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Digital Food Safety Management Systems:

General Industry & Regulatory Best Practice Guidance

October 2023

FDA

Michigan Department of AGRICULTURE & Rural Development

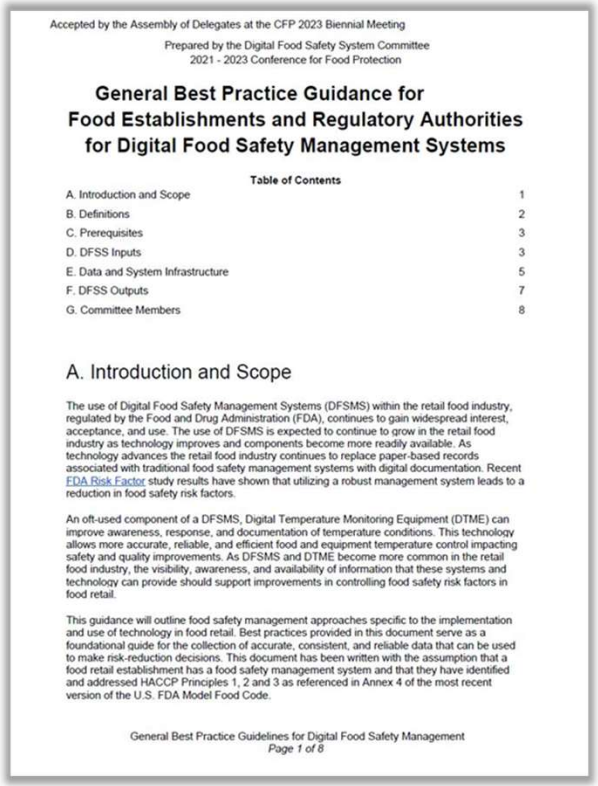
MALPH MICHIGAN ASSOCIATION FOR LOCAL PUBLIC HEALTH

AGENDA

- CFP Committee Background
- Best Practice Guidance Review
- DFSMS Examples

Digital Food Safety System Committee

- Council/Issue: 2020_11_021
- Charges:
  1. Identifying best practices, existing guidance documents, and research that relate to the use of digital food safety management systems including digital temperature monitoring equipment.
  2. Developing a guidance document for food establishments and regulatory authorities that establishes General Best Practice Guidelines for Digital Food Safety Management Systems including digital temperature monitoring equipment.
  3. Determining appropriate methods of sharing the committee's work, including but not limited to a recommendation that a letter be sent to FDA requesting that the Food Code, Annex 4 (Management of Food Safety Practices - Achieving Active Managerial Control of Foodborne Illness Risk Factors), Annex 2 (References, Part 3-Supporting Documents) be amended by adding references to the new guidance document as well as any existing guidance documents that the committee recommends, and the posting of information on the CFP website.
  4. Reporting the committee's findings and recommendations to the next Biennial Meeting of the Conference for Food Protection.
- Members:
  - 21 Voting (11 Industry, 7 Reg, 1 Consumer, 1 Academic)
  - 15 At Large
  - 3 Federal Consultants (FDA, CDC, USDA)



Accepted by the Assembly of Delegates at the CFP 2023 Biennial Meeting

Prepared by the Digital Food Safety System Committee
2021 - 2023 Conference for Food Protection

General Best Practice Guidance for Food Establishments and Regulatory Authorities for Digital Food Safety Management Systems

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A. Introduction and Scope

The use of Digital Food Safety Management Systems (DFSMS) within the retail food industry, regulated by the Food and Drug Administration (FDA), continues to gain widespread interest, acceptance, and use. The use of DFSMS is expected to continue to grow in the retail food industry as technology improves and components become more readily available. As technology advances the retail food industry continues to replace paper-based records associated with traditional food safety management systems with digital documentation. Recent FDA Risk Factor study results have shown that utilizing a robust management system leads to a reduction in food safety risk factors.

An oft-used component of a DFSMS, Digital Temperature Monitoring Equipment (DTME) can improve awareness, response, and documentation of temperature conditions. This technology allows more accurate, reliable, and efficient food and equipment temperature control impacting safety and quality improvements. As DFSMS and DTME become more common in the retail food industry, the visibility, awareness, and availability of information that these systems and technology can provide should support improvements in controlling food safety risk factors in food retail.

