



FSMA's New Sanitary Transportation Rule: How to Prepare Your Game Plan for Compliance

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Today's Speakers



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Agenda

- Overview: Final Rule on Sanitary Transportation of Human and Animal Food
- Areas of Focus
- Using Driver Training to Help Prepare
- Resources
- Q & A

Overview: Final Rule on Sanitary Transportation of Human and Animal Food



Final Sanitary Transport Rule

- Game Plan

- Read the Rule!!

- <https://www.gpo.gov/fdsys/pkg/FR-2016-04-06/pdf/2016-07330.pdf>

- <https://www.federalregister.gov/articles/2016/04/06/2016-07330/sanitary-transportation-of-human-and-animal-food>

- Determine if you are covered by the rule

- Review existing contracts, procedures, protocols and identify gaps

- Fill the gaps

- Robust recordkeeping is a must!

- Test your systems

- Face compliance with confidence



What?

- The proposed rule addresses:
 - Safety of human and animal food during transportation operations
 - Foods requiring temperature control to prevent the food from becoming unsafe during transportation
 - Foods not fully packaged
 - Consider of the type of food, its stage in the production cycle to determining sanitary conditions and controls needed for transportation



Who?



Shipper

Person who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially



Loader

Person that loads food onto a motor or rail vehicle during transportation operations



Carrier

Person who physically moves food by rail or motor vehicle in commerce within the United States



Receiver

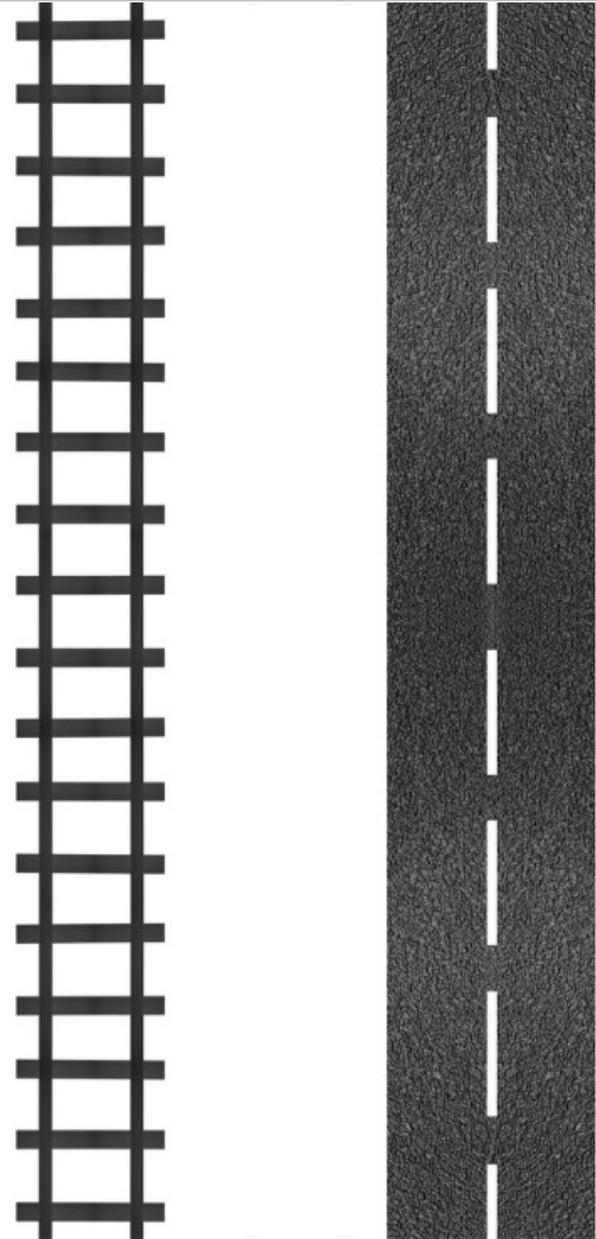
Person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food

