMO.

61-34.1 VII.B.14.b.(9-10)(New) Moved from old VII.B.13. to be consistent with the current PMO.

61-34.1 VII.B.14.b.(11-14) Moved from old VII.B.20. to be consistent with the current PMO.

61-34.1 VII.B.15.(new) Chemical storage and drug storage and use criteria revised to be consistent with the current PMO.

61-34.1 VII.B.16(new) Info was previously in VII.B.17., but renumbered to be consistent with the current PMO.

61-34.1 VII.B.16.a.&b.(2) A requirement to have both hot and cold or warm running water at handwash sink added to be consistent with the current PMO.

61-34.1 VII.B.17.(new) Info was previously in VII.B.18, but renumbered to be consistent with the current PMO.

61-34.1 VII.B.17.b.(1) “Other approved hand drying device” added to be consistent with VII.B.17.a.

61-34.1 VII.B.17.b.(2) Terminology changed to be consistent with the current PMO.

61-34.1 VII.B.18.(new) In current regulation, but renumbered to be consistent with the current PMO and corresponding inspection report.

61-34.1 VII.B.18.a.&b. Specific raw milk cooling criteria, including recording thermometers, added to be consistent with the current PMO.

61-34.1 VII.B.19(new) In current regulation, but renumbered to be consistent with the current PMO and corresponding inspection report.

61-34.1 VII.B.19.a.&b.(9-10) Specific criteria for the storage of feed added to this section to be consistent with the current PMO.

61-34.1 VII.B.19.b.(7) Reference added to Appendix C of the current PMO for insect and rodent control measures.

61-34.1 VII.B.20.(old) Deleted after moving requirements to VII.B.14 to be consistent with the current PMO and corresponding inspection report.

61-34.1 VII.B.21.(old) Deleted after moving criteria to VII.B.19. to be consistent with the current PMO and corresponding inspection report.

61-34.1 VII.C. Two paragraphs added for plants desiring to be regulated under a Hazard Analysis Critical Control Point (HACCP) system.

61-34.1 VII.C.1. Floor structure criteria also applied to plants manufacturing dry milk or mild products so as to be consistent with the current PMO.

61-34.1 VII.C.2.a. The word “packaged” added to be consistent with the current PMO.

61-34.1 VII.C.2.b.(1) Wording simplified and structural requirements applied for plants manufacturing dry milk or milk products so as to be consistent with the current PMO.

61-34.1 VII.C.3.e. “Flies” changed to “insects” to be consistent with the current PMO.

61-34.1 VII.C.4.a. Requirements for lighting and ventilation also applied to rooms where milk is packaged to be consistent with the current PMO.

61-34.1 VII.C.4.b.(1) Another acceptable way to measure light levels (lux) added to be consistent with the current PMO.

61-34.1 VII.C.4.b.(4) Ventilation requirement added for plants condensing and/or drying milk and milk products to be consistent with the current PMO.

61-34.1 VII.C.5.a. Section modified to include additional activities required to be done in separate rooms to be consistent with the current PMO.

61-34.1 VII.C.5.b.(1) Section rewritten to include additional activities in a plant that are required to be done in separate rooms to be consistent with the current PMO.

61-34.1 VII.C.5.b.(5) Note added as reference to requirements for facilities cleaning and sanitizing milk tank trucks to be consistent with the current PMO.

61-34.1 VII.C.6.b.(2) Processing rooms for condensed or dried products added to areas in which toilet room doors cannot open to be consistent with the current PMO.

61-34.1 VII.C.7.b.(2) Specific criteria added for individual water source criteria to meet the requirements of DHEC’s R.61-58.

61-34.1 VII.C.7.b.(3) Air gap criteria added to be consistent with the current PMO.

61-34.1 VII.C.7.b.(5) “Milk products” added to be consistent with the current PMO.

61-34.1 VII.C.7.b.(7) Water frequency determination criteria added to be consistent with the current PMO.

61-34.1 VII.C.7.b.(10) Steam vacuum evaporation potable water supply criteria added to be consistent with the current PMO.

61-34.1 VII.C.9.a.&b.(1) Additional areas with equipment limitations added to be consistent with the current PMO.

61-34.1 VII.C.9.b.(5) Product dust control measures added to be consistent with the current PMO.

61-34.1 VII.C.10.a. Additional criteria for piping, fittings and connections added to be consistent with the current PMO.

61-34.1 VII.C.10.b.(2)(d) Section separated from (c) above to be consistent with the current PMO.

61-34.1 VII.C.10.b.(5)(a) Specific welded pipeline inspection criteria deleted to be consistent with the current PMO.

61-34.1 VII.C.10.b.(5)(b) “Pipe” added before “line” to be consistent with the current PMO.

61-34.1 VII.C.10.b.(8) Threaded or welded exception made for pipelines in drying chambers to be consistent with the current PMO.

61-34.1 VII.C.11.b.(3) Additional criteria for joints, unacceptability of tile floors in dryers and condition that grease and oil be kept out of milk and milk products added to be consistent with the current PMO.

61-34.1 VII.C.11.b.(4) “Distributor” changed to “similar equipment” to be consistent with the current PMO.

61-34.1 VII.C.11.b.(5) Additional criteria and exceptions made for product contact surfaces to be in compliance with the current PMO.

61-34.1 VII.C.11.b.(6) Exception made to allow threaded connections for safety purposes in high pressure lines to be in compliance with the current PMO.

61-34.1 VII.C.11.b.(8) “Dry whey” added to be consistent with the current PMO.

61-34.1 VII.C.11.b.(10) The word “Closures” added in name of Guidelines and criteria added for condensed and dry milk and milk product packaging.

61-34.1 VII.C.11.b.(11) Construction criteria for dry milk product sifters added, and Association name changed in “Note” to be consistent with the current PMO.

61-34.1 VII.C.12. Cleaning and sanitizing criteria for containers and equipment changed to be consistent with the current PMO. Specifically, requirements added for milk condensers, dryers and milk tank trucks; requirements added for allowances of extended runs; requirements added for recording devices for tanks; updates make for laboratory testing of multi-use and single-service containers and closures; and requirements updated for plants using multi-use plastic containers for pasteurized milk and milk products.

61-34.1 VII.C.13. Additional criteria for storage of multi-use containers, equipment and utensils added to be consistent with the current PMO.

61-34.1 VII.C.14. “Liners and bags” added to list of single-service material that must meet certain criteria to be consistent with the current PMO.