This guidance will outline food safety management approaches specific to the implementation and use of technology in food retail. Best practices provided in this document serve as a foundational guide for the collection of accurate, consistent, and reliable data that can be used to make risk-reduction decisions. This document has been written with the assumption that a food retail establishment has a food safety management system and that they have identified and addressed HACCP Principles 1, 2 and 3 as referenced in Annex 4 of the most recent version of the U.S. FDA Model Food Code.

Introduction & Scope

- FDA Risk Factor Study results recommend the use of robust management systems
- Use of Digital Food Safety Management Systems (DFSMS) continue to gain widespread acceptance and use
- Foundational guidance for the collection or accurate, consistent and reliable data
- DFSMS provide access to data points that are hard to gather in paper-based management systems
- Digital Temperature Monitoring Equipment (DTME) allows more accurate, reliable and efficient food and equipment temperature control
- This document has been written with the assumption that a food retail establishment has a food safety management system and that they have identified and addressed HACCP Principles 1, 2 and 3 as referenced in Annex 4 of the most recent version of the U.S. FDA Model Food Code.

Fast Food Restaurants	Non-existent FSMS	Well-developed FSMS
Average # of out of compliance items	4.5	1.7

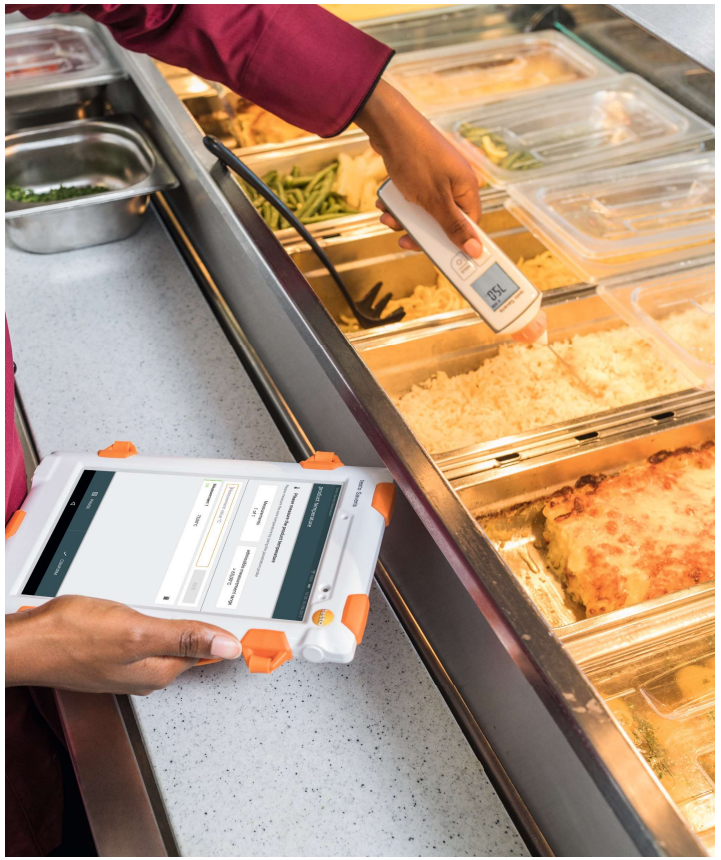
Full-Service Restaurants	Non-existent FSMS	Well-developed FSMS
Average # of out of compliance items	5.8	2.1

Definitions

- Digital Food Safety Management Systems (DFSMS):
  - Interactive digital/electronic archive to store and analyze data that supports the FDA definition of FSMS
  - Ongoing control, monitoring, and record keeping of specific procedures intended to control foodborne illness risk factors
  - Is intended to enable a proactive approach to controlling real-time operational risk factors
  - Includes active user-based interactions, real-time feedback, generates reports
- Digital Temperature Monitoring Equipment (DTME):
  - Automated purpose-built temperature measuring devise(s)
  - Captures and stores data and connects to a DFSMS
  - Capable of alerts and reports
- Software:
  - The total set of programs, rules, and any documentation used to support the operation of technology-based system