<https://www.gpo.gov/fdsys/pkg/FR-2016-04-06/pdf/2016-07330.pdf>

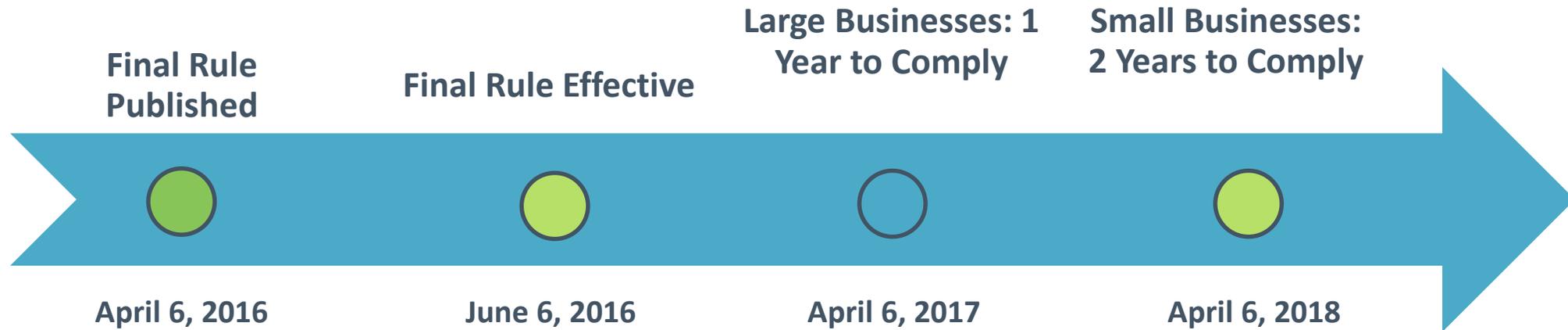
Where?

- Applies to:
 - Food to be consumed in the United States
 - Food directly transported into the U.S.

Types of Transportation	Affected?
Motor Vehicle	✓
Rail	✓



New Regulatory Requirements Timetable



Small Business

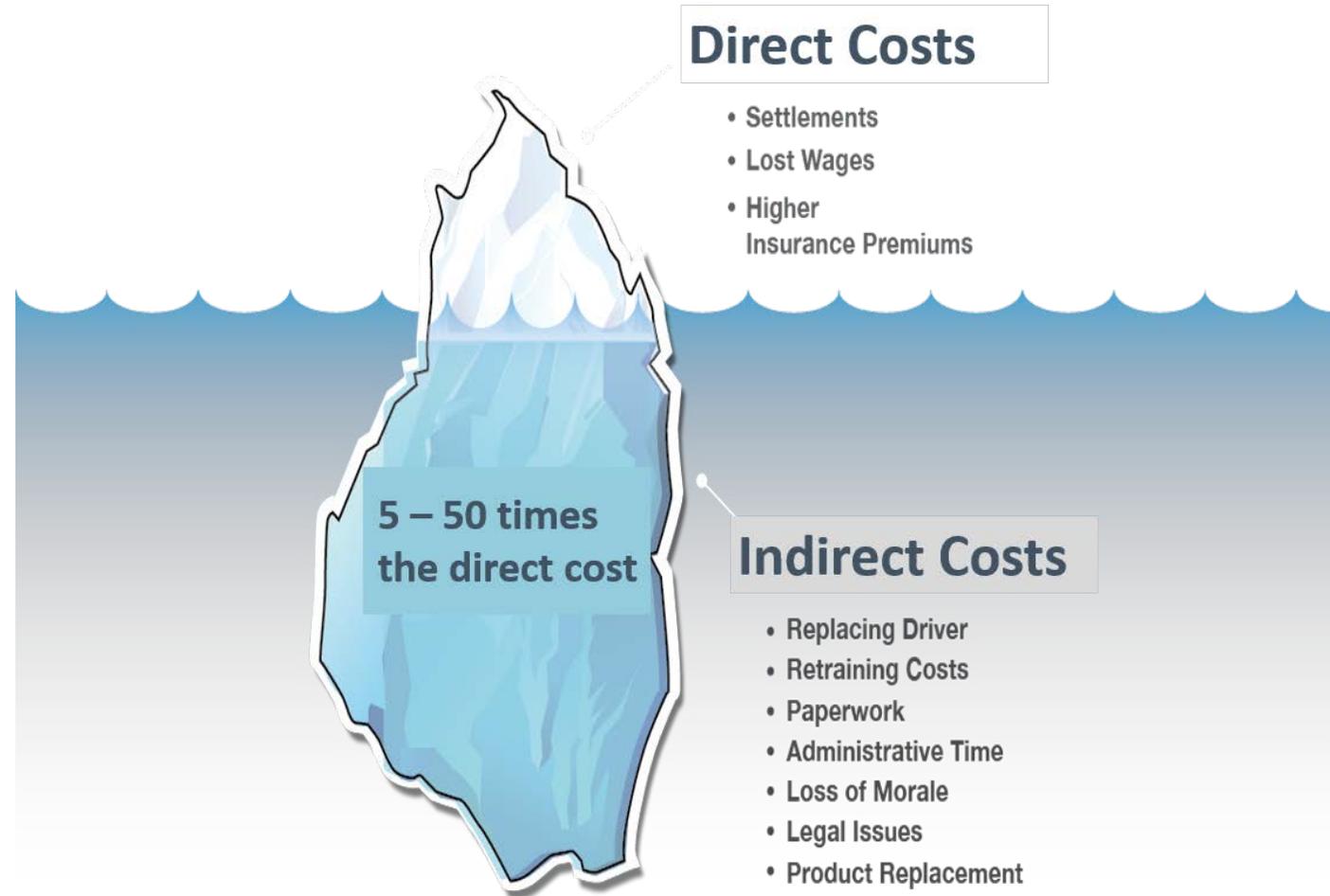
- Specified that employee limit is fewer than 500 full-time equivalent employees.
- Specified the limit of \$27,500,000 annual receipts.