61-34.1 VII.C.15. The section contains many changes of which all are being made to be consistent with the current PMO. The minor changes include such things as adding “Grade A” before milk and milk products, revising nomenclature of “transport tankers” and Grade “A” dairy products, and adding “and milk products” after the word “milk”The Astrobiology Field LaboratorySeptember 26, 2006Final report of the MEPAG Astrobiology Field Laboratory Science Steering Group (AFL-SSG)SSG Members: Andrew Steele and David Beaty (co-chairs), , Jan Amend, Bob Anderson, Luther Beegle, Liane Benning, Janok Bhattacharya, David Blake, Will Brinckerhoff, Jennifer Biddle, Sherry Cady, Pan Conrad, John Lindsay, Rocco Mancinelli, Greg Mungas, Jack Mustard, Knut Oxnevad Jan Toporski, Hunter Waite(For correspondence, please contact a.steele@gl.ciw.edu 202-478-8974, or David.Beaty@jpl.nasa.gov, 818-354-7968)This report has been approved for public release by JPL Document Review Services (Reference Ref. # CL#06-3307), and may be freely circulated. Suggested bibliographic citation:Steele, A., Beaty, D.W., Amend, J., Anderson, R., Beegle, L, Benning, L, Bhattacharya, J., Blake, D., Brinckerhoff, W., Biddle, J., Cady, S., Conrad, P., Lindsay, J., Mancinelli, R., Mungas, G., Mustard, J., Oxnevad, K., Toporski, J., and Waite, H. (2005). The Astrobiology Field Laboratory. Unpublished white paper, 72 p, posted Dec., 2005 by the Mars Exploration Program Analysis Group (MEPAG) at http://mepag.jpl.nasa.gov/reports/index.html.Table of ContentsTable of Contents2Membership41.0EXECUTIVE SUMMARY52.0AFL CHARTER82.0DEFINTIONS104.0INTRODUCTION125.0SCIENCE GOALS135.1 Assumptions135.2 Objectives165.2.1 Habitability165.2.2 Extinct or Extant Life. Abiotic or Prebiotic Material175.2.2.1 What techniques have been used to detect and characterize terrestrial and meteoritic biosignatures?225.2.2.2 What are the challenges for AFL in the search for biosignatures on Mars?235.3 Preservation Potential256.0Precursor Discoveries257.0Mission Site Selection267.1 Sediments277.2 Hydrothermal297.3 Ice337.4 Water388.0Core Mission Components398.1 Payload strategy408.2 Core Measurements and Instrumentation418.3 Sampling and Precision Sub sampling468.3.1 Obtaining a sample478.3.2 Sedimentary deposits:488.3.3 Precision sampling of a core488.3.4 Ice Samples498.3.5 Liquid and Heat extraction of organics498.3.6 Contamination concerns528.4. Time resolved Measurements529.0Engineering analysis of AFL core5310.0Planetary Protection5611.0Relationship between AFL and MSL5712.0The Future of AFL5713.0References5914.0Appendix 1. Discoveries AFL must respond to.6615.0Appendix 2 - Instrument descriptions and capabilities67MembershipDuring the course of the SSG several breakout groups were formed to answer specific issues related to our discussions. These are as follows;AFL subcommitteesSedimentary sub-team. Pan Conrad, leader.Hydrothermal sub-team. David Blake, leaderIce sub-team. Luther Beegle, leaderSample preparation sub-team. Jan Toporski, leaderDefinitions sub-team. Pan Conrad, leaderInstruments sub team. Will Brinkerhoff leaderWater sub-team. Jan Amend, leaderEXECUTIVE SUMMARYThe AFL SSG was asked to develop an analysis of a possible future mission called the Astrobiology Field Lab. This mission is a generic concept, consisting of a lander equipped with a major in-situ laboratory capable of making significant advancements towards MEPAG’s Goal I (“Determine if life ever arose on Mars”). In essence, the purpose of this analysis was to evaluate the question, “what is the most that can be accomplished in this area by in situ means?” In order to give the analysis team room to work, financial and timing constraints were very loose. Although at the time of convening this exercise 2013 was the closest discussed deadline and so considerations were given to what technically could be accomplished for this deadline. The AFL SSG considered the problem at several levels:What overall programmatic exploration strategies are needed to achieve Goal I? Results from many missions will contribute to these strategies, and a mixture of ambiguous and definitive outcomes will need to be accommodated.What result would AFL need to deliver to make a meaningful contribution to this strategy?What are the engineering options for configuring a landed mission that would make such a contribution?Programmatic exploration strategiesIn order to plan missions during the period 2013-1018, it is necessary to predict the state of human knowledge at that time. Although this is hard to do in detail, it is possible to reach some important generalities. First of all, habitability is the potential of an environment (and applied to either the past or the present) to sustain life. By this definition, habitability will be the integrated and accumulated knowledge of many missions and many different kinds of scientific investigations. However, as with any other potential, it will not be possible to achieve certainty unless life itself is discovered. Habitation, on the other hand, is a simple yes-no question. A key planning question, therefore, is when has the habitability potential risen high enough that a habitation test can be justified? Although it has been generally assumed in the past that these two objectives need to be pursued sequentially, the AFL SSG has concluded that organisms and their environment together constitute a system, and each produces an effect on the other. Many kinds of investigations of this system can simultaneously provide information about both. This implies that habitability and habitation can be investigated together. This expands significantly on the current mission concept for MSL, with AFL having an expanded instrument suite dedicated more towards life detection and precision sample handling than MSL. Moreover, the process of life detection on Mars involves two sequential steps: 1). Proposing that a set of phenomenon are, or could be, biosignatures. This will constitute a working hypothesis that life is or was present. 2). Establishing that at least one of these biosignatures is definitive. This requires extensive effort and careful planning and a number measurements mutually confirming each other. Finally, we know that some kinds of scientific investigations will measure signs of both extinct and extant life without needing to distinguish between these two possibilities before launch. Given the expected state of our knowledge about Mars during the period 2013-2018, the AFL SSG has reached three conclusions: It is both possible and reasonable to do life detection first, then determine whether it is extinct or extant on the basis of a positive result.Missions during this period can reasonably begin the process of life detection by characterizing potential biosignatures.It is reasonable to set mission objectives that relate to both habitability AND habitation. It is not necessary to choose one at the expense of the other.Finally if a definitive biosignature is located by AFL instrumentation and missions must be configured to definitively characterize that life signature. It is only by thorough study of a positive signal will skepticism be kept to a minimum and the maximum understanding of how this relates to the formation of life on earth be understood.Engineering optionsThe AFL SSG has concluded that the following overall scientific objective is both achievable by AFL as early as 2013 (although 2018 was also postulated as a target from the pathways document, Figure 1), and is a significant extension of currently planned missions: For at least one Martian environment of high habitability potential, quantitatively investigate the geological and geochemical context, the presence of the chemical precursors of life, and the preservation potential for biosignatures, and begin/continue the process of life detection.By targeting an environment of high habitability potential, a response to prior discoveries is implied. Investigating the context is a reflection of the reality that our understanding of habitability will not be complete by 2013 we need to plan for more work. Understanding prebiotic chemistry is necessary to allow planetary-scale life-related predictions, especially in the contingency that life is not found in a specific experiment. Understanding preservation is key to interpreting the results of biosignature investigations, and is also critical feed-forward to future missions. Finally, life detection, as AFL SSG defines it, is a process that will take time. It is reasonable to expect that missions like AFL will play a significant role in this process, but unreasonable to expect that they will bring it to a conclusion.Engineering options for an AFL missionThe AFL SSG has defined a landed mission that can achieve the above objective. There are multiple possible variations of what could be called “AFL”, and different scientists see these variations in different context, and with different systems of priority. However, it is possible to define an invariant base that is common to most versions, along with a discovery-responsive and competition-responsive cap. The basic landed system needs to be able to accomplish four things:Acquire the right samples (access a place with high general habitability potential, understand preservation potential, have a high ability for scientific sample selection, capable sample acquisition system)Know the context (Setting, mineralogy, chemistry, relationships)ID best place on the sample (Mid-scale observations.Precision sub-sampling (down to mm scale) for investigation by analytical suite)At least 3 mutually confirming A/B measurements (Suites of observations by different means of the same or related phenomena will be necessary to reach definitive conclusions).Initial engineering concepts for this mission place AFL as a COSPAR level 4B mission.2.0AFL CHARTERThe AFL SSG was given the following charter. IntroductionThe Mars Program Office at NASA HQ (Code S) requests a study of the preliminary scientific options and engineering characteristics of the AFL mission. This mission was identified in the final report of the MSPSG (Mars Science Program Synthesis Group).Starting assumptions (to be refined)Assumptions for each mission need to be compiled separately.Assume TBD mission must be ready to launch as early as TBD.Science priorities will be derived from the MEPAG Goals document.Requested Tasks:Develop a set of candidate whole mission concepts. For each:Define preliminary general science objectives, and science floor (the level below which the mission is not worth flying).Identify and evaluate the primary science tradesDetermine whether instruments capable of addressing the science objectives are likely to be available in time.Landing site accessibility: Propose the size of the latitude band which needs to be held open for this mission, the landing precision, and required ability to land in rough terrainIdentify possible facility subsystems related to sample acquisition and sample preparation. Describe the essential engineering constraints on the missionDetermine if positioning in the pathways makes a difference to the science/engineering of the mission.Describe how the mission fits into NASA’s long-range strategic framework for the exploration of MarsBased on the above analysis, present a prioritized set of preliminary options for consideration by NASA HQ. MethodsThe SSG is asked to conduct its business primarily by telecons, e-mail, and or web-based processes. There is enough budget to convene 1 or 2 face-to-face meetings.Logistical support will be provided by the Mars Program Science Office.TimingIt is expected that the team will be ready to start its deliberations in mid-November.A mid-term telecon status check by Jim Garvin, Dan McCleese, and Bruce Jakosky is requested after the new year.The near-final report of the AFL SSG is requested by Feb. 28, 2004.It is expected that the results of this study will be presented to MEPAG at its June, 2004 meeting. Feedback from this discussion will be incorporated in the final report, which will be due July 31, 2004.Report FormatIt is requested that the results be presented in the form of both a PowerPoint presentation and a white paper. Additional supporting documents can be prepared as needed. After the white paper has been accepted by program management (including the MEPAG executive committee), it will be posted on a publicly accessible web site.The report should not include any material that is a concern for ITAR (as is true of everything done by MEPAG).Note, the bulk of this work and the draft white paper was completed by September 2004. There have been unavoidable delays to its publication. In the meantime thinking about AFL has progressed. This document reflects the thinking in September 2004. Whilst engineering and programmatic changes have occurred since then, the strength of this document lies in the science definition for the mission.DEFINTIONSDuring the course of the AFL-SSG discussions several questions related to the MSPSG statement arose. Specifically these questions relate to the definitions of, for example, the terms habitability (or what constitutes a habitat) and biosignature. Critical questioning by the group resulted in the formation of a definitions subgroupThe following definitions were decided upon by that group. These definitions are consistent through this document and although we cannot suggest the wider community adopt these definitions it is suggested that some consensus within the MEPAG members is reached to prevent numerous iterations of this process in other reports. Abiotic Chemistry Mainly carbon based chemistry the speciation and composition of which has remained simple with the production of all different isomeric possibilities and show no chiral or species preferences. In this scenario complex molecules may only be kerrogenous in nature (type iv) and similar to that found in meteorites. Biosignature Any phenomenon produced by life (either modern or ancient). Two sub-definitions: Definitive Biosignature: A phenomenon produced exclusively by life.  Due to its unique biogenic characteristics, a definitive biosignature can be interpreted without question as having been produced by life. Potential Biosignature: A phenomenon that may have been produced by life, but for which alternate abiotic origins may also be possible.Extant lifeGeneral reference to living or recently dead organisms which may also possess a fossil record. Extinct life General reference to past life (and no longer present on the planet). If evidence remains, it is ONLY fossil. Habitability A general term referring to the potential of an environment (past or present) to support life of any kind. In the context of planetary exploration, two further concepts are important: Indigenous habitability is the potential of a planetary environment to support life that originated on that planet, and exogenous habitability is the potential of a planetary environment to support life that originated on another planet. HabitatAn environment (defined in time and space) that is or was occupied by life.Life detectionThe process of investigating the presence of biosignatures (including potential biosignatures). Life detection can apply to either past or present life.Micro BioSensors (not to exclude organic chemical detection)Miniaturized instruments or instrument suites that are developed from technology such as Micro Electronic Machine Systems (MEMS), Micro electronic optic systems (MEOS), Microfluidics, Micro Total Analytical Systems (uTAS) or Lab-on-a-Chip (LOC).Prebiotic Chemistry Mainly carbon based chemistry the speciation and composition of which has a complexity and has produced a number of polymeric systems that could be used for structural, metabolic processes and information storage and retrieval.Present life investigation One that specifically targets living or recently dead organisms. Time resolved studies on seasonal and daily (with perhaps higher frequency) time scales may be required to confirm observations that a biosignature of present life has been detected.Preservation PotentialThe potential for a particular biosignature to survive and therefore be detected in a particular habitat.Primary Sample Geological material (e.g. rock, regolith, dust, atmosphere, ice) acquired from its natural setting on Mars.  Note: specific locations where data are collected by contact instruments are referred to as "targets", not samples.Secondary Sample Any sample derived from the primary, including splits, extracts, sub-samples, etc.4.0INTRODUCTION The primary science driver for the mission concept was to define the first Mars mission to concentrate fully on Astrobiology science goals (as defined within the recently updated Astrobiology roadmap). Therefore, to define the preliminary general science objectives, and the science floor, the level below which the mission is not worth flying. The Astrobiology Field Lab was created as a concept by the Mars Science Program Synthesis Group (MSPSG) during their Pathways planning discussions in 2002-03 and can be paraphrased as; Astrobiology Field Laboratory. “This mission would land on and explore a site thought to be a habitat. Examples of such sites are an active or extinct hydrothermal deposit or a site confirmed by MSL to be of high astrobiological interest, such as a lake or marine deposits or a specific polar site. The investigations would be designed to explore the site and to search for evidence of past or present life. The mission will require a rover with “go to” capability to gather “fresh” samples for a variety of detailed in situ analyses appropriate to the site. In situ life detection would be required in many cases.” (From MSPSG (2003)However, MSPSG deferred to a successor team (AFL-SSG) the definition of AFL’s specific scientific and engineering constraints, possibilities, and priorities. The AFLSSG team was initially convened in October 2003 and operated through a number of telecons and one face to face meeting. Therefore this team was asked to plan during a constantly shifting science focus and have constantly endeavored to keep abreast of the Mars Exploration Rover findings and review the goals and outcomes of the SSG accordingly. Undertaking this activity at a time when 3 new space craft have started to explore Mars has been exciting, inspiring and already produced new evidence to which we have responded. Many notions of how to perform this mission have therefore been updated from preconceived notions held before specifically, the MER data was returned. We hope that these changes reflect a renewed sense of optimism and realization of the location of interesting samples to interrogate with instrumentation currently under development.5.0SCIENCE GOALS5.1 Assumptions To undertake this task the AFL-SSG was asked to consider the following assumptions; Assume AFL will need to be ready to launch as early as the 2013 opportunityAssume all missions scheduled before 2013 are successful.The MSL entry-descent-landing (EDL) system has successfully been demonstrated, and the engineering heritage can be used on AFL.Assume the primary goal of AFL is to make a major advance in astrobiology. Assume a cost cap approximately equal to that of Ground Breaking Mars Sample Return.These assumptions are based on the timeline suggested by the Pathways SSG, summarized in Figure 1.Figure 1. A summary diagram of the pathways proposed by MSPSG.From Figure 1 it can be seen that the pathways leading to AFL are propelled by the discoveries of hydrothermal habitats and the search for evidence of past life. During the course of the AFL-SSG discussions several questions related to the MSPSG statement arose. Specifically these questions relate to the definitions of, for example, the terms habitability (or what constitutes a habitat) and biosignature. Critical questioning by he group resulted in the formation of a definitions subgroup the results of which are shown in Section 2. Responses to discoveries other than pathway to discover hydrothermal habitats as shown in Figure 1 were deemed necessary and led to the formation of the hydrothermal, ice, sedimentary and water subgroups. Through these discussions the parallel nature of exploration and engineering goals in different environments was explored and a “core” of similar themes and objectives arrived at that included life detection philosophy, measurements, rover capabilities and sample preparation. This notion is explored further in section 8.1.2. Other questions arising from the MSPSG guidelines and our discussions related to “the capability to gather fresh samples” which led to the formation of the sample preparation subgroup. The mention of in-situ life detection led to the Instrument subgroup surveying and documenting the current instruments in development.Several assertions for the completion of these science goals were formulated and are as follows:1.By 2013 a full model of the potential habitability of Mars, organized by environment, and applicable to both the present and geological past will be partially understood. Therefore the Mars program will have to choose to either; select one environment with a high habitability potential and test for habitation or continue to refine the habitability models to allow better targeting of a subsequent habitation mission.Therefore we forecast one of two conditions will be true in 2013:•More likely: Models of habitability require either further definition or further confirmation before a specific test for habitation should be attempted.•Less likely: At least one environment (past or present) with high habitability and preservation potential has been identified, and a habitation test is justified.We therefore questioned whether AFL would be effective in both scenarios. Which further reinforced the concept of defining a core set of mission parameters (Section 8).2.Organisms and their environment together constitute a system. Each produces an effect on the other. Some kinds of investigations can simultaneously provide information about both the environment (e.g. habitability potential) and associated life forms (habitation).3.Traditional Mars mission planning has involved choosing scientific objectives and investigations for EITHER prebiotic chemistry, extinct OR extant life. (PP policy is structured the same way.) However, some kinds of scientific investigations will detect all of the above categories and potentially measure the signs of life without prior need to assume search parameters that will pre-categorize whether it is extant or extinct. 