Prerequisites

- DFSMS hardware and software should be designed to meet the goals of an established Risk Control Plan that includes:
  - HACCP Principles 1, 2 and 3 as referenced in Annex 4 of the most recent version of the U.S. FDA Model Food Code.
- DFSMS should be utilized as a supporting aspect to HACCP Principles specifically:
  - Principle #4: Establish Monitoring Procedures
  - Principle #5: Establish Corrective Actions - implementation of the corrective action specifically
  - Principle #6: Verification/Sharing for equivalency for regulatory checks
  - Principle #7: Record keeping procedures and documentation
- Appropriate training, roles and responsibleness defined



Digital Food Safety System Inputs

- Digital Food Safety System Equipment (DFSSE):
  - Purpose built stationery and handheld measurement tools capable of collecting, storing and transmitting data into software
  - Must meet design and placement characteristics in Chapter 4 of the most recent version of the U.S. FDA Model Food Code and meet or exceed NSF Standard 2 - Food Equipment or equivalent.
- Stationary Monitoring Device:
  - Purpose built devices permanently or semi-permanently affixed, mounted, installed, attached to equipment or surface using **food grade** mounting/installing materials, maintained free of accumulated soil,
  - If/when there is no device display, access to the data should be easily accessible/viewable
  - Must meet the requirements of the U.S. FDA Model Food Code 4-204.112 Temperature Measuring Devices.

Digital Food Safety System Inputs (Cont.)

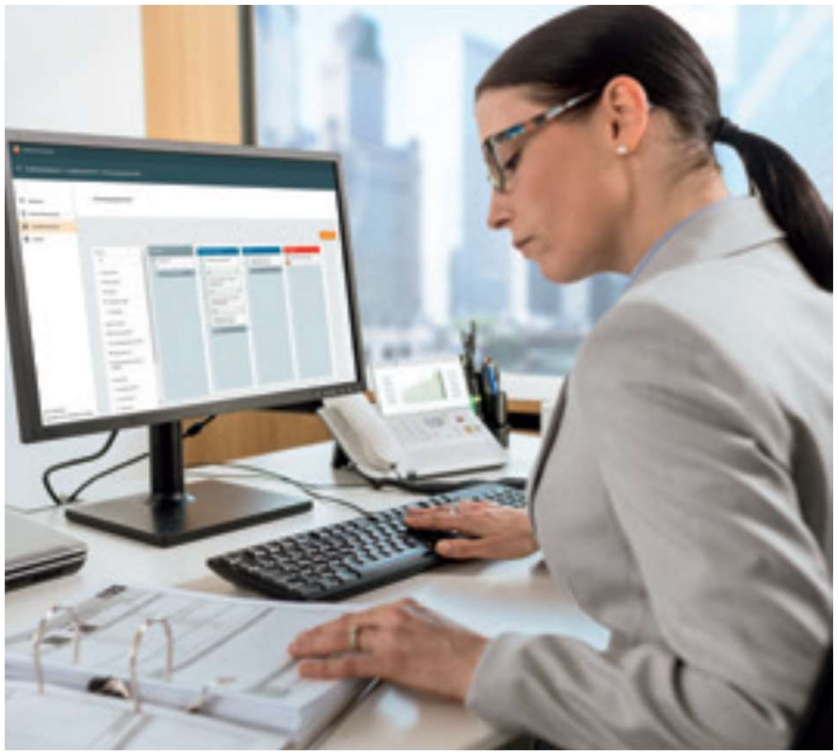
- DFSSE Accuracy:
  - Must meet the most recent version of the U.S. FDA Model Food Code 4-203.11 & 4-203.12.
    - Handheld ± 2°F (± 1°C)
    - Stationary ± 3°F (± 1.5°C)
  - If/when a handheld or stationary temperature device does not have a display; the operator should be able to easily demonstrate/record the reading/actual monitored temperature (value) for review and record.
- DFFSE Functionality:
  - System operation functionality are recommended to be conducted to verify that DFSMS, DFSSE and DTME are operating as intended.
  - Records of software and equipment functionality verification be maintained and readily available.