The Cost of Driver Non-Compliance With Existing Regulations

The case for training: avoiding just one incident

Incident Cost	4% Margin	3% Margin	2% Margin
\$25,000	\$625,000	\$833,333	\$1.25 million
\$50,000	\$1.25 million	\$1.7 million	\$2.5 million
\$100,000	\$2.5 million	\$3.3 million	\$5 million
\$200,000	\$5 million	\$6.7 million	\$10 million
\$500,000	\$12.5 million	\$16.7 million	\$25 million
\$1 million	\$25 million	\$33.3 million	\$50 million

The Hidden Costs of Incidents



Areas of Focus



Areas of Focus



#1: Vehicles and Transportation Equipment



#2: Transportation Operations



#3: Information Exchange



#4: Training



#5: Records



#6: Waivers



#1: Vehicles and Transportation Equipment

Vehicles and transportation equipment designed for clean-ability and intended use to keep food safe during transportation operations

- maintained in a sanitary manner
- designed, maintained, and equipped as necessary to provide adequate temperature control
- stored to prevent pest harborage or becoming contaminated



#2: Transportation Operations

- Conducted under conditions and controls to prevent food from becoming unsafe during transportation operations.
- Take into account the type of food and the stage of production.
- Effective controls to protect food from contamination may include measures such as:
 - Segregation
 - Isolation
 - Use of packaging
 - Hand washing
 - Use vehicles designed to maintain the food at proper temperature



<https://www.gpo.gov/fdsys/pkg/FR-2016-04-06/pdf/2016-07330.pdf>



Shipper Requirements

- Responsible for identifying the conditions required to keep the product safe in transport and assuring they are complied with.
- Includes developing and implementing written procedures
 - Cleaning and sanitizing vehicles and equipment
 - Inspection of equipment prior to loading
 - Ensuring previous loads for bulk containers do not make food unsafe
 - Food is transported under adequate temperature control for safety
 - Pre-cooling of vehicles or transportation equipment if necessary