4.As our exploration of Mars (through robotic and sample return missions and terrestrial studies on Martian meteorites) proceeds, anomalous features will be discovered that are POSSIBLE biosignatures for Martian life forms. It is important that this Observation of POSSIBLE biosignatures can be made by relatively simple observations (e.g. geological, textural, geochemical). Such features would constitute a working hypothesis, NOT confirmation that life exists and has been detected.Concluding that evidence of a Martian life form (past or present) has been discovered requires proving that a POSSIBLE biosignature was produced by the activities or remains of Martian life. Unless a POSSIBLE biosignature is proven to be a DEFINITIVE biosignature – an object or phenomenon that could only have been produced by life – it may not possible to prove the presence or former presence of life on Mars using AFL alone. However, the AFL mission has been configured so that it will not miss POSSIBLE biosignatures if they occur in a similar habitat and with similar character to those found on Earth and may indeed detect those non-earth centric signatures that would, without prior knowledge of the state of an unknown biochemistry, appear to be reasonably measurable.Once several POSSIBLE biosignatures are identified, additional efforts will need to be made to prove that they definitively represent extant life or former life, or determine whether the group of POSSIBLE biosignatures is CONSISTENT with the hypothesis that life exists or once existed on Mars.The current MEPAG goals document highlights the following strategy for Goal 1 “The search for Life” Determining if life ever arose on Mars is a challenging goal. The essence of this goal is to establish that life is or was present on Mars, or if life never was present to understand the reasons why Mars did not ever support its own biology. A comprehensive conclusion will necessitate understanding the planetary evolution of Mars and whether Mars is or could have been habitable and will need to be based in multi-disciplinary scientific exploration at scales ranging from planetary to microscopic. The strategy we have adopted to pursue this goal has two sequential aspects: Assess the habitability of Mars (which needs to be undertaken environment by environment), and in environments which can be shown to have high habitability potential, to test for prebiotic processes, past or present life. These constitute two high-level scientific objectives. A critical means to achieve both of these objectives is to characterize Martian carbon chemistry and carbon cycling. The science associated with carbon chemistry is so fundamental to the overall life goal that we have established it as a third primary science objective. To some degree, these overarching scientific objectives can be addressed simultaneously, as each requires basic knowledge of the distributions of water and carbon on Mars and an understanding of the processes that govern their interactions. Importantly this statement points out that the seemingly differing goals, habitability, Carbon chemistry and the search for biosignatures, overlap and can therefore be addressed to a significant degree by the interpretation of measurements undertaken by certain instruments. Examples, habitability demands the presence of Carbon, biosignatures are often Carbon based etc. Amino acid analysis, n alkane distributions, selection of informational and catalytic polymers based on a narrow range of particular molecules and isomers of a particular molecular group. For example nucleic acids contain ACTGU on earth, but may contain LMNOP on Mars, it is the presence of a narrow range of the possible purines and pyrimidines available through abiotic processes that would constitute a biosignature. This could be true of any potential novel biomolecule and it may be that upon detecting a small range of the possible isomers of a particular compound speculation as to their informational or catalytic roles can begin. Therefore AFL can reasonably begin the process of life detection by characterizing potential biosignatures.5.2 ObjectivesProposed overall scientific objective of AFL: For at least one Martian environment of high habitability potential, further investigate the potential for habitability, the potential presence of the chemical precursors of life, the potential for preservation of biosignatures, and possible signs of life. This objective must balance the need to be a significant extension beyond currently planned missions, yet not an unrealistic extension of current technology. The detailed objectives proposed include (in no order of importance); 1.Within the region of Martian surface operations, identify and classify Martian environments (past or present) with different habitability potential, and characterize their geologic context.2.Quantitatively assess habitability potential.Measure isotopic, chemical, mineralogical, and structural characteristics of samples, including the distribution and molecular complexity of carbon compounds. Assess biologically available sources of energy, including chemical and thermal equilibria/disequilibria.Determine the role of water (past or present) in the geological processes at the landing site3.Investigate the factors that will affect the preservation of potential signs of life (past or present) on Mars 4.Investigate the possibility of prebiotic chemistry on Mars (including non-carbon chemistry)5.Document any anomalous features that can be hypothesized as POSSIBLE Martian biosignatures. This will constitute a set of working hypotheses, which will need refinement and further testing on Mars or in return samples. 5.2.1 Habitability A definition for habitability is contained in section 2. From the first assumption above the following recommendation was made: Habitability models have the potential to integrate many different classes of information that have been made recently and will be acquired over the next decade. However, they will be most effective if placed on a semi-quantitative footing (see Appendix II for an example). This question was then followed up in discussions within the definitions subgroup and illustrated by Figure 2.Habitability should be described by measurable parameters that index the potential of an environment to support life. Only in this way can the scientific community achieve consensus regarding whether or not a given environment is habitable, either for Martian or Earthly life. For any living system, certainly there will be a range of environmental requirements, outside of which life will be unsupportable. Even though we have no information on potential Martian biological requirements, we can learn from universal Earthly life requirements. The AFL study group has agreed that Earth life requires water and certain chemical raw materials such as carbon, hydrogen, nitrogen, phosphorus and a few others in trace amounts (Williams and Fraústo da Silva, 1996). We also know that life makes products from these raw materials with the additional requirement for an energy source, so sufficient habitat space must be available for the products to be mobilized or diffuse away, otherwise metabolic reactions would run to equilibrium, or possibly reverse. On Earth, the chemistry of life involves oxidation-reduction reactions, and metabolism from the archaea to some highly-evolved eukarya requires electron donor/receptor pairs. The spatial distribution of both oxidized and reduced forms of ions involved in respiration may be as important as their concentration in the context of biological requirements.We assume that the astrobiology community will have made progress toward consensus regarding the indexing of habitability before the launch of an AFL mission, as the concept of habitability will have an impact on missions with the scope of Terrestrial Planet Finder to SSE missions in search of present or past Martian habitable environments. One approach toward such progress may lie in development of terms that lead to a probabilistic evaluation—a scale of habitability based upon measurements of agreed-upon parameters such as threshold concentrations of water and other raw materials, energy, etc. 5.2.2 Extinct or Extant Life. Abiotic or Prebiotic Material It is important to recall that life on Mars may be composed of many molecules that differ from those of Earth life. However, most current hypotheses on extraterrestrial life maintain that Martian life, if it exists or once existed, will resemble life on Earth in that it will be: 1) composed of carbon, 2) based on a ‘nucleic acid like’ replication mechanism and 3) packaged in cellular compartments. Measuring the distribution, isomerization and quantities of carbon species limits the search to life based on carbon chemistry, an appropriate goal that reflects the strategies used to locate the biosignatures of ancient carbon-based life forms on Earth. Potential organic carbon species that would need to be distinguished by AFL are given in Table 2.In the search for biosignatures on Mars the interpretation of measurements will determine whether a particular results indicates the category to which a particular a/biosignature should be placed i.e. pre/abiotic extinct or extant. The important issue is to make the correct measurements to ensure the sensitive detection of molecules of interest can be undertaken.Figure 2 Illustrated the cross cutting relationships between the searches for habitability in comparison with the search for evidence of past or present habitation. From assertions 2 and 3 and illustrated by Figure 2 the implications are that: The distinctions between investigations of habitability potential, habitation, extinct life, and extant life are blurred. It is possible to configure a mission that has relevance to ALL of these subjects.Without evidence of liquid water on Mars, the potential to locate extant Martian life is less, as all conceivable life forms require liquid water. Hence the focus of upcoming missions on determining whether liquid water is available. Until this information is known, an AFL mission will need to be prepared to detect both extinct and extant life, as well as be able to distinguish abiotic and prebiotic material. We assume that the investigation of abiotic and prebiotic chemistry will be useful in evaluating the postulated meteoritic and cometary delivery of exogenous organics to the lithosphere and the formation of organic material by indigenous hydrothermal processes. The current MER information that Mars harbors environments that contained liquid water in the past indicates that the possibility of discovering extinct life has increased.All information gained from AFL will be useful with regard to either describing what kind of life exists/existed on Mars or describing conditions found on Mars and determine why life evolved on Earth and not Mars (assuming the conditions on Mars are similar to those on Earth). The search for the signatures of prebiotic chemicals or components of life–past or present will provide important information that will advance the field of astrobiology and the understanding of our own planet. In addition, there is now considerable evidence pointing to the presence of methane in the atmosphere on Mars (Kerr 2004a.b commentary). This implies that geological processes on Mars could provide a chemical potential and carbon source that could be used by microorganisms and may indicate the presence of hydrothermal sites and liquid water. The generation and fate of atmospheric methane on Mars would be a significant goal for missions that fly prior to AFL. Such measurements would significantly improve our understanding of habitability.Investigating early planetary surface chemical processes on Mars is important to understanding two possible program-level exploration outcomes:If life is not present at a specific test site, can we predict that it might exist elsewhere? If life never formed on Mars, WHY?Studying such issues will also address specific goals, issues:Understand planetary evolution through elucidating organic chemical input i.e. meteoritic versus abiogenic synthesis reactions.Mars may give clues to the prebiotic evolution of the Earth. On Earth an unaltered geologic record of early planetary evolution (4.5-3.8 Ga) does not exist. Allow conjecture as to why life did not start on Mars (should that be the outcome). Were the chemical processes and building blocks present there as on Earth?By definition, a biosignature is an indicator of life or biological activity. Therefore, by definition, the discovery of even one biosignature on Mars would indicate that life once existed on the red planet. However, discoveries of ancient POSSIBLE biosignatures on Earth and Mars have shown that it can be extremely difficult, if not impossible, to prove their biogenic origin. Our inability to prove an object or phenomenon’s biogenic origin (i.e., biogenicity) is hampered by the fact that inorganic processes can produce abiotic mimics of biosignatures. Hence the need to make a distinction between a POSSIBLE biosignature and a DEFINITIVE biosignature.A DEFINITIVE biosignature is one that has attributes that can ONLY be produced by life or biological activity. Until such time that a POSSIBLE biosignature is proven to be a DEFINITIVE biosignature, the former constitutes a working hypothesis that requires additional characterization. AFL will contain the necessary equipment to detect POSSIBLE biosignatures (e.g., microfossils, biofabrics, biominerals, biomarkers, biomolecules isotopes, etc.). However, short of locating a living or perfectly preserved cell that displays the structural complexity indicative of biosynthesis, establishing that a POSSIBLE biosignature is DEFINITIVE evidence for life will require further testing. It will also be necessary to prove that a biosignature is indigenous to Mars and not a contaminant, regardless of whether we discover it on Mars or in rocks or sediment returned to Earth from a future sample return mission from Mars. These considerations underscore the need to distinguish a DEFINITIVE biosignature from a POSSIBLE biosignature. This underscored the goal of the definitions sub group that postulated that only by producing several mutually supporting lines of evidence (i.e. possible biosignatures) could a definitive biosignatures be postulated.The lack of a conclusive set of criteria for life detection and preservation has been illustrated recently by two debates; the search for the oldest evidence of life on Earth and the raging debate on the claims for life in ALH84001 (McKay, 1996). The scientific controversies over the former debate, that of the earliest evidence of life on Earth, have recently intensified but are still unresolved (Schidlowski, 1988; Schopf, 1993; Mojzsis et al., 1996; Rosing, 1999; Mojzsis and Harrison, 2000; Brasier et al., 2002; Fedo and Whitehouse, 2002, Pasteris and Wopenka, 2003, Furness 2004). The common denominator in both of these debates is the underlying difficulty, or inability to demonstrate conclusively the biological origin of the respective evidence, which in either of the above cases would have to be seen as conclusively proving the presences of fossil microbial life. However, a consensus that has emerged from these discussions, and is now seen as a critical requirement, is the demand for further lines of evidence in addition to any morphological data that supports such extraordinary claims. Since the inception of the second debate, that of life in Martian meteorite ALH84001, it has become evident that there is no consensus on the nature of life in extraterrestrial materials. Indeed techniques supposed to detect life failed, for whatever reason, to conclusively detect the presence of terrestrial organisms within this meteorite (Steele et al., 1999, 2000, Toporski, 2000). Recent studies suggest that the mass spectrometry experiments on the Viking lander would have missed 3x107 bacteria per gram of Martian regolith (Glavin et al., 2001). These examples are beginning to show that only by means of a multi-disciplinary, multi-instrument scientific approach, will the above questions be answered. It is clear that a great deal of additional systematic experimentation and testing must be undertaken in terrestrial environments to better determine the criteria by which biogenicity and therefore preserved biosignatures can be quantified.Though there are a number of ways of categorizing biosignatures, microbial biosignatures found in ancient Earth rocks can be organized into three categories: bona fide microfossils, microbially influenced structures, and chemical fossils, also known as chemofossils (Cady et al., 2003). Bona fide microfossils, which may include cellular and/or extracellular remains (e.g., carbonaceous microfossils), display structural and chemical characteristics that confirm their biological origin. Microbially influenced sedimentary structures (e.g., biogenic stromatolites and microbialites), display biofabrics and morphologies known to have been produced by the presence and/or activity of biofilms or microbial mats. Chemofossils (e.g., biomarkers and biominerals), display chemical, isotopic, and structural characteristics indicative of biological activity. Among the chemical biosignatures that have been identified as applicable to past and present biological activity on Earth are the biominerals, that is, minerals formed by biotic processes, either directly, or indirectly. Biominerals have been found in the fossil record that date back to the Precambrian. It has been suggested that biominerals could be important indicators of life and thus could play an important role in the search for past or present life on Mars (Schwartz et al., 1992, Cady et al 2003). Furthermore, organic components (biomarkers) that are often associated with biominerals are believed to play crucial roles in both pre-biotic and biotic reactions. For measurements carried out on Mars, a crucial step will be the in situ quantification of the nature, structure and concentration of biosignatures as a function of depth and time. The search for biosignatures requires an extensive knowledge of the context in which they are found. The types of rocks and paleoenvironments that have the highest potential to trap and preserve biosignatures on Earth and Mars include: mineralized sinters, evaporite basins, mineralized soils, subsurface sedimentary systems, permafrost and ground-ice (Farmer and Des Marais, 1999). Recent data from the Mars orbiter, which suggests the presence of reduced gases of biological or volcanic origin, indicate that gas seeps in any type of terrain should also be targeted for possible biosignatures. On Earth, additional criteria such as tectonic setting and alteration history are taken in consideration when looking for biosignatures. The amount of alteration a deposit has experienced since its time of formation is particularly important for assessing the preservation potential of a deposit (see next section).Typical lithologies for searching for biosignatures of past life in ancient terrestrial settings are similar to the ones we hope to find on Mars. Interestingly the haematite rich sites like those found by the MER rovers at Meridiani and Gusev may not be the ideal sites to search for Carbon signatures due to the poor preservation of organic material in haematite (Sumner 2004). Settings with a higher preservation potential include aqueously deposited chemical sediments, such as cherts, carbonates, or phosphates, which are known to be effective at preserving biosignatures on Earth. Because the spatial scale or distribution of such deposits on Mars is presently unknown, and because of the difficulty of resolving mineral mixtures using available or recently acquired remote spectral data (i.e., TES, THEMIS or CRISM), the acquisition of data at high spatial resolution (30-100m/pixel) from selected locations is considered a crucial precursor to defining an adequate landing site for the AFL mission.A critical component for identifying biosignatures on any planetary body is the ability to assess in-situ the potential for an aqueous geochemical environment to create and support life. As an example for Mars, in-situ characterization could provide evidence as to whether the chemical composition of the evaporites located in suspected ancient water bodies were biologically influenced or possessed the chemical parameters within which life may have existed, or may still exist.It is almost certain to be the case that any life signature found on Mars will become the basis for intense debate and necessary follow up investigations. These investigations must be targeted at characterization of any positive signal.If investigations prove negative for all forms of carbon / biosignatures then spatially resolved measurements must be undertaken to different sites to ensure all reasonable target areas have been explored. Table 2. Possible sources of organic carbon that need to be distinguished in Martian samples. 5.2.2.1 What techniques have been used to detect and characterize terrestrial and meteoritic biosignatures?1. Morphological observation using microscopic tools (Light, SEM, TEM, AFM, Fluorescence). The controversy mentioned earlier regarding the oldest fossils on Earth illustrate that it is difficult using all available analytical tools in a laboratory to unambiguously determine if something is truly of biological origin. Recognizing a fossil using the criterion of shape alone poses some challenges, particularly without actually being on the surface of Mars and knowing a priori whether it has a fossil record. In contrast, observing movement in extant life is easy. However, not all extant life moves, especially microbes, therefore making it difficult to determine if it is alive by shape alone. Interdisciplinary multi-instrument approaches have been shown to be effective for studies on deep subsurface ecosystems on Earth (e.g., Fisk et al., 2003; Steele et al., 2002; Toporski et al., 2002; Steele).2. Biochemical analyses. A range of analyses based on either pure chemical or biochemical methods have proven to be useful on Earth in determining if a sample is of biological origin. However, in difficult cases it has usually taken several different methods of analyses to determine if a sample is unequivocally of biological origin. Carbon isotopes have successfully been correlated with individual Proterozoic microfossils (House et al., 2000) and FT-RAMAN spectra were obtained on presumed Proterozoic microfossils (Schopf et al., 2002). Furthermore, fossil and modern bacterial biofilms have been classified using a combination of bulk and spatially resolved measurements including XPS, EDX, XRD, Time of Flight – Secondary Ion Mass Spectroscopy (ToF-SIMS), pyrolysis GCMS, GCMS, GC-IRMS confocal laser microscopy and Raman and infrared microspectroscopy (Steele et al., 2001; Toporski, 2001; Toporski 2002; Toporski 2004, Hall-Stoodley et al, 2004; Benning et al 2004). Only the combination of a multiple-set of instruments lead to a unequivocal determination of the specific characteristics of biofilms. 