THE DAIRY PRACTICES COUNCIL®

SETUP/REMODEL OF A QC LABORATORY
&
DEVELOPMENT OF A QC PROGRAM

Publication: DPC 111

MARCH 2014

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ABSTRACT

This guideline emphasizes the importance of using standard operating procedures (SOPs) to ensure that testing is performed correctly every time. The ability to generate results in a repeatable, reproducible manner is crucial to using quality testing constructively.
This document provides an outline to identify the parameters to be considered in establishing a new laboratory, or remodeling an existing laboratory. Also discussed are development parameters for a dairy quality assurance/quality control program.

PREFACE

This Guideline was prepared by the Laboratory and Quality Control Procedures Task Force under the lead authorship of Ms. Kathrene Dutrow of Packaging Consultants International (PCI), with assistance from Mr. Christopher Hylkema of the New York State Department of Agriculture and Markets, Mr. Christopher Thompson of the USDA Federal Milk Market Admistrator's Office- Atlanta, GA, and other members of the Laboratory and Quality Control Procedures Task Force (Task Force III), under Director Mr. Pat Healy, USDA Federal Milk Market Administrator's Office- Kansas City, MO.

GUIDELINE PREPARATION AND REVIEW PROCESS

The Dairy Practices Council (DPC) Guideline development and update process is unique and requires several levels of peer review. The first step starts with a *Task Force* subcommittee made up of individuals from industry, regulatory and educational institutions interested in and knowledgeable about the subject to be addressed. Drafts, called "*white copies*," are circulated until all members of the subcommittee are satisfied with the content. The final "*white copy*" may be further distributed to the entire Task Force; DPC Executive Board; state and federal regulators; educational and industry members; and anyone else the Task Force Director and/or the DPC Executive Vice President feel would add strength to the review. Following final "*white copy*" review and corrections, the next step requires a "*yellow cover*" draft to be circulated to representatives of participating Regulatory Agencies referred to as "*Key Sanitarians*." Key Sanitarians may suggest changes and insert footnotes if their state standards and regulations differ from the text. After final review and editing, the Guideline is distributed in the distinctive DPC "*green cover*" to DPC members and made available for purchase to others. These guidelines represent our state of the knowledge at the time they are written. Currently, DPC Guidelines are primarily distributed electronically in pdf format without colored covers, but the process and designation of the steps remains the same. Contributors listed affiliations are at the time of their contribution.

DISCLAIMER

The DPC is not responsible for the use or application of the information provided in this Guideline. It is the responsibility of the user to ensure that the information addresses their needs and that any action taken complies with appropriate regulations and standards.

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Introduction

The testing and analysis of dairy products for food safety, for customer request or for a particular product standard is in a constant state of evolution. We have available more methods for testing than ever before, from traditional wet chemistry methods to the latest rapid test kits that detect everything from antibiotic drug residues to *Listeria* species to milk protein and everything in between. Small operators / on-farm processors / makers of value-added products or small niche products (such as Artisan cheeses, ice cream, yogurt) do not necessarily need to make a huge investment to monitor and/or test products. However, any method of testing should be validated and continuously verified to assure that meaningful information is always being provided. The overall test methodology should be cost-effective so that testing can be continuous as well as functional.

Quality control and/or quality assurance should be mandated as a routine practice in the laboratory. The effort expended in performing a test properly and interpreting the results should be worthwhile, and the data resulting from that test can then be appropriately used to make decisions about the dairy's operation. It is not necessary to be a trained scientist, as most testing can be performed after some quick/informal training. The biggest issue generally is the method for interpreting results - what do the results tell you about your operation? For this reason, this guideline emphasizes the importance of using standard operating procedures (SOPs) to ensure that testing is performed correctly every time. The ability to generate results in a repeatable, reproducible manner is crucial to using quality testing constructively.

Depending on the size of the laboratory contemplated, personnel training and cross-training in various procedures may be required. A larger laboratory will have to establish levels of security for recording and reporting test results, as well as access to data for review and editing, and release to a customer or a regulatory authority. It is equally important to have some resources at hand, such as consultants, regulatory personnel, cooperative extension associates, and reference materials, etc. to help with interpretation of undesired results (i.e. high counts, out-of- specification chemistry results).

The following outline identifies the parameters to be considered in establishing a new laboratory, or remodeling an existing laboratory. The responses to these questions will drive the final configuration and capabilities of the laboratory space and equipment.