<https://www.gpo.gov/fdsys/pkg/FR-2016-04-06/pdf/2016-07330.pdf>



Loader Requirements

- Inspect for sanitary condition when loading food not completely enclosed by a container
 - Physical condition, free of pests, free of previous cargo
- Verify each refrigerated cold storage compartment or container is adequately prepared, pre-cooled if necessary, and in sanitary condition



<https://www.gpo.gov/fdsys/pkg/FR-2016-04-06/pdf/2016-07330.pdf>

Carrier Requirements

- Provide equipment that meets the shippers requirements – temp control and sanitary condition
- When there is a written agreement with the shipper:
- Demonstrate to shipper and receiver that the carrier has maintained required temperature
- Implement written procedures
 - For cleaning, sanitizing (if needed), and inspecting transportation equipment to maintain sanitary condition
 - To comply with temperature control monitoring requirements
 - For bulk vehicle requirements
- Pre-cool transport compartments to shipper's required temperature
- Provide, on request from shipper information about the last previous cargo and / or most recent cleaning for bulk vehicle
- Provide and document training



<https://www.gpo.gov/fdsys/pkg/FR-2016-04-06/pdf/2016-07330.pdf>

Receiver Requirements:

- Determine whether the food being received was subjected to significant temperature abuse
 - Product temperature
 - Ambient temperature of the vehicle
 - Refrigeration unit's temperature settings
 - Sensory inspection



<https://www.gpo.gov/fdsys/pkg/FR-2016-04-06/pdf/2016-07330.pdf>

Requirement for All

- “If a covered person or company at any point in the transportation chain becomes aware of a possible failure of temperature control or any other condition that may render a food unsafe, that food must not be sold or distributed until a determination of safety is made”
 - Qualified Individual - qualified by training or experience to make such a determination, i.e., he should have a scientific understanding of how the temperature deviation could affect the growth of pathogens or production of toxins in the food



<https://www.gpo.gov/fdsys/pkg/FR-2016-04-06/pdf/2016-07330.pdf>
<http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM494118.pdf>



#3: Information Exchange

- Exchange of information
 - Protocols for shippers, loaders, carriers & receivers
 - Prior cargo and / or wash tickets
 - Cleaning of transportation equipment
 - Temperature set points between the shipper, loader, carrier, and receiver, as appropriate to the situation
 - Upon request, carriers must provide the operating temperature specified by the shipper and demonstrate temperature was maintained during transport



#4: Training



- Requires carriers to provide awareness training to personnel including drivers engaged in transportation operations when the carrier and shipper have agreed via written contract that the carrier is responsible for the sanitary conditions during transportation operations.
 - Address the responsibilities of the carrier under this rule
 - FDA will develop and place on Web site a course that can be downloaded or taken online to meet the requirements of this provision
 - Carriers would also be able to print a copy of a certificate of participation in the course to satisfy the training recordkeeping requirement of the rule
 - Participation in FDA course is not be mandatory.
 - Training from other sources, or conducted in-house by carriers, may also meet the requirements
 - Taken initially and as changes occur
 - Record must include date of training, type of training and person(s) trained

<https://www.gpo.gov/fdsys/pkg/FR-2016-04-06/pdf/2016-07330.pdf>

#5: Records



- Electronic records do not need to meet 21CFR11
- Records retained for a period 12 months beyond the last date of the activity described by the record
- Allow offsite storage of all records, except for the written procedures provided that the records can be retrieved and made available within 24 hours of a request for official review



#6: Waivers



- Procedures by which the FDA will consider waivers
- Two waivers in the works:
 - Shippers, carriers, and receivers that hold valid permits and are inspected under the National Conference on Interstate Milk Shipments' (NCIMS) Grade "A" Milk Safety program, because shipments of Grade "A" milk and milk products by such entities are already subject to NCIMS controls subject to state enforcement with FDA oversight; and
 - Food establishments that hold valid permits issued by state, local, territorial, or tribal regulatory agencies (e.g., restaurants, grocery stores) when acting as shippers, carriers, or receivers, because food shipments are already subject to controls under the Retail Food Program with state or local enforcement and FDA oversight