5.2.2.2 What are the challenges for AFL in the search for biosignatures on Mars?1. Tested Technologies. Of the techniques listed in table 1 those that have been shown to be successful during space missions include: gas chromatography, mass spectrometry, simple thermal analysis, Mossbauer and some types of interactive chemical techniques (e.g., the Viking biology experiments (see Mancinelli 1998 for review).For Mars applications, it is necessary for the detector to be sensitive to the picogram level and capable of responding to a broad variety of compounds, i.e., have universal response. A flight proven detector that is both universal and sufficiently sensitive is the metastable ionization detector. The primary disadvantage of gas chromatography is the small margin of error associated with the column retention times for definitive identification of compounds, which can lead to mis-identification of compounds with similar retention times. This disadvantage should be minimized by use of multiple columns with different separation capabilities (i.e., different column coatings or packings) and calibration standards. A GC/MS has been used successfully on space missions, including the Viking mission The disadvantages are that the MS cannot be simultaneously tuned to be sensitive for the analysis of low and high molecular weight substances at the same time, and it is a bulky and heavy instrument. Various types of analytical instruments equipped with different pyrolytic devices have been used during space missions. These ranged from simple pyrolysis (combustion) to step-wise heating of samples and measuring the power input and temperature. Step-wise heating is usually followed by collecting any volatiles evolved from the sample during heating, and identifying and quantifying them by GC, or GC/MS. For example, heating samples of soil from earth in a step-wise fashion would first volatilize adsorbed water and gases (e.g., CO2, and lower molecular weight organic compounds) at the lower temperatures. At higher temperatures, water from mineral hydration, CO2 from carbonate decomposition, and volatiles from pyrolysis of higher molecular weight organics would be released. Although this technique allows one to analyze the evolved gases, it does not yield any direct information regarding the nature of the sample (e.g. clays vs. hydrated silicates). Mossbauer spectroscopy provides information on the valence state of specific elements (i.e., Fe, Sn, Sb, Ru, and Au), how these elements are combined in the structure of a compound, and the magnetic properties of the sample. Mossbauer spectroscopy can provide information about H2O only if it is associated with the elements Fe, Sn, Sb, Ru, or Au. This again is an area where micro total analytical systems and micromachining may allow significant weight and energy savings.2. Non-tested technologies. Scanning electron microscopy-energy dispersive X-ray spectrometry (SEM-EDS), which maps electron intensities for identification of elements with atomic numbers greater than sodium, although windowless detection allows all elements heavier than boron to be detected. Electron spectroscopy for chemical analyses (ESCA) quantitatively determines the valence states and bonding energies of most naturally occurring elements (excluding hydrogen and helium). This technique is limited to analysis of the top 1-10 monolayers of the sample. X-ray diffraction (XRD) analysis directly and nondestructively probes atomic scale structural correlations of mineral samples yielding sample mineralogy along with information about the presence of H2O. X-ray fluorescence (XRF) analysis non-destructively provides information on the elemental composition of a sample for elements having atomic numbers greater than that of boron. However, no information is given about how those elements are combined in the sample. Rutherford backscattering spectrometry (RBS) maps the elemental composition and distribution measured on sample surfaces (the top 0.5 – 3 microns). Elements that can be analyzed by this non-destructive technique range from Li to U. Secondary ion mass spectrometry (SIMS) analysis has a very high sensitivity and can identify all elements including hydrogen and deuterium. A mass spectrometer (MS) provides information on elemental and molecular composition, including that of H2O, and the isotopic abundances found in a sample. Differential scanning calorimetry (DSC), in which the amount of heat required to maintain isothermal conditions between the sample and an inert reference placed in a continuously heating oven, is recorded, and the enthalpy provided directly. Sample identification is made by examination of the patterns of exotherms and endotherms along a temperature scale. The DSC provides quantitative data to ~700°C. For temperatures >700°C the signal-to-noise ratio becomes too great. Differential thermal analysis (DTA) is similar to DSC in that the sample and an inert reference are heated at the same rate, but to ~1200°C. The temperature of the sample and reference are monitored simultaneously. It differs from DSC in that when endothermic and exothermic events occur in the sample, no attempt is made to keep the sample and reference isothermal to each other. In DTA, the temperature difference between the sample and the reference is recorded as a function of oven temperature and provide the information for sample identification. The thermogram obtained from a DTA or DSC analysis provides information on the mineralogy and chemical composition of the sample. Where the DTA or DSC is coupled to a gas chromatograph (GC), the GC collects and analyzes the volatiles (including H2O) evolved from the sample as it is heated. Specifically for extant life detection interactive chemical methods were performed as part of the Viking mission. This approach is fraught with problems. It assumes prior knowledge of Martian organism metabolism. Using these culturing methods only detect 1-2% of the microbes in earth soil can be detected. A distribution mass peaks obtained by a mass spectrometer of alkanes showing a decrease in concentration with increasing carbon number would indicate abiotic processes. Similarly a predominance of biogenic amino acids with an excess of the L isomer would indicate extant or recently extinct life. Whereas, a suite of racemized biogenic amino acids may indicate fossil life. Detection of hopanes by Time of Flight Mass Spectrometry may also be indicative of life. Field ATP luminometry measurements of the cryptoendolithic communities may provides a rapid method of detecting relative amounts of metabolic turnover in microbial communities. None of these techniques would provide definitive evidence of life during the MSL mission. Clearly, multiple approaches need to be done on samples to determine if they contain viable extant organisms. For example, if organic mass gas chromatography spectrometry analyses combined with deep UV florescence, SEM and RAMAN all point toward life, then there is a high probability that the sample may contain life.5.3 Preservation PotentialA biosignature preservation model, guided by data from AFL, will be critical to long term Martian life detection strategy. That is to say that AFL in detecting carbon chemistry in various sites of possible habitability (see definition) can indicate whether such niche areas could preserve clues of Martian life. This must be modeled by suitable experimentation in laboratories before suitable interpretation of any data can be undertaken. We still do not know the exact composition of the mysterious Martian oxidant postulated in the Viking experiments.Long-range Astrobiological exploration of Mars will require an understanding of the preservation potential of biosignatures. This is an important part of the scientific logic of going from possible biosignature to confirmed biosignature.Lessons from Earth•Life processes produce a range of biosignatures, and geological processes progressively alter and ultimately destroy them.•Understanding the potential for preservation has been a key part of biosignature interpretation. Application to Mars•We don’t know the biosignatures of Martian life forms (if they exist).•However, with appropriate data, it should be possible to postulate a preservation model relating biosignatures as we understand them on Earth to various Martian geologic environments. This model will likely have important predictive value in guiding future search strategy. Models predict that biomolecules and organisms can survive in simulated conditions such models need refinement and to address diagenetic processes in predicted conditions (Scheurger et al., 2003).6.0Precursor DiscoveriesRelevant data may already be available but two major classes of discovery would be of essential relevance to AFL mission planning:MRO•Sending AFL to a hydrothermal site is impossible with present knowledge, because none are known. However, the CRISM spectrometer on MRO is very powerful, and it has potential to discover the mineralogic expression of hydrothermal zones. Phoenix•Phoenix will be the first lander designed to acquire and analyze ice-bearing samples.•It will collect data of relevance to each of the three primary components of habitability (water, carbon, energy), and thus is capable of returning a result which significantly improves or reduces our interest in sending AFL to an ice-related site. Table 3 A summary of types and amounts of biomolecules present in a single bacterial cell and compared to known preservation potential for such molecules.? – debate over the data. Total mass of the organic inventory is based on the assumption that most terrestrial prokaryotes contain approximately 10-13 g of carbon per cell. 7.0Mission Site SelectionFour subgroups were founded to begin to address the need for AFL to respond to the discoveries and requirements for as yet to be determined site. Through this process a core mission concept was arrived at and presented to the engineers for costing.There are four obvious general types of site in which the overall scientific goal of AFL (major advance in A/B) can be pursued:•The sedimentary record.•Fossil (inactive) hydrothermal systems•Sites with ice •Sites where it may be possible to sample liquid waterWe do not have enough information as of this writing to know how these four options would be prioritized by a future SDT. Future discoveries could have a major effect on planning. At the time of writing this document all of the above sites may be postulated to currently exist on Mars. The sedimentary record has been explored by at Gusev and Meridiani by Spirit and Opportunity respectively (Squyres et al., 2004; Grant et al., 2004; Morris et al., 2004; Kerr 2004c (commentary); Arvidson et al., 2004; Bertelsen et al., 2004; Herkenhoff et al., 2004; Gellert et al., 2004). Fossil (slightly active) hydrothermal systems may be concluded from initial papers outlining the concurrence of water vapour, shallow ground ice and methane at Arabia Terra, Elysium Planum and Arcadia Memnoma, (See Kerr 2004a,b and c for commentary). Sites with ice and the obvious poles or shallow “dirty” ice sites such as Phoenix proposes to explore. Sites with possible hydrothermal activity represent a chance to sample liquid water, although this may be at some distance below the surface. To remain flexible to current and future discoveries we Figure 3 Shows the antecedent discoveries that will impact and guide the choice of sites and final payload of the AFL mission 7.1 SedimentsHere we present a mission concept with the overall goal of finding evidence for past or present life in the Martian stratigraphic record in an environment that is highly likely to have formed from the subaqueous deposition of sediment in a shallow marine or lacustrine environment such as exposed in craters at both the Spirit and Opportunity sites (Squyres et al., 2004; commentary by Kerr 2004c). ObjectivesSpecific supporting objectives that support this goal are to:Assess spatially resolved changes in mineralogy with depth on a scale consistent with the depth of individual strata.Determine the abundance and nature of organic chemicals at the same scales as above.Seek information regarding water cycling from the strata, eg. is there free or bound water in any of the layers? Ice? Hydrous mineral phases?Confirm the depositional environment. Determine provenance of the sedimentAssess the fossil preservation potential of the environment. Factors which might be considered are temperature, rock type, local weather, UV flux, depositional regime as suggested by sedimentary structuresApproachCentral to this mission is the selection of a landing site that possesses multiple outcrops of layered sedimentary rock. We would use remote sensing methods that possess sufficient spatial resolution to resolve individual layers to acquire information from several outcrops. Subsequently, a rover would visit at least one 3D outcrop of layered sedimentary rock, measuring variation in chemistry, mineralogy and texture of the strata for at least 100 meters along the strike and ten meters in the dip of the outcrop. Subsurface penetration would be an important feature of this mission for the acquisition of subsurface samples that are from depths great enough to extend beyond the level of surface oxidation. This may mean accessing a depth of one meter in a horizontal area, though it would be desirable to penetrate the exposed bedding along the slope of an outcrop in a larger feature such as the wall of a crater. Examining the subsurface of such beds would only require a relatively shallow penetration (perhaps a few centimeters), and we would then have access to the primary sediment without having to go through the more recent Aeolian deposits.Required measurements for meeting the scientific objectives must be conducted at multiple spatial scales, and we recommend three suites of instruments that can provide integrated measurements a la the remote sensing, non-contact/contact and analytical suite designations originally suggested by the MEPAG PSIG for the MSL mission. Both spectroscopy and imaging will be key to an integrated science package, and we assume technical progress in science autonomy before the launch of AFL that optimizes science operations on the Martian surface. There are several engineering /science trade issues associated with taking a large number of measurements from a large outcrop in three dimensions. Some of them are:“Go to” mobility is required. The degree of mobility will be complementary to the degree of precision of the landing.The ability to land in a terrain which is rougher than previous targets would be valuable. A priority should be given to precision targeting and hazard tolerance.Fresh material should be exposed with a RAT or its descendent. Surface penetration is also required to a level below any weathering layers, a few cm to perhaps a meter.Sample acquisition and some processing, at least to the level of crushing will be required.There will be a requirement for positioning—perhaps a laser range finder. Autonomy should be plentiful—not just for the rover, but for some of the scientific operations in order to maximize efficient use of resources.Landing Site SelectionOne of the primary assumptions of this mission concept is that we will have advanced in our ability to assess habitability for a range of potential landing sites by the missions that are to precede AFL. For example, recent inferences made regarding the environment of deposition for the MER B landing site, Meridiani Planum would suggest that it is an excellent candidate site for an astrobiology follow-up mission. However, as of the time of this writing, there are few exposed examples of the cross-bedded rock from which the shallow marine inferences were drawn at that site. Much of the Martian surface will be mapped in exquisite detail by the time the AFL mission site selection is made, and there are likely to be other candidate target areas that demonstrate appropriate geomorphological and mineralogical character to suggest deposition in a standing body of water. For example Northeast Holden crater, may be a good candidate; geomorphological evidence strongly suggests classical deltaic deposition (Bhattacharya, in prep):Figure 4 Holden crater 7.2 HydrothermalScience theme: Assess past Martian Astrobiology in an inactive hydrothermal system.The apparent harsh climate at the surface of Mars suggests that, should life exist on Mars, the most likely energy source would be subsurface / chemosynthetic rather than surface / photosynthetic. Hydrothermal systems are attractive sites for Astrobiological exploration because they contain all of the requisites for the origin and maintenance of a biosphere and the subsequent preservation of its biosignatures. In such systems, water is typically present in the liquid state in a near-surface environment. Both thermal and chemical energy are made available for use by chemosynthetic organisms as a result of water-rock interactions. Common reactions between mafic/ultramafic minerals, water and volcanic gases such as CO2 lead to the formation of reduced carbon compounds that could have been the building blocks of early life. Secondary mineralization of hydrothermal deposits by carbonate, silica, and other hydrothermal precipitates can preserve evidence of prebiotic carbon chemistry as well as evidence of life. Finally, while the bulk of a hydrothermal system is quite likely to be beyond detection in the subsurface, surface expressions of such systems should be morphologically and mineralogically identifiable from space. However, even when surface expressions of hydrothermal systems are missing or cryptic, impact gardening, mass wasting and simple erosion by wind or water will dissect and expose such systems over geologic time. The detection of the correlation between the concurrence of water vapour, shallow ground ice and methane at Arabia Terra, Elysium Planum and Arcadia Memnoma, may indicate such a system exists in these areas (See Kerr 2004a,b and c for commentary).Finding hydrothermal areas:At present, we know of no bona fide hydrothermal zones or regions on Mars. However, the apparent association of fluvial features with volcanic terrains in many places on Mars suggests that such areas must be common. One can deduce from the young crystallization age of most Martian meteorites (which appear to post-date major fluvial/lacustrine features on the planet) that volcanism and (presumed) associated hydrothermal activity persisted throughout Mars history. Indeed, a number of Mars meteorites (including the famous meteorite ALH84001) contain carbonates or minor hydrous phases suggestive of a hydrothermal setting (Treiman et al 2002). Clues to the presence of fossil (inactive) hydrothermal zones include morphological, mineralogical and chemical features. A morphological feature could consist, for example, of a spring mound (positive topographic feature) associated with evidence of water flow. A mineralogical feature could consist of surface deposits of carbonates, silica, etc. Global surveys of hydrogen in the near-subsurface, discussed largely in the context of near-surface water, could in some cases represent hydrated mineral phases associated with hydrothermal features.Future missions will provide clues, perhaps even compelling evidence of past hydrothermal activity. The Mars Reconnaissance Orbiter will have a high-resolution camera from which morphological data will be obtained. CRISM will provide high resolution chemical or mineralogical maps of surface features. Orbital or landed neutron detectors and radar sounding devices could provide maps of near-surface water over large areas of the Mars surface. The ’07 Phoenix Scout mission, as well as Mars ’09 MSL will provide in-situ information on both morphology and mineralogy at the sub-meter to sub-millimeter scale. Five possible landing site hydrothermal geologic settings are envisioned: Point source hydrothermal zones (igneous-driven convection systems). Point source hydrothermal zones are well known on the Earth – as for example those present in Yellowstone National Park (a continental-type environment) (e.g., Walter and Des Marais, 1993) or at the mid-ocean ridges (oceanic-type “black smokers”) (e.g., Kelly et al., 2001). These features should be identifiable by their morphology and their mineralogy/chemistry (Farmer, 1998). High-resolution mineralogical data should allow the identification of systems such as these, which may vary in size from kilometers (Grand Prismatic hot spring, the largest hot spring on Earth, is ~1 km in size) to meters in size. Mineralogical signatures of these systems range from monomineralic deposits (silica, carbonate, sulfide, oxide) to polymineralic assemblages. In general, the areal extent of hot springs, which are the surficial expression of point-source hydrothermal zones, are dwarfed when compared to the volume of hydrothermally altered rock in which chemosynthetic life could live in the subsurface (Cady et al., 1997). As a result, even without a large surface expression of hydrothermal activity, one could search for hydrothermal alteration minerals similar to those found around ore deposits on Earth (Horn, 1996). Surface and near-surface deposits of hydrothermal systems will contain a variety of alteration minerals that vary as a function of the underlying mineralogy of the system (e.g., oxides, carbonates, sulfates, hydrated minerals, etc).Impact-generated hydrothermal systems (craters). Newsom et al. (2001) reviewed many of the key concepts that support a search strategy for life on Mars in aqueous and hydrothermal deposits associated with Martian impact craters. For example, impact craters on Earth (e.g., the Sudbury impact crater, 1.85 Ga ; ~250 km diameter in Sudbury, Ontario) contain extensive evidence of post-impact hydrothermal activity. Impact melt and uplifted basement heat sources could sustain hydrothermal activity and keep crater lakes from freezing for thousands of years, even under cold climatic conditions (Newsom et al., 1996). Post-impact fluids could result from dewatering of deeply buried hydrated materials, and the breach of local aquifers or regional cryospheres. The lifetimes of impact-generated hydrothermal systems depend on the size and cooling rate of the heat source, the permeability and depth of the disturbed zone, the presence of deeply buried water or hydrated materials, and the rate of burial of the impact melt (e.g., Newsom et al., 2001). The lifetime of hydrothermal systems, which is perhaps long enough to create or sustain a biota, has been estimated as 104 – 105 years for terrestrial craters 100 km in diameter, and up to 106 years for 180-km diameter craters. Impact-generated hydrothermal zones may be quite common in areas of subsurface water or permafrost, such as those areas present in the high latitudes. The surface manifestation of such a system could be mineralogical or morphological, but would be co-located with an identifiable impact structure from which it was generated. Serpentinizing terranes. The single most widespread environment of chemical disequilibrium on present-day Earth is the oceanic crust (Deming and Baross, 1995; McCollom and Shock, 1997). The composition of the modern lower crust and upper mantle of the Earth is essentially the same as that of the early Earth and Mars (Nisbet, 1987; Longhi et al., 1992), and the early histories of these two planets are similar. It follows that an understanding of these zones of chemical disequilibria on Earth would be of great value in devising a search strategy for similar regions on Mars.In addition to being potential sites for the genesis of life, hydrothermal systems associated with serpentinization are also excellent candidate sites for the study of prebiotic biogeochemistry. On Earth there is abundant evidence for the formation of abiotic organic compounds along the modern mid-ocean ridge system where it has been linked to serpentinization (H2 source) and hydrothermal activity (Rona et al., 1992; Bougault et al., 1993; Charlou and Donval, 1993; Holm and Charlou, 2001; Schroeder et al., 2002; Kelley and Fruh-Green, 1991; 2001). Serpentinization has also been linked to hydrogen and methane generation onshore in association with ophiolites (Neal and Stanger, 1983; Abrajano et al., 1988). This may also be an explanation of the observations of methane in the Martian atmosphere (Kerr 2004a,b)An excellent example of subsurface life on Earth is associated with the “Lost City hydrothermal complex” located in an off-axis area of the mid-Atlantic ridge hydrothermal system (Kelley, et al. 2001). Similar sites have been described elsewhere (Chapelle et al, 2002; Stevens and McKinley, 1995; Mottl et al., 2003). In locations such as this, ultramafic rocks from the oceanic crust react with water to form secondary minerals such as serpentine. The process is exothermic, and yields a volume increase of nearly 60%. This type of hydrothermal activity is distinct from all others in that no external source of heat is required (the heat generated by the reaction is sufficient to initiate or perpetuate the system), and the volume increase produced by the reaction results in a self-perpetuating system in which cracks formed in freshly altered material create pathways for water to react with fresh ultramafic rock. Th in several locations. Major changes include the allowances for sampling milk while the milk tank truck manhole is not adequately covered, adding criteria for air systems used on milk drying equipment, adding criteria for adequate separation of different types of products and adding specific objections for handling products in a milk plant that may create a public health hazard.