Issues to Consider in Establishing a Testing Laboratory

Why do you need a lab?

a. What types of testing will be conducted?
    i. Are you receiving raw commingled milk? If yes, then you are required to test for beta lactam drug residues by an approved method.
b. How fast do you need the test result(s)? Is the immediacy of the testing result a driving issue?

c. How many analysts and how much time will be available?
d. How important is quality/quantity of testing?
e. Is control of test information important?
f. Where do you want to strike the balance of cost vs. quality/quantity?
g. How much space is available?
h. Is this a complete or gradual construction/modification?
i. What will be relocated during construction/modification?

Maintaining a laboratory vs. the cost of sending samples to a private lab for testing

j. This would depend on the size of the lab/program that you are considering.
k. It will depend on the type of testing required, and the frequency.
l. Tests that require special equipment, chemicals, or technical expertise may be more cost-effective when sent out.

Considerations for the New or Remodeled Laboratory Space

Size (how many analysts, how many tests, how many machines)

a. Generally speaking you want six feet of workspace per analyst / test; however, in small operations you may not need this much.
b. Counter space should be large enough for the needed equipment and space for sample handling and paperwork. Always keep in mind though that if you think you can "deal" with a smaller space it will only seem to get smaller and more cramped as your business grows – if you are building new, it is better and more cost-effective to go a little bigger now than to have to expand or "live with it" later; if you are utilizing existing space then you may have to become a creative organizer down the line, which can still work.
c. Work bench – height should be comfortable for those using it.
    i. NOTE: look at some science supply catalogs for standard heights of benches / base cabinets
    ii. Consider leveling feet on base cabinets to control level of bench top
d. Floor load – for specialized instrumentation (consider anti-static materials, granite)

HVAC system

e. Positive air flow
f. Good ventilation
g. Temperature controlled
h. Filtered
i. Adequate to handle heat load of equipment utilized

Plumbing – This includes sink(s), drain(s), neutralizing capability, waste disposal

Electrical - Consider the electrical voltage and wattage requirements for standard and specialized equipment and instrumentation. Ground Fault Interupter (GFI) circuits and outlets should be used throughout the laboratory. Extension cords shall not be used as a permanent means of wiring, so a sufficient number of outlets, properly placed throughout the laboratory is necessary.

Lighting

a. 100 foot candles
b. Laboratory lighting should be even, screened to reduce glare, and provide adequate working illumination. Prevent shadows at working surface.

Materials – floors, walls, ceilings

a. Easily cleaned. Impervious flooring and wall material.
b. Chemical resistant
c. Properly supported
d. Level bench tops (and ability to be leveled)
e. Static-free or static-minimized
f. If using hazardous and explosive reagents, an explosion hatch should be considered.
g. Consider properly plumbed and sealable floor drains to increase the cleanabilty of floors.

Storage (New, used, build your own)

a. Cabinets, shelves
b. Refrigerators
c. Freezers

Chemical storage

a. Flammables/explosives
b. Is there a need to segregate (ex. Acid vs. alkaline storage) – may need fire-proof or explosion proof cabinet, chemical labeling

Safety (location, accessibility, storage, service)

a. First aid kit
b. Eye wash station
c. Chemical spill kits
d. Chemical safety showers
e. Lab apparel and laundry, safety glasses, gloves, etc.
f. Fire extinguishers (type appropriate for application and work environment)
g. Emergency contacts and protocol

Fume Hood (check local ordinances before venting to outside of building)

a. Need vs. design/type
b. Service, validation, verification

Disposal of Hazardous Materials or Wastes

a. Methodology
   i. Bacteria culturing / plating – used plates MUST be autoclaved or released to a private bio-hazard disposal service
   ii. Autoclave performance testing should be conducted. See the latest edition Of Standard Methods for Dairy Products for autoclave testing.
   iii. Handling – is laboratory associated with a processing plant? Used plates / films can become a product contamination issue if not handled properly. Consider a handwash/foot bath station immediately outside the lab to prevent cross contamination.
   iv. Pathogen testing shall not be conducted in a laboratory associated with a processing plant – if necessary, conduct tests in separate building by designated personnel or contract to private laboratory
b. Local regulations
c. Arrangements

Equipment (service, validation, verification)

a. Autoclave
b. Incubators
c. Hot plates
d. Water baths
e. Microscopes
f. Ovens
g. Test Apparatus (testing method(s) required)
   i. Instrumentation and associated apparatus, reservoirs, etc.
   ii. Temperature measuring devices and/or monitoring systems
   iii. Must include service, validation, verification
   iv. Mercury avoidance and available technology