Data and System Infrastructure

- DFSMS Data:
  - Data are measurement values and active user inputs
    - Examples: Digital checklists, quality and safety measurements (Temperature, pH, TPM, PPM, Humidity, Time, etc.)
  - Data points are permanent and stored sequentially as a time-based progression of record
  - Changes to original data points should be identifiable
  - Data may be stored locally (on-site) or virtually (cloud based),
  - Data access must be readily available for use and display on-site
- DTME Data:
  - Stationary, hand-held and integrated sensors are the most common
  - DTME devices should have the ability to cache/store data during interruption(s) and the ability to send cached/stored data when connectivity is restored.
- Verification/Immutability:
  - A DFSMS should include digital signature record(s) or other means of tracking history of inputs.
  - Correction/adjustment of data entries, should identify the person, reason and reference to the originally captured data.

Data and System Infrastructure (Cont.)

- Data and System Integrity and Access:
  - Data integrity and access are important to ensure accurate and reliable data is captured
  - Reasonable controls to ensure that data is not able to be altered in an unauthorized manner and changes are captured.
  - Limiting access and encryption protocols are strongly encouraged
    - Encryption Examples: Passwords,
    - Access Examples: User Management
- Manual Data Entry:
  - If/when permitted Manual data entry are documented
- Manual Back-Up:
  - Best practice to support business continuity is to plan for and account for data storage/access in the event of a DFSMS failure.