61-34.1 VII.C.16. New criteria listed for aseptic processing and handling milk or milk products by using reverse osmosis (RO), ultra-filtration (UF) evaporating and/or condensing equipment to be consistent with the current PMO.

61-34.1 VII.C.16.c. Batch pasteurizer criteria revised to be consistent with the current PMO.

61-34.1 VII.C.16.d. High-Temperature-Short-Time Pasteurizer criteria revised to be consistent with the current PMO.

61-34.1 VII.C.16.e. Aseptic Processing System criteria revised to be consistent with the current PMO.

61-34.1 VII.C.16.f. Criteria revised for pasteurizers and aseptic processing systems employing regenerative heating to be consistent with the current PMO.

61-34.1 VII.C.16.g. Pasteurization and aseptic processing records, equipment tests and examinations revised, including testing and temporarily sealing pasteurization equipment by trained plant employees, to be consistent with the current PMO.

61-34.1 VII.C.17. Cooling criteria for whey and whey products and additional criteria for use of re-circulated cold water added to be consistent with the current PMO.

61-34.1 VII.C.18. Additional criteria and wording added for mechanical packaging operations, including those for condensed and dry milk products, to be consistent with the current PMO.

61-34.1 VII.C.19. Section revised to include additional acceptable sealing processes and practices for milk and milk products, including dry milk products, to be consistent with the current PMO.

61-34.1 VII.C.20. Additional criteria added or revised to include the prohibited use of tobacco products in milk processing and handling areas and the need to provide and use specific protective clothing in milk drying chambers to be consistent with the current PMO.

61-34.1 VII.C.21. Additional criteria added or revised for milk tank cars, milk tank trucks, and portable shipping bins used to transport milk and milk products to be consistent with the current PMO.

61-34.1 VII.C.22.b.(5.) Criteria for keeping dry milk plant roofs clean added to be consistent with the current PMO.

61-34.1 VIII. Section revised to be consistent with the animal health criteria now required in the current PMO.

61-34.1 IX. Additional criteria added to ensure that only Grade “A” milk and milk products are sold to plants for the commercial preparation of Grade “A” milk and milk products to be consistent with the current PMO.

61-34.1 X.2. Deleted because no longer required by DHEC’s regulation governing food establishments.

61-34.1 XI. Requirements for selling milk and milk products in South Carolina from outside manufacturers extended to condensed and dried products, added criteria to allow milk and milk products to be sold in South Carolina from plants operating under a HACCP regulatory program and updated reciprocity requirements of the NCIMS program to be consistent with the current PMO.

61-34.1 XII. Added the requirement for DHEC to review plans for milk tank truck cleaning facilities to be consistent with the current PMO.

61-34.1 XIII. Revised and added criteria relating to personnel health for those employed by a milk plant to be consistent with the current PMO.

61-34.1 XIV. Revised actions that must be taken when employees who handle milk or milk products are found to have or highly suspected to have contagious infections to be consistent with the current PMO.

**Instructions:** Replace R.61-34.1 in entirety with this amendment**.**

**Text of Amendments**

R. 61-34.1. PASTEURIZED MILK AND MILK PRODUCTS

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SECTION I.  DEFINITIONS AND STANDARDS

A.  Definitions

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

1. ABNORMALITIES OF MILK means

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

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

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

2.  AND/OR means "and" shall apply where appropriate, otherwise "or" shall apply.

3.  ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS means the products hermetically sealed in a container and so thermally processed in conformance with 21 CFR 113 and the provisions of this Regulation so as to render the product free of microorganisms capable of reproducing in the product under normal non-refrigeration conditions of storage and distribution. The product shall be free of viable microorganisms (including spores) of public health significance.

4.  ASEPTIC PROCESSING means the milk product has been subjected to sufficient heat processing, and packaged in a hermetically sealed container, to conform to the applicable requirements of 21 CFR 113 and the provisions of Section VII.C.16. of this Regulation and maintain the commercial sterility of the product under normal non-refrigerated conditions.

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

6. BULK MILK HAULER/SAMPLER means any person who collects official samples and may transport raw milk from a farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any State to sample such products.

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

8. BUTTERMILK means the fluid product resulting from the manufacture of butter from milk or cream. It contains not less than 8.25 percent of milk solids not fat. It shall also include:

a.Grade “A” Dry Buttermilk - dry buttermilk which complies with the applicable provisions of the Pasteurized Milk Ordinance (PMO)

b.Grade “A” Dry Buttermilk Products - dry buttermilk products which comply with the applicable provisions of the PMO.

c.Concentrated (Condensed) Buttermilk - the product resulting from the removal of a considerable portion of water from buttermilk.

d.Grade “A” Concentrated (Condensed) and Dry Buttermilk and Buttermilk Products - concentrated (condensed) or dry buttermilk and buttermilk products which comply with the applicable provisions of the PMO. The words “concentrated (condensed) and dry milk products” shall be interpreted to include concentrated (condensed) and dry buttermilk and buttermilk products.

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

10. CODE OF FEDERAL REGULATIONS (CFR) means the 2003 Code of Federal

Regulations.

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

12. COFFEE LIGHTENER, COFFEE WHITENER, COFFEE MILK, OR MILK FOR COFFEE means a milk product consisting of at least 5 percent but no more than 10.5 percent milkfat, to which approved ingredients may have been added.

13. CONCENTRATED (CONDENSED) MILK means the fluid product, unsterilized and unsweetened, resulting from the removal of a considerable portion of the water from the milk, which, when combined with potable water in accordance with instructions printed on the container label, results in a product conforming with the milkfat and milk solids not fat levels of milk.

14. CONCENTRATED (CONDENSED) MILK PRODUCTS means homogenized concentrated (condensed) milk, concentrated (condensed) skim milk, concentrated (condensed), reduced fat or lowfat milk, and similar concentrated (condensed) products made from concentrated (condensed) milk or concentrated (condensed) skim milk which when combined with potable water in accordance with instructions printed on the container label, conform with the definitions of the corresponding milk products in this section.

15. CONCENTRATED (CONDENSED) SKIM MILK (GRADE “A”) means concentrated (condensed) skim milk, which complies with the applicable provisions of the PMO.

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

17. CREAM means the liquid milk product high in fat which is separated from milk which may have been adjusted by adding thereto: milk, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Cream contains not less than 18 percent milkfat.

18. DAIRY FARM means any place or premises where one or more lactating animals (cows, goats, sheep water buffalo, or other hooved mammal) are kept for milking purposes, and from which a part or all of the milk or milk product(s) is provided, sold, or offered for sale to a milk plant, transfer station, or receiving station.

19. DAIRY PLANT SAMPLERmeans a person responsible for the collection of official samples for regulatory purposes outlined in Section 6 of the PMO. This person is an employee of DHEC and is evaluated at least once every two-year period by a State Sampling Surveillance Officer.

20. DRUG means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C), but does not include devices or their components, parts, or accessories.

21. EGGNOG OR BOILED CUSTARD means the product defined in 21 CFR 131.170.

22. FOOD ALLERGENS mean proteins in foods that are capable of inducing an allergic reaction or response in some individuals. There is scientific consensus that the following foods account for more than 90% of all food allergies: peanuts, soybeans, milk, eggs, fish, crustaceans, tree nuts, and wheat.

Reference: FDA Compliance Policy Guide 555.250 - Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens available on the Internet at:

http://www.fda.gov/ora/compliance\_ref/cpg/cpgfod/cpg555-250.htm

23. FROZEN MILK CONCENTRATE means a frozen milk product with a composition of milkfat and milk solids not fat in such proportions that when a given volume of concentrate is mixed with a given volume of water the reconstituted product conforms to the milkfat and milk solids not fat requirements of whole milk. In the manufacturing process, water may be used to adjust the primary concentrate to the final desired concentration. The adjusted primary concentrate is pasteurized, packaged, and immediately frozen. This product is stored, transported, and sold in the frozen state.

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

25. GRADE A DRY MILK AND WHEY PRODUCTS means the products which have been produced for use in Grade A pasteurized or aseptically processed milk products and which have been manufactured under the provisions of the PMO.

26.HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) DEFINITIONS FOR USE IN CONJUNCTION WITH APPENDIX K OF THE PMO:

a.AUDIT means an evaluation of the entire milk plant, receiving station or transfer station facility and National Conference on Interstate Milk Shipments (NCIMS) HACCP System to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements.

b.CENTRALIZED DEVIATION LOG means a centralized log or file identifying data detailing any deviation of critical limits and the corrective actions taken as required in Appendix K of the PMO.

c. CONTROL means:

To manage the conditions of an operation to maintain compliance with established criteria.

(2) The state where correct procedures are being followed and criteria are being met.

d. CONTROL MEASURE means any action or activity that can be used to prevent, eliminate, or reduce a significant hazard that is managed at a Critical Control Point.

e. CORRECTIVE ACTION means procedures followed when a deviation occurs.

f.. CRITICAL CONTROL POINT (CCP) means a step at which control can be applied and is essential to prevent or eliminate a milk or milk product safety hazard or reduce it to an acceptable level.

g.CRITICAL LIMIT (CL) means a maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a milk or milk product safety hazard.

h.CRITICAL LISTING ELEMENT (CLE) means an item on the Milk Plant, Receiving Station or Transfer Station NCIMS HACCP System Audit Report identified with a double star (\*\*). The marking of a CLE by a State Rating Officer or FDA auditor, indicates a condition that constitutes a major dysfunction likely to result in a potential compromise to milk or milk product safety, or that violate NCIMS requirements regarding drug residue testing and traceback or raw milk sources, whereby a listing may be denied or withdrawn.

DAIRY HACCP CORE CURRICULUM shall consist of:

(1) Basic HACCP training; plus

(2) An orientation to the requirements of the NCIMS HACCP Program.

j.DEFICIENCY means an element inadequate or missing from the requirements of the HACCP System or Appendix K of the PMO.

k.DEVIATION means a failure to meet a CL.

l.HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) means a systematic approach to the identification, evaluation, and control of significant milk or milk product safety hazards.

m.HACCP PLAN means the written document, which is based upon the principles of HACCP and delineates the procedures to be followed.

n.HACCP SYSTEM means the implemented HACCP Plan and Prerequisite Program, including other applicable NCIMS requirements.

o.HACCP TEAM means the group of people who are responsible for developing, implementing, and maintaining the HACCP System.

p.HAZARD means a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

q.HAZARD ANALYSIS means the process of collecting and evaluating information on hazards associated with the milk under consideration, to decide which are reasonably likely to occur and must be addressed in the HACCP Plan.

r.MONITOR means to conduct a planned sequence of observations or measurements to assess whether a CCP is under control or to assess the conditions and practices of all required Prerequisite Programs.

s.NON-CONFORMITY means a failure to meet specified requirements of the HACCP System as described in Appendix K of the PMO.

t.POTENTIAL HAZARD means any hazard to be evaluated by the hazard analysis.

u.PREREQUISITE PROGRAMS (PPs) mean procedures, including Good Manufacturing Practices (GMPs), which address operational conditions that provide the foundation for the HACCP System. The required PPs specified in Appendix K. of the PMO are sometimes called Sanitary Standard Operating Procedures (SSOPs) in other HACCP Systems.

v.VALIDATION means the element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP Plan, when properly implemented, will effectively control the hazards.

w.VERIFICATION means those activities, other than monitoring, that determine the validity of the HACCP Plan and that the HACCP System is operating according to the plan.