Exemptions:

- Transportation of food by air or ship (however, it does apply to shippers, including those in other countries, who ship food to the U.S. by air or ship and arrange for the transfer of the intact container onto a rail or motor vehicle for transportation within the U.S.)
- Transportation activities performed by a farm
- Transportation of live food animals, except molluscan shellfish
- Transportation of food that is completely enclosed by a container, except if such food requires temperature control for safety
- Transportation of human food byproducts intended for use as animal food without further processing
- Transportation of compressed food gasses
- Transportation of food contact substances (i.e., food packaging)
- Transportation of food that is transshipped through the U.S.
- Transportation of food that is imported for future export and is not consumed or distributed in the U.S.
- Shippers, loaders, carriers, or receivers that have <\$500,000 in average annual revenue
- Food when it is located in a food facility that is regulated throughout the entire facility by the U.S. Department of Agriculture

Using Driver Training to Help Prepare





Are you ready for the sanitary transport rule?

- Yes
- No
- I don't know

Drivers are the Conduit

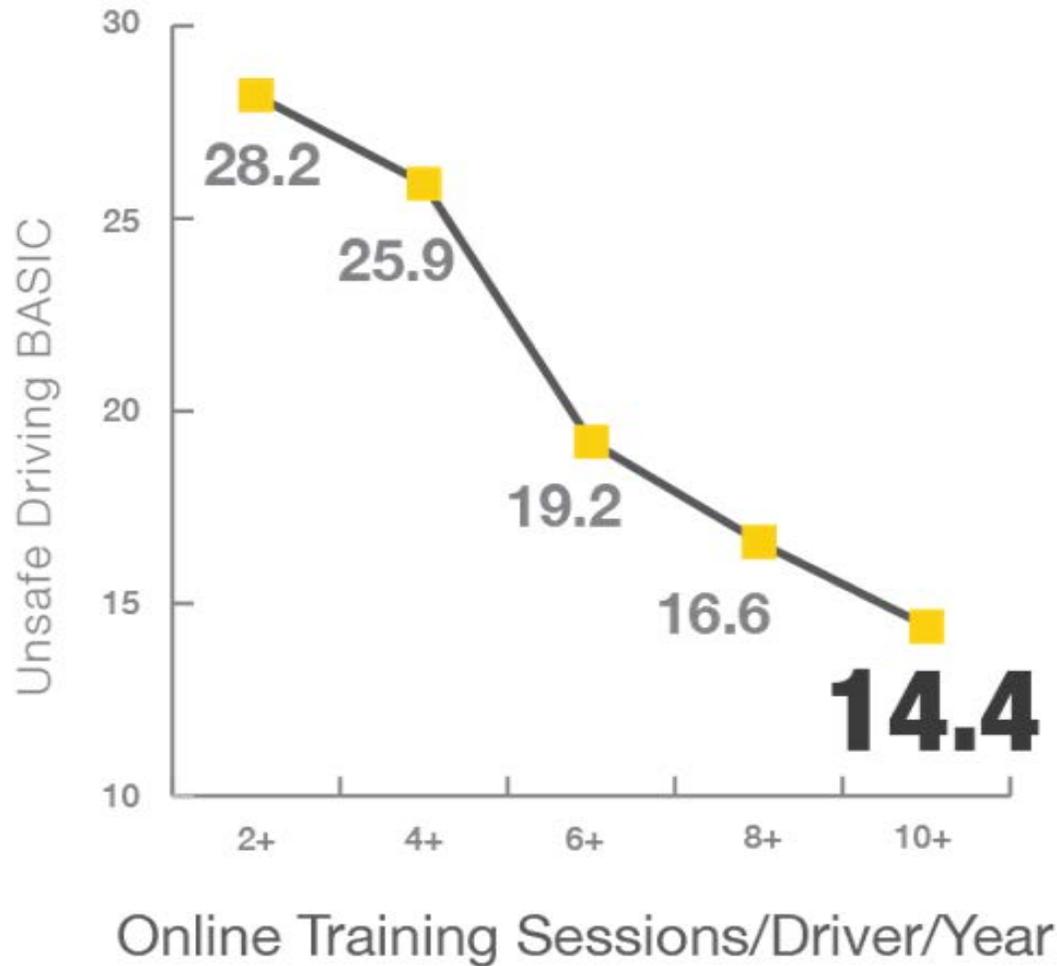
- Drivers:
 - Transfer product between shippers and receivers
 - Maintain the cold chain
 - Responsible for meeting delivery requirements
 - Must drive safely to meet timelines
 - Department of Transportation requirements
 - FSMA
 - “While FDA intends to conduct some inspections, the Department of Transportation (DOT) will establish procedures for transportation safety inspections to be conducted by DOT or state agencies”