Digital Food Safety System Outputs

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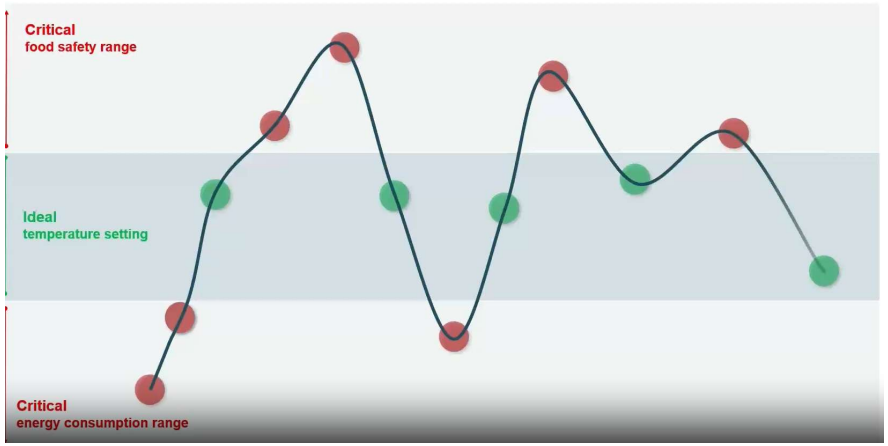
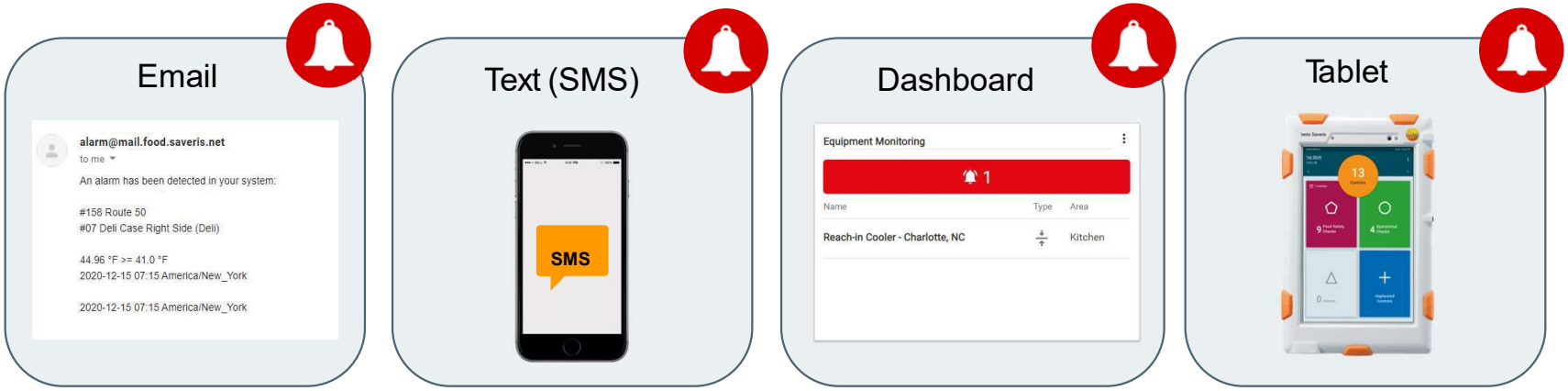
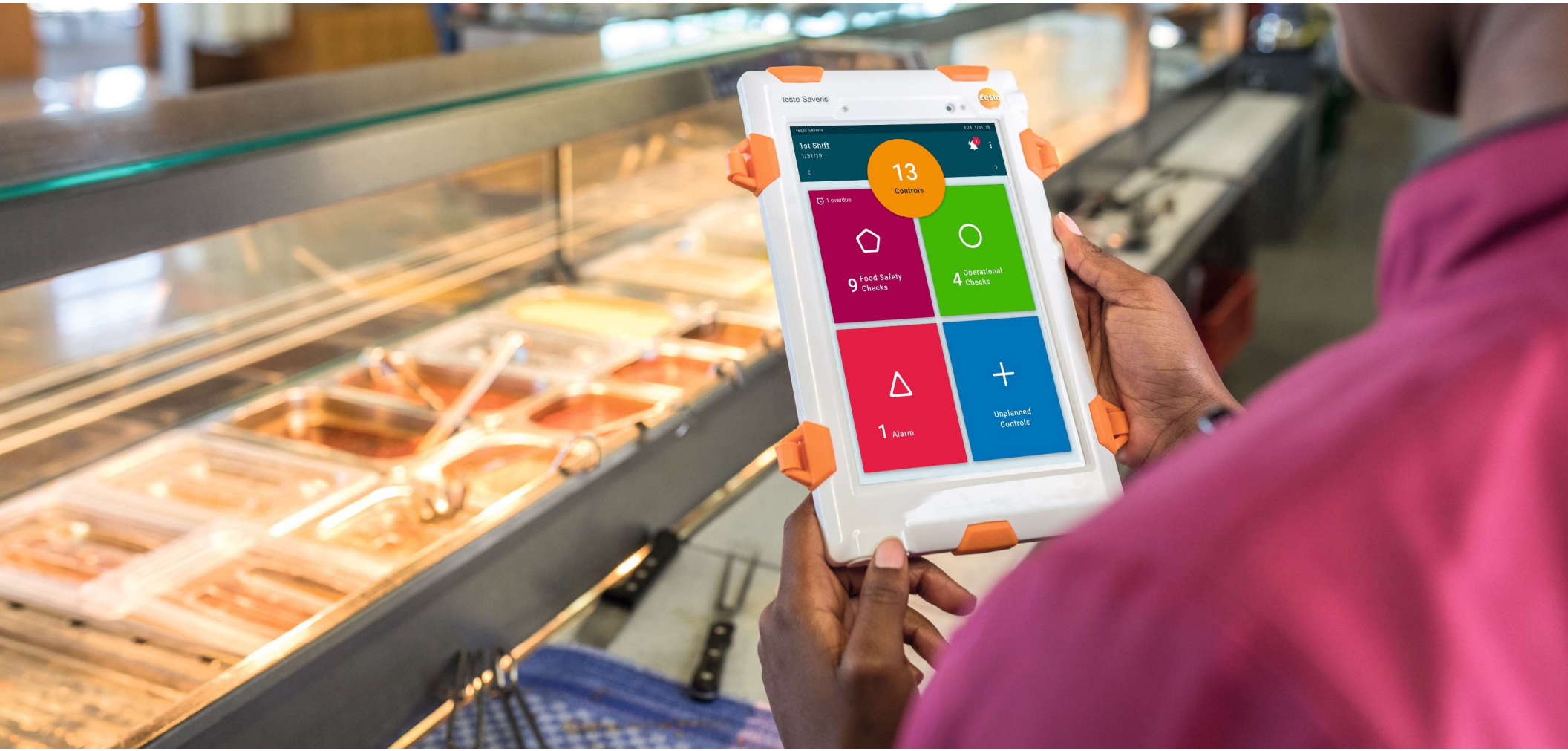
- System Outputs and Notification(s):
  - Include tailored notifications around programable measurement parameters
  - Best practice is to set one (or more) corrective action if/when a measurement parameter is not met or achieved along with time-based escalation protocols
    - Output Examples: Reporting, trending, etc.
    - Nonfiction examples: Email, SMS/Text, Visual & audible indicators, etc.