27. HERMETICALLY SEALED CONTAINER means a container that is designed and intended to be secure against the entry of microorganisms and thereby maintain the commercial sterility of its contents after processing.

28. HOMOGENIZED means the milk or a milk product has been treated to insure breakup of the fat globules to such an extent that after 48 hours of quiescent storage at 4.4°C (40°F), no visible cream separation occurs on the milk; and the fat percentage of the top 100 milliliters of milk in a quart, or of proportionate volumes in containers of other sizes, does not differ by more than 10 percent from the fat percentage of the remaining milk as determined after thorough mixing.

29. HOOVED MAMMALS MILK means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy hooved mammals. This product shall be produced according to the sanitary standards of this Regulation.

30. INDUSTRY PLANT SAMPLER means a person responsible for the collection of official samples for regulatory purposes at a milk plant, receiving station or transfer station as outlined in Appendix N of the PMO. This person is an employee of the milk plant, receiving station or transfer station and is evaluated at least once every two year period by a State Sampling Surveillance Officer or a properly delegated Sampling Surveillance Regulatory Official.

31. LACTOSE-REDUCED MILK, LACTOSE-REDUCED REDUCED FAT MILK, LACTOSE-REDUCED LOWFAT MILK, OR LACTOSE-REDUCED SKIM MILK means the product resulting from the treatment of milk, reduced fat milk, low fat milk, or skim milk as defined in this Regulation by the addition of safe and suitable enzymes to convert sufficient amounts of the lactose to glucose and/or galactose so that the remaining lactose is less than 30 percent of the lactose in milk, reduced fat milk, lowfat milk or skim milk.

32. LOW-SODIUM MILK, LOW-SODIUM REDUCED FAT MILK, LOW-SODIUM LOWFAT MILK OR LOW-SODIUM SKIM MILK means the product resulting from the treatment of milk, reduced fat milk, lowfat milk, or skim milk as defined in the Regulation by a process of passing the milk, reduced fat milk, lowfat milk. or skim milk through an ion exchange resin process or any other process which has been recognized by the Food and Drug Administration that effectively reduces the sodium content of the product to less than 10 milligrams in 100 milliliters.

33. MILK DISTRIBUTOR means any person who offers for sale or sells to another any milk or milk products.

34. MILK HAULER means any person who transports raw milk and/or raw milk products to or from a milk plant, receiving station or transfer station.

35. MILK PLANT means any place, premises, or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed, condensed, dried, packaged, or prepared for distribution.

36. MILK PRODUCER means any person who operates a dairy farm and provides, sells, or offers milk for sale to a milk plant, receiving station, or transfer station.

37. MILK PRODUCTS include cream, light cream, light whipping cream, heavy cream, heavy

whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, half-and-half, sour half-and-half, acidified sour half-and-half, cultured sour half-and-half, reconstituted or recombined milk and milk products, concentrated (condensed) milk, concentrated (condensed) milk products, concentrated (condensed) and dry milk products, nonfat (skim) milk, reduced fat or lowfat milk, frozen milk concentrate, eggnog, buttermilk, buttermilk products, whey, whey products, cultured milk, cultured reduced fat or lowfat milk, cultured nonfat (skim) milk, yogurt, lowfat yogurt, nonfat yogurt, acidified milk, acidified reduced fat or lowfat milk, acidified nonfat (skim) milk, low-sodium milk, low-sodium reduced fat or lowfat milk, low-sodium nonfat (skim) milk, lactose-reduced milk, lactose-reduced reduced fat or lowfat milk, lactose-reduced nonfat (skim) milk, aseptically processed and packaged milk and milk products as defined in this Section, milk, reduced fat, lowfat milk or nonfat (skim) milk with added safe and suitable microbial organisms and any other milk product made by the addition or subtraction of milkfat or addition of safe and suitable optional ingredients for protein, vitamin or mineral fortification of milk products defined herein.

Milk products also include those dairy foods made by modifying the federally standardized products listed in this Section in accordance with 21 CFR 130.10-Requirements for foods named by use of a nutrient content claim and a standardized term.

This Definition shall include those milk and milk products, as defined herein, which have been aseptically processed and then packaged.

Milk and milk products which have been retort processed after packaging or which have been concentrated (condensed) or dried are included in this Definition only if they are used as an ingredient to produce any milk or milk product defined herein or if they are labeled as Grade “A” as described in Section IV.

Powdered dairy blends may be labeled Grade “A” and used as ingredients in Grade “A” dairy products, such as cottage cheese dressing mixes or starter media for cultures used to produce various Grade “A” cultured products, if they meet the requirements of this Regulation. If used as an ingredient in Grade “A” products, such as those listed above, blends of dairy powders must be blended under conditions, which meet all applicable Grade “A” requirements. Grade “A” powder blends must be made from Grade “A” powdered dairy products, except that small amounts of functional ingredients, (total of all such ingredients shall not exceed 5% by weight of the finished blend) which are not Grade “A” are allowed in Grade “A” blends when the finished ingredient is not available in Grade “A” form, i.e., sodium caseinate. This is similar to the existing FDA position that such dairy ingredient in small cans of freeze-dried starter culture need not be Grade “A”.

This definition is not intended to include dietary products (except as defined herein), infant formula, ice cream or other frozen desserts, butter or cheese. It does, however, include:

DRY MILK PRODUCTS - products resulting from the drying of milk or milk products and

any product resulting from the combination of dry milk products with other wholesome dry ingredients.

GRADE “A” DRY MILK PRODUCTS - dry milk products, which comply with the applicable

provisions of this Regulation*.*

38. MILK SHAKE MIX means the fluid product made only from Grade A pasteurized milk with the addition of harmless flavoring, sugar, stabilizer, and milk solids. The product shall contain not less than 3.25 percent milkfat and not less than 25 percent and not more than 30 percent total solids.

39. MILK TANK TRUCK means a bulk milk pickup tanker and a milk transport tank.

40. MILK TANK TRUCK CLEANING FACILITY means any place, premises, or establishment, separate from a milk plant, receiving station or transfer station, where a milk tank truck is cleaned and sanitized.

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

42.MILK TRANSPORT TANK means a vehicle including the truck and tank used by a milk hauler/sampler to transport bulk shipments of milk from a transfer station, receiving station or milk plant to another transfer station, receiving station or milk plant.

43. MILK TRANSPORTATION COMPANY means the person responsible for a milk tank truck(s).

44. MISBRANDED MILK AND MILK PRODUCTS means any milk or milk products are deemed to be misbranded when:

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

b.  The milk and milk products do not conform to the definitions as contained in this Regulation; and

c.  The products are not labeled in accordance with Section IV of this Regulation.

d.  Violation of Chapter 403 of the Federal Food, Drug, and Cosmetic Act as amended (21 U.S.C. 342) will be considered as a violation of this Regulation.

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

46. OFFICIAL LABORATORY means a biological, chemical, or physical laboratory which is under the direct supervision of DHEC.

47. OPTIONAL INGREDIENTS means ingredients used in milk products approved by DHEC.

48. PASTEURIZATION means the process of heating every particle of milk or milk product in properly designed and operated equipment, to one of the temperatures given in the following table and held continuously at or above that temperature for at least the corresponding specified time:

TemperatureTime

\*63ºC (145ºF) 30 minutes

\*72ºC (161ºF) 15 seconds

89ºC (191ºF)1.0 second

90ºC (194ºF)0.5 second

94ºC (201ºF)0.1 second

96ºC (204ºF) 0.05 second

100ºC (212ºF) 0.01 second

\*If the fat content of the milk product is 10 percent or more, or if it contains added sweeteners, or if it is concentrated (condensed), the specified temperature shall be increased by 3°C (5°F): Provided, that eggnog shall be heated to at least the following temperature and time specifications:

TemperatureTime

69ºC (155ºF)30 minutes

80ºC (175ºF)25 seconds

83ºC (180ºF)15 seconds

Provided further, that nothing in this definition shall be construed as barring any other pasteurization process which has been recognized by the Food and Drug Administration to be equally efficient and which is approved by DHEC.

49. PASTEURIZED MILK ORDINANCE (PMO) means the Grade “A” Pasteurized Milk Ordinance, 2003 Revision, promulgated by the National Conference on Interstate Milk Shipments (NCIMS) and endorsed by the United States Department of Health and Human Services, Public Health Service, Food and Drug Administration for regulating the production, transportation, processing, handling, sampling, examination, labeling and sale of all Grade “A” milk and milk products sold and consumed in the United States.

50. PERSON means any individual, milk plant operator, partnership, corporation, company, firm, trustee, association or institution.

51. RECEIVING STATION means any place, premises, or establishment where raw milk is received, collected, handled, stored or cooled and prepared for further transporting.

52. RECONSTITUTED OR RECOMBINED MILK AND MILK PRODUCTS means milk or milk products defined in this section which result from reconstituting or recombining of milk constituents with potable water when appropriate.

53. REGULATORY AUTHORITY means the authorized representative of the South Carolina Department of Health and Environmental Control, hereinafter known as DHEC.

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

55. SHEEP MILK means the normal lacteal secretion practically free of colostrum, obtained by the complete milking of one or more healthy sheep. Sheep milk shall be produced according to the sanitary standards of this Regulation. The word "milk" shall be interpreted to include sheep milk.

56. STERILIZED means the condition achieved by application of heat, chemical sterilant(s) or other appropriate treatment that renders the piping, equipment and containers free of viable microorganisms.

57. TRANSFER STATION means any place, premises, or establishment where milk or milk products are transferred directly from one milk tank truck to another.

58. ULTRA-PASTEURIZED means that a dairy product shall have been thermally processed at or above 138ºC (280ºF) for at least two seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions. (Refer to 21 CFR 131.3)

59. WATER BUFFALO MILK means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy water buffalo. Water buffalo milk shall be produced according to the sanitary standards of this Regulation. The word “milk” shall be interpreted to include water buffalo milk.

60. Whey Products mean any fluid product removed from whey; or made by the removal of any constituent from whey; or by the addition of any wholesome substance to whey or parts thereof.

a. GRADE “A” WHEY PRODUCTS mean any fluid product removed from whey; or

made by the removal of any constituent from whey; or by the addition of any wholesome substance to whey or parts thereof which have been manufactured under the provisions of this Regulation.

b. DRY WHEY PRODUCTS mean products resulting from the drying of whey or whey

products and any product resulting from the combination of dry whey products with other wholesome dry ingredients.

GRADE “A” CONCENTRATED (CONDENSED) AND DRY WHEY AND WHEY

PRODUCTS mean concentrated (condensed) or dry whey and whey products, which complies with the applicable provisions of this Regulation. The words "concentrated (condensed) and dry milk products" shall be interpreted to include concentrated (condensed) and dry whey and whey products.

B.  Standards

1. The Grade A milk and milk products covered by this Regulation include cream, light cream, light whipping cream, heavy cream, heavy whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, half-and-half, sour half-and-half, acidified sour half-and-half, cultured sour half-and-half, reconstituted or recombined milk and milk products, concentrated (condensed) milk, concentrated (condensed) milk products, concentrated (condensed) and dry milk products, nonfat (skim) milk, reduced fat or lowfat milk, frozen milk concentrate, eggnog, buttermilk, buttermilk products, whey, whey products, cultured milk, cultured reduced fat or lowfat milk, cultured nonfat (skim) milk, yogurt, lowfat yogurt, nonfat yogurt, acidified milk, acidified reduced fat or lowfat milk, acidified nonfat (skim) milk, low-sodium milk, low-sodium reduced fat or lowfat milk, low-sodium nonfat (skim) milk, lactose-reduced milk, lactose-reduced reduced fat or lowfat milk, lactose-reduced nonfat (skim) milk, aseptically processed and packaged milk and milk products, milk, reduced fat, lowfat milk or nonfat (skim) milk with added safe and suitable microbial organisms and any other milk product made by the addition or subtraction of milkfat or addition of safe and suitable optional ingredients for protein, vitamin or mineral fortification of milk products defined herein.

Milk products also include those dairy foods made by modifying the federally standardized products listed in this Section in accordance with 21 CFR 130.10-Requirements for foods named by use of a nutrient content claim and a standardized term.

Milk and milk products,which have been aseptically processed and then packaged are also covered by this Regulation.

Milk and milk products which have been retort processed after packaging or which have been concentrated (condensed) or dried are included only if they are used as an ingredient to produce any milk or milk product defined herein or if they are labeled as Grade “A.”

Powdered dairy blends may be labeled Grade “A” and used as ingredients in Grade “A” dairy products, such as cottage cheese dressing mixes or starter media for cultures used to produce various Grade “A” cultured products, if they meet the requirements of this Regulation. If used as an ingredient in Grade “A” products, such as those listed above, blends of dairy powders must be blended under conditions, which meet all applicable Grade “A” requirements. Grade “A” powder blends must be made from Grade “A” powdered dairy products, except that small amounts of functional ingredients, (total of all such ingredients shall not exceed 5% by weight of the finished blend) which are not Grade “A” are allowed in Grade “A” blends when the finished ingredient is not available in Grade “A” form, i.e., sodium caseinate. Examples: small cans of freeze-dried starter culture not labeled as Grade “A.”

This Regulation is not intended to include dietary products (except as defined herein), infant formula, ice cream or other frozen desserts, butter or cheese.

2. All Grade A milk and milk products shall meet the definitions and standards for milk and cream products as set for in Parts 131 and 133 (for cottage cheese products) of 21 CFR and Appendix L. of the PMO.

3. All Grade “A” raw milk or milk products for pasteurization, ultra-pasteurization, or aseptic processing and all Grade "A" pasteurized, ultra-pasteurized or aseptically processed milk and milk products, shall be produced, processed**,** manufactured and pasteurized, ultra-pasteurized, or aseptically processed to conform to the following chemical, physical, bacteriological and temperature standards and the sanitation requirements of this Section.

No process or manipulation other than pasteurization, ultra-pasteurization or aseptic processing; processing methods integral therewith; and appropriate refrigeration shall be applied to milk and milk products for the purpose of removing or deactivating microorganisms. Provided, that in the bulk shipment of cream, nonfat (skim) milk or reduced fat or lowfat milk, the heating of the raw milk, one time, to temperatures greater than 52ºC (125ºF) but less than 72ºC (161ºF), for separation purposes, is permitted when the resulting bulk shipment(s) of cream, nonfat (skim) milk or reduced fat or lowfat milk are labeled heat-treated. In the case of heat-treated cream, the cream may be further heated to less than 75ºC (166ºF) in a continuing heating process and immediately cooled to 7ºC (45ºF) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason.