Records (service, validation, verification, security)

a. Short and long term storage (file cabinets, need for fireproof or moisture-proof storage)
b. Paper or electronic; electronic back-up systems
c. Organization (form design, traceability, topical and sequential arrangement, etc.)
d. Quality Assurance (QA) Manual - accessible, organized and user friendly
e. Standard Operating Procedures (SOPs) - do not say it unless you are actually doing it.
f. Safety Data Sheets (SDS) – accessible, organized and user friendly
g. Chemical/biological reagent inventory, tracking, disposal, re-order (manual or automatic) - accessible, organized and user friendly

Water System(s) (distilled, deionized, reverse-osmosis, or a combination)

a. Reagent grade
b. Microbiologically Suitable
c. Parts per Million (PPM) or parts per billion(PPB) grade

d. Service, validation, verification

The discussion that follows outlines the basic requirements for establishing a quality control program. It is intended for the small producer that possesses limited resources for the management of a testing and document system that supports a dairy operation and its compliance status.

Establishing a Quality Control/Quality Assurance Program

Test identification

A basic quality control/quality assurance program provides the basis to ensure that the data generated by the laboratory's testing is repeatable and reproducible with a minimum acceptable variability. It promotes confidence that the decisions made based on the data are appropriate and cost-effective, rather than non-essential or in fact detrimental to the operation.

Standard operating procedures

Any test worth performing should be performed according to a standard operating procedure (SOP). The first task in establishing a new quality control program is to identify the tests to be performed. In the dairy industry, the following organizations and/or references have SOPs documented for the most common tests performed:

Dairy Practices Council - http://www.dairypc.org/catalog/guidelines/dairy-laboratory-testing

Standard Methods for the Examination of Dairy Products, H. Michael Wehr and Joseph F. Frank, 2004; American Public Health Association, 17th Ed

International Dairy Federation - http://www.fil-idf.org

The resources listed above can also be used to establish required SOPs for the maintenance and calibration of laboratory equipment.

Sampling plans

Having identified the tests to be performed, the sampling program needs to be established. Sampling plans identified as acceptable to regulatory authorities are outlined in the above-listed resources.

Record-keeping

Recordkeeping encompasses all areas of the laboratory operation. Records of *maintenance and calibration* of the laboratory equipment need to be kept, according to the requirements of the individual state regulatory agency responsible for the laboratory.

Records of *lot numbers of all testing materials* need to be kept, including chemicals, chemical test kits, laboratory supplies (Petri dishes, pipettes). This may include copies of purchase orders and receiving records.

Records to be maintained for *testing* will include:

- the identity of the person performing the test
- the source of the sample
- the date and time that the test was performed
- the test performed, along with any control samples
- the test results
- any follow-up testing/repeat testing if the results were positive or non-compliant
- the site where the test was performed
- any prior testing for a presumptive positive test result

Records need to be kept of any document or any information that supports claims to organic status or other attributes.

Management systems

Having accumulated the relevant test procedures, maintenance and calibration procedures, and the structure for recording results, it is recommended that an overall process for maintaining and retaining the information is created. While an overall quality assurance manual is not required, an organization of the information is important to demonstrating to the regulatory agencies that you are operating in compliance.

Identify how long you intend to keep records. This applies to both paper and digital records. Document the backup procedure if one is utilized for digital records. Records retention is a laboratory decision for quality and testing records (this is not necessarily true for financial and accounting records). Note: If a laboratory is an Interstate Milk Shippers (IMS) listed lab, official testing records, such as antibiotic residue testing on incoming loads of milk, must be kept for 2 years. Other IMS record retention requirements may vary depending on the tests being performed.

Having the standard operating procedures organized in a binder is a simple method for keeping them available for reference and also for demonstrating compliance. This is true as well for laboratory equipment maintenance and calibration records. Whatever method is chosen, communicate to all who use the procedures, records and documents how they are to be managed. This creates the simplest management system to implement.

References

DPC 34, Butterfat Determination of Various Products

DPC 21, Raw Milk Quality Tests

DPC 60, Trouble Shooting Microbial Defects in Dairy Processing Plants: Product Line-Sampling and Hygiene Monitoring

Standard Methods for the Examination of Dairy Products, American Public Health Association, 2004.

US Food and Drug Administration, Official Laboratory Evaluation Forms (FDA 2400 Forms)

Bacteriological Analytical Manual (BAM), US FDA