DFSMS Examples



Source: US Centers for Disease Control

DFSMS Examples

Final Cooking Temperature Rotisserie Chicken

- >165°F → Correct Temperature Reached
- <165°F → Visual Disruptive Interruption → Correct Temperature Reached

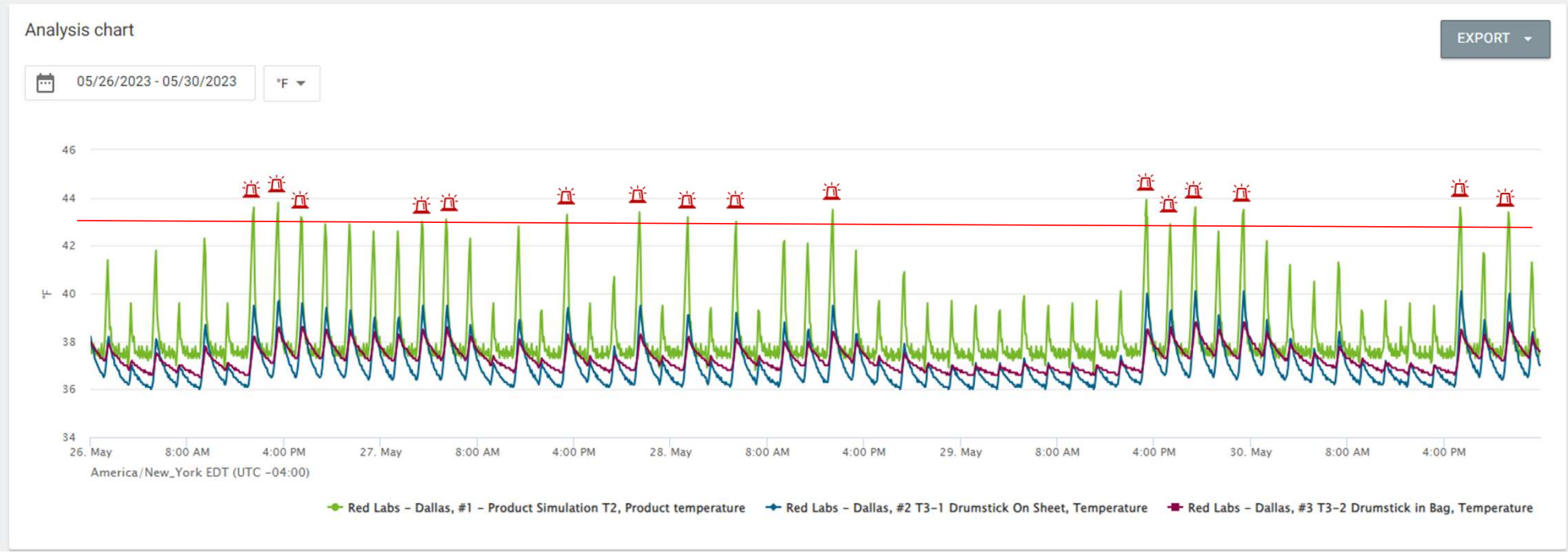
Product simulation: Real World Test Example

Products Studied:

Chicken Drumstick on open cooking sheet

Chicken Drumstick Stored in Bag

Product simulation: Real World Test Example



	T-2 Air Temperature	T3-1 Product Temperature Drumstick in Bag	T3-2 Product Temperature Drumstick On Sheet pan
Avg	38.16°F	37.29°F	36.98°F
Max	43.90°F	38.80°F	40.10°F
Min	36.70°F	36.50°F	36.00°F