Milk plants, receiving stations and transfer stations participating in the NCIMS HACCP Program, shall also comply with the requirements of Appendix K. of the PMO.

Whey shall be from cheese made from Grade "A" raw milk for pasteurization as provided in this Regulation.

Buttermilk shall be from butter made from Grade "A" cream, which has been pasteurized prior to use in accordance with the pasteurizing and aseptic processing requirements of this Regulation. Provided, that this requirement shall not be construed as barring any other heat treatment process which has been recognized by the fdato be equally efficient in the destruction of staphylococcal organisms and which is approved by DHEC.

Buttermilk and whey used in the manufacture of Grade "A" milk and milk products shall be produced in an approved milk/cheese plant.

Whey shall be from:

a. Cheese made from Grade "A" raw milk for pasteurization, which has been pasteurized prior to

use, in accordance with the pasteurizing and aseptic processing requirements of this Regulation, or

b. Cheese made from Grade "A" raw milk for pasteurization, which has been heat-treated to a

temperature of at least 64oC (147oF) and held continuously at that temperature for at least twenty-one seconds or to at least 68oC (153oF) and held continuously at that temperature for at least fifteen seconds, in equipment meeting the pasteurization requirements provided for in this Regulation. Provided, that this requirement shall not be construed as barring any other heat treatment process which has been recognized by the FDAto be equally efficient in the destruction of staphylococcal organisms and which is approved by DHEC.

SECTION II.  ADULTERATED OR MISBRANDED MILK OR MILK PRODUCTS

A.  General

1.  No person shall, within the State of South Carolina or its jurisdiction, produce, provide, sell, offer, or expose for sale, or have in possession with intent to sell any milk or milk product which is adulterated or misbranded: provided, that in an emergency, the sale of pasteurized milk and milk products which have not been graded, or the grade of which is unknown, may be authorized by DHEC in which case such products shall be labeled "ungraded".

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

3.  Milk and milk products shall be examined by DHEC as often as may be necessary to determine freedom from adulteration or misbranding. DHEC may, upon written notice to the owner or person in charge, place a hold order on any milk or milk product which it determines, or has probable cause to believe, to be unwholesome or otherwise adulterated or misbranded. Under a hold order, milk or milk products shall be permitted to be suitably stored. It shall be unlawful for any person to remove or alter a hold order, notice, or tag placed on milk or milk products by DHEC, and neither such milk or milk products nor the containers thereof shall be relabeled, repacked, reprocessed, altered, disposed of, or destroyed without permission of DHEC, except on order by a court of competent jurisdiction.

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

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

6.  When milk is found to be adulterated by the presence of drugs, pesticides, herbicides, or other poisonous substances, it shall be impounded and additional samples analyzed. Milk found to be adulterated shall be disposed of until analysis shows the product not to be adulterated. If testing reveals milk positive for drug residues, the milk shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA Compliance Policy Guide (CPG 7126.20). DHEC shall determine the producer(s) responsible for the drug residue violation and immediately suspend the producer’s Grade "A” permit or equally effective measures shall be taken to prevent the sale of milk containing drug residues and a penalty shall be imposed. Future pick-ups are prohibited until subsequent testing reveals the milk is free of drug residue. The penalty shall be for the value of all milk on the contaminated load plus any costs associated with the disposition of the contaminated load. DHEC may accept certification from the violative producer’s milk marketing cooperative or purchaser of milk as satisfying the penalty requirements. The Grade “A” producer’s permit may be reinstated, or other action taken, to allow the sale of milk for human food, when a representative sample taken from the producer’s milk, prior to commingling with any other milk, is no longer positive for drug residue. Whenever a drug residue test is positive, an investigation shall be made to determine the cause. The farm inspection is completed by DHEC to determine the cause of the residue and actions taken to prevent future violations including:

a. On-farm changes in procedures necessary to prevent future occurrences as recommended by

DHEC.

b. Discussion and education on the Drug Residue Avoidance Control measures outlined in

Appendix C. of the PMO.

After a third violation in a twelve-month period, DHEC shall initiate administrative procedures pursuant to the revocation of the producer’s Grade “A” permit under the authority of Section III.of this Regulation, due to repeated violations.

7.  When pasteurized milk or milk products are found to be adulterated by drugs, pesticides, herbicides, or other poisonous substances, the adulterated products shall be removed from the market, disposed of, and sale stopped until analysis proves the product to be free from adulteration.

B.  Administrative Procedures

1.  This section of the Regulation shall be used in impounding the product, preferring charges against persons who adulterated or misbrand their milk or milk products, or label them with any grade designation not authorized by DHEC under the terms of this Regulation, or who sell or deliver ungraded milk or milk products except as may be permitted under this section in an emergency. An emergency is defined as a general and acute shortage in the milkshed, not simply one distributor's shortage.

2.  When two of the last four samples of a pasteurized product are in violation of the milkfat or milk solids not fat standard for that product a warning letter will be issued. When three of the last five samples are in violation the permit will be suspended in accordance with the South Carolina Administrative Procedures Act, Sections 1-23-310 et. seq., 1976 Code of Laws of South Carolina as amended.

SECTION III.  PERMITS

A.  General

1.  It shall be unlawful for any person who does not possess a permit from DHEC to manufacture, bring into, send into, or receive into South Carolina or its jurisdiction; have in storage, sell or offer for sale therein, or or offer to give away any milk or milk products defined in this Regulation. Grocery stores, restaurants, soda fountains, and similar establishments where milk or milk products are served or sold at retail, but not processed, may be exempt from the requirements of this section.

2.  Only a person who complies with the requirements of this Regulation shall be entitled to receive and retain such a permit. Permits shall not be transferable with respect to persons and/or locations. Brokers, agents, and distributors representing, buying from, and/or selling condensed and dry milk from, or to, a permitted milk plant are not required to have a separate permit.

3.  DHEC shall suspend such permit, whenever it has reason to believe that a public health hazard exists; or whenever the permit holder has violated any of the requirements of this Regulation; or whenever the permit holder has interfered with DHEC in the performance of its duties provided that DHEC shall, in all cases except where the milk or milk product involved creates, or appears to create, an imminent hazard to the public health; or in any case of a willful refusal to permit authorized inspection, serve upon the holder a written notice of intent to suspend permit, which notice shall specify with particularity the violation(s) in question and afford the holder such reasonable opportunity to correct such violation(s) as may be agreed to by the parties, or in the absence of agreement, fixed by DHEC before making any order of suspension effective. A suspension of permit shall remain in effect until the violation has been corrected to the satisfaction of DHEC.

3. It shall be unlawful for any person to manufacture, package, and/or store non-Grade “A” condensed or dry milk products in a permitted Grade “A” milk plant in South Carolina without a separate DHEC permit for those specific products. All non-Grade “A” condensed or dry milk products shall be plainly identified, and processed, packaged and stored separately from all Grade “A” products.

4. a. DHEC shall suspend such permit whenever:

(1) it has reason to believe that a public health hazard exists;

(2) the permit holder has violated any of the requirements of this Regulation, including

willful refusal to allow an authorized inspection/audit;

(3) the permit holder has interfered with DHEC in the performance of its duties; or

(4) the milk or milk product involved creates, or appears to create, an imminent hazard to the public health, as defined in Section III.B.2.a. below.

b. A suspension of permit shall remain in effect until the violation has been corrected to the

satisfaction of DHEC.

5. Upon repeated violation(s) and/or suspension(s), DHEC may revoke such permit following reasonable notice to the permit holder and an opportunity for a hearing, pursuant to the South Carolina Administrative Procedures Act, Sections 1-23-310 et. seq, 1976 Code of Laws of South Carolina as amended.

B.  Administrative Procedures

1. Issuance of Permits - Every milk producer, milk distributor, milk hauler, bulk milk pickup tanker, and each milk plant, receiving station, milk tank truck cleaning facility, transfer station operator, and milk transportation company shall hold a valid permit. Milk producers who transport milk or milk products only from their own dairy farms and employees of a milk distributor or milk plant operator who possesses a valid permit and employees of a milk transportation company that possesses a valid permit and transports milk or milk products from a milk plant, receiving station or transfer station shall not be required to possess a bulk milk hauler/sampler’s permit. Grocery stores, restaurants, soda fountains, and similar establishments where milk and milk products are served or sold at retail but not processed, may be exempt from the requirements of this section.

Suspension of Permits

a. When the permit suspension is due to violations other than bacterial, coliform, somatic cell,

cooling temperature, or drug residue test standards, the permit holder, manager or other authorized representative is notified by certified mail or hand delivery of the intent to suspend the permit in thirty days unless a written request for a hearing is filed with DHEC. If no request is made in thirty days, the permit is suspended until the violations are corrected. If a written request for a hearing is made within thirty days, a hearing will be provided. If the hearing upholds the findings of DHEC, the permit shall be suspended until the reasons for the suspension have been corrected.

b. DHEC may without warning, notice, or hearing suspend a permit when an imminent health

hazard exists. An imminent health hazard includes, but is not limited to, violations of bacterial, coliform, somatic cell, cooling temperature, or drug residue test standards. Following permit suspension, all manufacturing operations shall immediately cease. DHEC shall promptly notify, in writing by certified mail or hand delivery, the specific reasons for which the permit was suspended and that an opportunity for a hearing will be provided if a written request is filed with DHEC by the permit holder within thirty days. If no written request is filed within thirty days, the suspension is sustained. During the hearing process, the permit shall remain suspended unless the imminent health hazard has been corrected.

c.  Hearings on suspension of permits provided for in this section shall be conducted in accordance, where applicable, with the South Carolina Administrative Procedures Act, Sections 1-23-310 et. seq., 1976 Code of Laws of South Carolina as amended.

3. Reinstatement of Permits

a. Any producer, distributor, bulk milk hauler/sampler, bulk milk pickup tanker, or milk

plant operator, receiving station, milk tank truck cleaning facility, transfer station operator, and milk transportation company, whose permit has been suspended may apply for the reinstatement of his permit. Any application for the reinstatement of a suspended permit must be in writing and must address all violations underlying the suspension and explain the steps taken to correct those violations. Within one week of the receipt of such application, DHEC shall make an inspection of the applicant's establishment, and as many additional inspections thereafter as are deemed necessary, to determine that the applicant's establishment is complying with the requirements. When the findings justify, the permit shall be reinstated.

b. When the permit suspension has been due to a violation of any of the bacteriological,

coliform, somatic cell, cooling temperature, or drug residue test standards, DHEC, within one week after the receipt of application for reinstatement of permit, may issue a temporary permit after determining by an inspection of the facilities and operating methods that the conditions responsible for the violation have been corrected.

c.When a permit suspension has been due to a violation of the somatic cell count standard,

DHEC may issue a temporary permit whenever resampling of the herd’s milk supply indicates the milk supply to be within acceptable limits as prescribed in Section VII. Samples shall then be taken at the rate of not more than two per week on separate days within a three-week period, and DHEC shall reinstate the permit upon compliance with the appropriate standards as determined in accordance with Section VI of this Regulation.

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

SECTION IV.  LABELING

A.  General

1.  All bottles, containers, and packages enclosing milk or milk products defined in Section I of this Regulation shall be labeled in accordance with the applicable requirements of the Federal Food, Drug and Cosmetic Act as amended, the Nutrition Labeling and Education Act (NLEA) of 1990 and regulations developed thereunder, the Code of Federal Regulations, and in addition shall comply with the applicable requirements of this section as follows:

2.  All bottles, containers, and packages enclosing milk or milk products except milk tank trucks, storage tanks, and cans of raw milk from individual dairy farms shall be conspicuously marked with:

a.  The words "Grade A" on the exterior surface. Acceptable locations shall include the principal display panel, the secondary or informational panel, or the cap/cover.

b.  The identity of the plant where pasteurized, ultra-pasteurized, aseptically processed, condensed and/or dried.

c.  The word "reconstituted" or "recombined" if the product is made by reconstitution or recombination.

d.  The volume or proportion of water to be added for reconstituting or recombining in the case of concentrated milk or milk products.

e. In the case of condensed or dry milk products, the following shall also apply:

(1) The identity of the Regulatory Agency issuing such permit; and if distributed by another party, the name and address of the distributor shall be shown by a statement, such as “Distributed by.”

(2) A code or lot number identifying the contents with a specific date, run, or batch of the product, and the quantity of the contents of the container.

f. The words "keep refrigerated after opening" in the case of aseptically processed milk and milk products.

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

3.  All vehicles and milk tank trucks containing milk or milk products shall be legibly marked with the name and address of the milk plant or hauler in possession of the contents.

4.  Milk tank trucks transporting raw, heat-treated or pasteurized milk and milk products to a milk plant from another milk plant, receiving or transfer station are required to be marked with the name and address of the milk plant or hauler and shall be sealed; in addition, for each such shipment, a shipping statement shall be prepared containing at least the following information:

a.  Shipper's name, address, and permit number. Each milk tank truck containing milk shall include the IMS Bulk Tank Unit (BTU) Identification Number(s) or the IMS Listed Milk Plant Number for farm groups listed with a milk plant, on the weigh ticket or manifest.

b.  Permit identification of hauler, if not employee of shipper.

c.  Point of origin of shipment.

d.  Tanker identity number.

e.  Name of product.

f.  Weight of product.

g.  Grade of product.

h.  Temperature of product when loaded.

i.  Date of shipment.

j.  Name of supervising regulatory agency at the point of origin of shipment.

k.  Whether the contents are raw, pasteurized, or in the case of cream, lowfat, or skim milk whether it has been heat-treated.

l. Seal number on inlet, outlet, wash connections and vents.

5. Each milk tank truck containing milk shall be accompanied by documentation, weigh ticket or manifest, which shall include the IMS BTU Identification Number(s) or the IMS Listed Milk Plant Number, for farm groups listed with a milk plant.

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

B.  Administrative Procedures - Emergency Supplies

The purpose of this Section is to require labeling that will permit easy identification of the milk and milk product and its origin. It is required that the milk or milk product be designated by its common or usual name.

1.  Labeling - When the sale of ungraded milk or milk products is authorized during emergencies, under the terms of Section II, the label must bear the designation "ungraded". When such labeling is not available, DHEC shall take immediate steps to inform the public that the particular supply is ungraded, and that the supply will be properly labeled as soon as the distributor can obtain the required labels.