<http://www.ofwlaw.com/2016/04/06/another-fsma-final-rule-sanitary-transportation-food/>

Compliance Training: What is the best approach?

- A ***blended learning*** strategy is correlated to best outcomes
- Consider online lessons to introduce/reinforce knowledge of new FSMA regulations
- Use “hands-on” for refresher or intro to proper vehicle inspections, reefer unit checks, cargo securement, etc.
- Group or prioritize drivers based on compliance history of drivers
- Use online lessons or safety messages proactively to sustain compliance and performance

Reduce Unsafe Driving Incidents with Training



Average CSA Unsafe Driving BASIC by Annual Online Training Sessions

Alchemy & Instructional Technologies, Inc. Partnership

- 74 PRO-TREAD courses available through Alchemy
- Available as eLearning
- Targeted training to the right person at the right time
- Consistent messaging to all drivers
- Easy-to-use technology
- Create and track learning plans for individuals or groups



Available Now

Alchemy has 7 courses available so you can start training now!

- Introduction to FSMA
- Driver Food Safety: SOPs Trailer Maintenance
- Driver Food Safety: SOPs Pre-Chilling Procedures
- Driver Food Safety: SOPs Maintaining Proper Temperature
- Driver Food Safety: SOPs Less Than Load (LTL) Delivery Stops
- Basic Food Defense for Drivers
- Effective Record Keeping Practices

Resources



Resource: FDA Webinar

- FSMA Final Rule on Sanitary Transportation of Human and Animal Food Webinar
- Monday, April 25th
- 11:00 am – 12:00 pm ET
- Speakers: Kari Barrett, Office of Foods & Veterinary Medicine
Mike Kashtock, Consumer Safety Officer, Center for Food Safety and Applied Nutrition
- To hear the presentation and ask questions, dial: 888-946-8408, passcode: FSMA
International: 1-773-756-4630
- To view the slide presentation during the webinar:
<https://www.mymeetings.com/nc/join.php?i=PW7654409&p=FSMA&t=c>
- For more information: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm494030.htm>



Resource: Guidance Document

- You will receive a copy of these slides
- FDA plans to issue a guidance document on the Final Rule
- PDF Version of the Final Rule
 - <https://www.gpo.gov/fdsys/pkg/FR-2016-04-06/pdf/2016-07330.pdf>
- FDA Fact Sheet
 - <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM494118.pdf>
- Federal Register
 - <https://www.federalregister.gov/articles/2016/04/06/2016-07330/sanitary-transportation-of-human-and-animal-food>

Optimize Your Workforce



Put Your Game Plan into Play!

- Reinforce business relationships between all stakeholders now
- Make sure you have written procedures in place
- Follow those procedures and keep good records
- Use training to ensure compliance and increase performance
- Document, document, document
- **The benefits of training far outweigh the cost**



For More Information

- Answer survey questions after the webinar if you would like to learn more about:
 - Alchemy's Learning, Communications, and Performance programs
 - PRO-TREAD Courses
- Reminder: you will receive an email with a recording of the webinar and slides in the next 48 hours

Q&A



THANK YOU

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