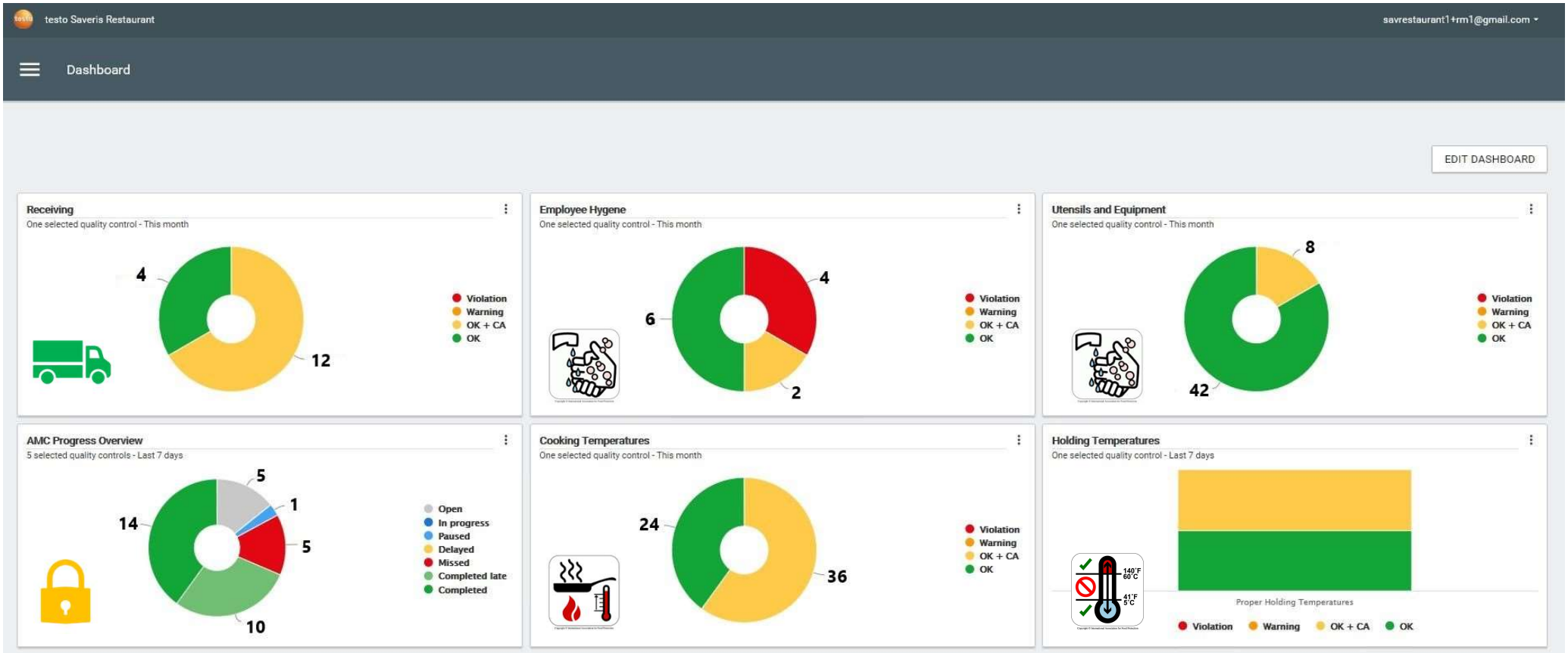
16 alarms

Product simulation: Real World Test Example

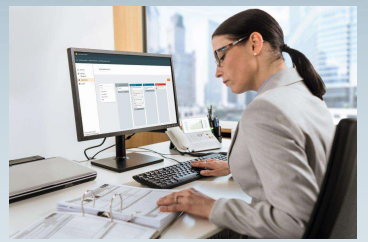
	T-2 Air Temperature	T-2 Product Simulation
Avg	37.64°F	37.64°F
Max	44.4°F	38.9°F
Min	36.3°F	37.1°F

8 alarms

DFSMS Examples



DFSMS and Risk Reduction



Monitoring
- Temperatures
- Reporting
- Alerts/Alarms

Procedures
- Guided
- Procedures
- Corrective Actions

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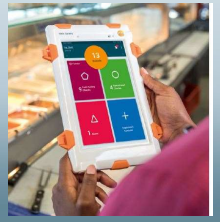
Training
- On the Spot
- Documented
- Consistent



Questions

CFP DFSMS Document

Eric Moore Contact Information

Thank You