2.  Identity Labeling - "Identity" as used in this section is defined as the name and address or permit number of the milk plant at which the pasteurization, ultra-pasteurization, aseptic processing, or condensing and/or drying takes place. It is recommended that the voluntary national uniform coding system for identification of pasteurization plants at which milk and milk products are packaged, be adopted in order to provide a uniform system of codes throughout the country.

a.  In cases where several plants are operated by one firm, the common firm name may be utilized on milk bottles, containers, or packages provided that the location of the plant at which the contents were pasteurized, ultra-pasteurized, aseptically processed, condensed and/or dried is also shown, either directly or by a code. This requirement is necessary in order to enable DHEC to identify the source of the pasteurized, ultra-pasteurized, aseptically processed, condensed and/or dried milk or milk products. The street address of the plant need not be shown when only one plant of a given name is located within the municipality.

b.  The identity labeling requirement may be interpreted as permitting plants and persons to purchase and distribute, under their own label milk and milk products processed and packaged at another plant provided that the label reads, "Processed at ... (name and address)", or that the processing and packaging plant is identified by a proper code.

3.  Misleading Labels - DHEC shall not permit the use of any misleading marks, words, or endorsements upon the label. DHEC may permit the use of registered trade designs or similar terms on the bottle cap or label when, in their opinion, they are not misleading and are not so used as to obscure the labeling required by the Regulation. For dry milk products, the outer bag must be preprinted Grade “A” before filling. The use of super grade designations shall not be permitted. However, this should not be construed as prohibiting the use of official grade designations awarded to dry milk products by the United States Department of Agriculture (USDA). Grade designations such as "Grade AA Pasteurized", "Selected Grade A Pasteurized", "Special Grade A Pasteurized", etc., give the consumer the impression that such a grade is significantly safer than Grade “A.” Such an implication is false, because the Regulation requirements for Grade “A” pasteurized, ultra-pasteurized or aseptically processed milk when properly enforced, will ensure that this grade of milk will be as safe as milk can practicably be made. Descriptive labeling terms must not be used in conjunction with the Grade “A” designation or name of the milk or milk product and must not be false or misleading.

SECTION V.  INSPECTION OF DAIRY FARMS AND MILK PLANTS

A.  General

1.  Each dairy farm, milk plant, receiving station, transfer station, and milk tank truck cleaning facility whose milk or milk products are intended for consumption within South Carolina or its jurisdiction and each bulk milk hauler/sampler who collects samples of raw milk for pasteurization, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, transfer station or receiving station and his bulk milk pickup tank and its appurtenances shall be inspected by DHEC prior to the issuance of a permit. Following the issuance of a permit, DHEC shall:

a.  Inspect each bulk milk pickup tanker and its appurtenances used by a bulk milk hauler/sampler who collects samples of raw milk for pasteurization for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, transfer station or receiving station at least every twelve months;

b.  Inspect each such bulk milk hauler/sampler’s, dairy plant sampler’s and industry plant sampler’s pickup and sampling procedures at least once every twenty-four months;

c.  Inspect each dairy farm at least once every three months;

d. Inspect each milk plant and receiving station at least once every three months, except that, for those milk plants and receiving stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K of the PMO.

e. Inspect each milk tank truck cleaning facility and transfer station at least once every six months, except that, for those transfer stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K of the PMO.

2. Should a violation of any requirement set forth in Section VII, or in the case of a bulk milk hauler/sampler, industry plant sampler or milk tank truck also Section VI and Appendix B of the PMO, be found to exist on an inspection/audit, a second inspection/audit shall be required after the time deemed necessary to remedy the violation, but not before three days. This second inspection/audit shall be used to determine compliance with the requirements of Section VII or in the case of a bulk milk hauler/sampler, industry plant sampler or milk tank truck also Section VI and Appendix B of the PMO. Any violation of the same requirement of Section VII, or in the case of a bulk milk hauler/sampler or milk tank truck also Section VI and Appendix B of the PMO, on such second inspection/audit, shall call for permit suspension in accordance with Section III and/or court action or in the case of an industry plant sampler, shall cease the collection of official regulatory samples until successfully re-trained and re-evaluated by DHEC. Provided, that when DHEC finds that a critical processing element violation involving:

a. Proper pasteurization, whereby every particle of milk or milk product may not have been heated to the proper temperature and held for the required time in properly designed and operated equipment;

b. A cross-connection exists whereby direct contamination of pasteurized milk or milk product is occurring; or

c. Conditions exist whereby direct contamination of pasteurized milk or milk product is occurring,

DHEC shall take immediate action to prevent further movement of such milk or milk product until such violations of critical processing element(s) have been corrected. Should correction of such critical processing element(s) not be accomplished immediately, DHEC shall take prompt action to suspend the permit as provided for in Section III of this Regulation. Provided, that in the case of milk plants producing aseptically processed milk and milk products, when an inspection of the milk plant and its records reveal that the process used has been less than the required scheduled process, it shall be considered an imminent hazard to public health and DHEC shall take immediate action to suspend the permit of the milk plant for the sale of aseptically processed milk and milk products in conformance with Section III of this Regulation.

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

4. DHEC shall also make such other inspections and investigations as are necessary for the enforcement of this Regulation.

5. Every permit holder shall, upon request of DHEC, allow access of officially designated persons to all parts of the permitted establishment or facilities to determine compliance with the provision of this Regulation. A distributor or plant operator shall furnish DHEC, upon request, for official use only, a true statement of the actual quantities of milk and milk products of each grade purchased and sold, and a list of all sources of such milk and milk products, records of inspections, tests, and pasteurization time and temperature records.

6. It shall be unlawful for any person who, in an official capacity, obtains any information under the provisions of this Regulation which is entitled to protection as a trade secret (including information as to the quantity, quality, source or disposition of milk or milk products, or results of inspections or tests thereof) to use such information to his/her own advantage or to reveal it to any unauthorized person.

B.  Administrative Procedures

1.  Inspection Frequency - One bulk milk tank truck inspection every twelve months or bulk milk hauler/sampler or industry plant sampler pickup and sampling procedures inspection each twenty-four months or one producer inspection or one milk plant or receiving station inspection every three months or one transfer station or milk tank truck cleaning facility inspection every six months is not a desirable frequency; it is instead a legal minimum. Bulk milk hauler/samplers, industry plant samplers, milk tank truck cleaning facilities, dairy farms, milk plants, receiving stations and transfer stations experiencing difficulty meeting requirements should be visited more frequently. Milk plants that condense and/or dry milk or milk products and which operate for a short duration of time or intermittent periods of time should also be inspected more frequently. For the purposes of determining the inspection frequency for dairy farms, milk plants, and receiving stations, the interval shall include the designated three-month period in addition to the remaining days of the month in which the inspection is due. For the purposes of determining the inspection frequency for receiving stations, the interval shall include the designated six-month period in addition to the remaining days of the month in which the inspection is due. Inspections of dairy farms shall be made at milking time as often as possible, and of milk plants at different times of the day, in order to ascertain if the processes of equipment assembly, sanitizing, pasteurization, cleaning, and other procedures comply with the requirements of this Regulation. For the purpose of determining the minimum audit frequency for milk plants, receiving stations and transfer stations regulated under the NCIMS HACCP Program the interval shall include the remaining days of the month in which the audit is due.

2.  Inspection Notification -  It is preferable that the inspector advise the owner or other responsible person of the intent to inspect upon arrival of the premises.

3.  Enforcement Procedure - This section provides that a dairy farm, bulk milk hauler/sampler, milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station, or distributor, except those processing aseptically processed milk and milk products, shall be subject to suspension of permit, and/or court action, if two successive inspections disclose violation of the same requirement.

a.  Experience has demonstrated that strict enforcement of the Regulation leads to a better and friendlier relationship between DHEC and the milk industry than does a policy of enforcement which seeks to excuse violations and to defer penalty thereof. The sanitarian's criterion of satisfactory compliance should be neither too lenient nor unreasonably stringent. When a violation is discovered, the sanitarian should point out to the milk producer, bulk milk hauler/sampler, industry plant sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station, or distributor the requirement that has been violated, discuss a method for correction, and set a time for correcting the violated requirement.

b.  The penalties of suspension or revocation of permit, and/or court action, are provided to prevent continued violation of the provisions of this Regulation, but are worded to protect the dairy industry against unreasonable or arbitrary action. When a condition is found which constitutes an imminent health hazard, prompt action is necessary to protect the public health; therefore, DHEC is authorized, in Section III, to suspend the permit immediately. However, except for such emergencies, no penalty is imposed on the milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank cleaning facility, milk plant, receiving station, transfer station, or distributor upon the first violation of any of the sanitation requirements listed in Section VII. A milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank cleaning facility, milk plant, receiving station, transfer station, or distributor found violating any requirement must be notified in writing and given a reasonable time to correct the violation(s) before a second inspection is made, but not before three days. The requirement of giving written notice shall be deemed to have been satisfied by the handing to the operator or by the posting of an inspection report, as required by this section. After receipt of a notice of violation, but before the allotted time has elapsed, the milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank cleaning facility, milk plant, receiving station, transfer station, or distributor shall have an opportunity to appeal the sanitarian's interpretation to DHEC or for an extension of the time allowed for correction.

4.  Enforcement Procedure - Aseptic Processing Milk Plants - Because aseptically processed milk and milk products are stored at room temperature and not refrigerated after processing, they must be considered an imminent hazard to public health whenever it is revealed by an inspection or a review of the processing records that the process is less than the required scheduled process and the products produced have not maintained their commercial sterility. Prompt action by DHEC to suspend the permit must be initiated in order to protect the public health. DHEC shall stop the sale of all under-processed product and follow at least the minimum requirements of 21 CFR 113.89 before releasing any product.

5.  Certified Industry Inspection - DHEC may certify industry personnel, with their consent, to carry out cooperatively the provisions of this Regulation with respect to the supervision of dairy farms, bulk milk hauler/sampler’s pickup and sampling procedures, and/or milk tank trucks. Industry personnel shall be certified every three years by DHEC. In order for DHEC to utilize certified industry inspections, it shall have on file and available for review, a written program that describes how the requirements of this Regulation and related documents shall be implemented. Delegation of the inspection and evaluation of bulk milk hauler/sampler's pickup and sampling procedures shall be done by the Sampling Surveillance Officer in accordance with the *Evaluation of Milk Laboratories* (EML). Reports of all inspections conducted by such personnel to determine compliance with the provisions of this Regulation shall be maintained by the industry at a location acceptable to DHEC. The Certified Industry Inspector may perform all punitive actions and all inspections for the issuance or reinstatement of permits.

Initial inspections and change of market inspections are required and shall be conducted by DHEC in conjunction with the Certified Industry Inspector. When a producer changes market, the producer records for the preceding twenty-four months shall be transferred with the producer, through DHEC, and will continue to be a part of the producer’s record. Industry personnel shall be certified every three years by DHEC.

At least annually, the Certified Industry Inspector shall attend an educational seminar provided by DHEC, or equivalent training acceptable to DHEC.

At least once in each six month period, DHEC shall inspect the records maintained by the Industry for the Certified Industry Inspection Program and conduct farm field work to assure the program meets the provisions of DHEC’s written plan and requirements of this Regulation and related documents.

Initial certification by DHEC shall not be made during the course of an official inspection. Re-certification by DHEC may be conducted during the course of an official inspection.

PURPOSE OF CERTIFICATION: The purpose of certification is to have the applicant formally demonstrate their inspection ability to apply proper interpretations of this Regulation, related documents, and DHEC’s procedures.

DESIGNATION OF INDIVIDUALS TO BE CERTIFIED: Candidates shall submit requests for certification to DHEC. The applicant for certification shall have had experience in the field of milk sanitation, and shall be an employee of a milk plant, a producer association, officially designated laboratory or shall be employed on a consulting basis.

RECORDING OF QUALIFICATION DATA: Prior to conducting the certification procedure, background information shall be secured on the applicant. This shall include academic training, experience in milk sanitation and related fields, in-service courses attended, etc. This information is to be retained by DHEC as part of the applicant's file, along with appropriate records of the applicant’s performance during the certification examination.

FIELD PROCEDURE:Only one applicant shall be certified at a time. The certification is to be conducted without prompting from DHEC or comparison of inspection results in any way until the entire procedure is completed. Initial certification shall not be made during the course of an official inspection by DHEC. At least twenty-five randomly selected dairy farms and/or five milk tank trucks shall be visited. After the necessary inspections have been completed, DHEC shall compare their results with those of the candidate. The percentage agreement for each item of sanitation shall be determined by dividing the number of agreements by the total number of dairy farms and/or milk tank trucks inspected.

CRITERIA FOR CERTIFICATION: In order to be certified, an industry inspector shall agree with DHEC eighty percent of the time on individual items of sanitation and shall further agree to comply with the administrative procedures established by DHEC for the program of dairy farm and/or milk tank truck supervision. DHEC should allow sufficient time to discuss the findings with the applicant.

DURATION OF CERTIFICATION:Certification of industry inspection personnel shall be for a period not exceeding three years from the date of formal certification or re-certification, unless revoked.

RE-CERTIFICATION:DHEC shall notify the certified industry inspector of the need for certification renewal at least sixty days prior to its expiration. If re-certification is desired, the inspector will make appropriate arrangements for the renewal procedure. Re-certification can be made for the succeeding three year period, by following the procedures outlined above. Provided*,* that re-certification may be conducted during the course of an official inspection by DHEC.

REPORTS AND RECORDS: Upon satisfactory completion of certification or re-certification, the certified industry inspector shall be issued a certificate. The milk plant(s) or officially designated laboratory(ies) employing the inspector shall be formally notified by letter of the certification. The letter shall outline the purpose of the certification and the conditions under which the certification may be retained. A copy of the notification letter, together with a copy of the qualification data above and a resume of the percentage agreement on individual items, shall be retained by DHEC.

REVOCATION OF CERTIFICATION:The certification of an industry inspector may be revoked by DHEC upon a finding that the inspector is:

a. Not in agreement with DHEC at least eighty percent of the time on Items of sanitation in a

field examination conducted as described in the FIELD PROCEDURE outlined above; or

b.Not complying with the established administrative procedures of DHEC; or

c.Failing to carry out the provisions of this Regulation in the course of the inspector's work.

6. INSPECTION/AUDIT REPORTS**:** A copy of the inspection/audit report shall be filed by DHEC and retained for at least twenty-four months. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used.

SECTION VI.  THE EXAMINATION OF MILK AND MILK PRODUCTS

A.General

1.  It shall be the responsibility of the bulk milk hauler/sampler to collect a representative sample of milk from each farm bulk tank prior to transferring milk from a farm bulk tank, truck, or other container. All samples shall be collected and delivered to a milk plant, receiving station, transfer station, or other location approved by DHEC.

2.  During any consecutive six months, at least four samples of raw milk for pasteurization, shall be collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least twenty days, and delivered in accordance with this section, from each producer. These samples shall be obtained under the direction of DHEC or shall be taken from each producer under the direction of DHEC and delivered in accordance with this section. During any consecutive six months, at least f