

OSHA Priorities in the Trump Administration and FSMA Update



Topics

- Status of OSHA In Trump Administration
- FY18 OSHA Inspection Data
- NGFA-OSHA Alliance
- Injury and Illness Recordkeeping
- Combustible Dust
- Tier II Reporting Requirements
- Walking Working Surfaces
- FSMA Update

Trump Administration and OSHA

Based on the rhetoric from the 2016
 presidential campaign trail, it was reasonable
 for employers to anticipate OSHA
 enforcement under a Trump Administration to
 differ significantly from the aggressive
 enforcement model employed by OSHA during
 the Obama Administration.

Trump Administration and OSHA

 The expectation was that a Trump OSHA would scale back enforcement, favor compliance assistance, slash OSHA's budget and staff to limit enforcement, retire national and local emphasis enforcement programs, revise enforcement policies that inflate civil penalties, and otherwise retool its approach to ease the regulatory burden on employers.

What Really Happened is...

- OSHA's FY19 budget is increasing by \$5M from the end of the Obama-era (nearly \$560M total);
- The number of National and Local Emphasis Enforcement Programs remains essentially the same (approx. 150 Local/Regional Emphasis Programs and 9 National Emphasis Programs), including new LEP for AN and anhydrous ammonia;

What Really Happened is...

- The total number of fed OSHA inspections actually increased, from 31,948 in FY2016 to 32,396 in FY2017 (the first increase in the number of inspections in nearly a decade);
- Repeat violations (with 10x higher civil penalties) have continued to increase as a percentage of all citations issued by OSHA;
- The number of cases with total proposed penalties of \$100K+ reached a record-high 218, increasing by 54 since 2016; and

OSHA Political Appointees



Nominee for Assistant Secretary of
OSHA
Scott A. Mugno
VP of Safety at
FedEx Ground



Loren Sweatt
Deputy Assistant Secretary of
OSHA

Sr. Policy Advisor to House Ed. & Workforce Committee

New Political Leadership at OSHA

Scott A. Mugno

- Former VP of Safety at FedEx Ground
- Still No Assistant Secretary of Labor for OSHA
- Longest ever vacancy for the top job
- In 2018, Scott Mugno was re-nominated and cleared by the Senate HELP Committee
- Sat for a full year waiting for a full Senate confirmation vote
- Vote never happened –nomination returned to the White House
- Renominated and only 2 years left in term

What is Taking So Long?

- Political Appointments
 - 4,000 overall
 - 1,200 confirmed by Senate
- Career staff are in "Acting" roles until political staff is appointed or confirmed.
- Career staff keep the "train running" but are not responsible for implementing the Administration's agenda.
- Political Arm Wrestling

Other Key Personnel Changes at OSHA

- Retirements in Career Leadership Ranks— Deputy Assistant Secretary
- Regional Administrators
- Directorate Heads & Others
- Area Directors
- Decline in CSHO #s

Deregulation and OSHA Staff

- Recent retirements has depleted the managerial staff at the National Office and 70 field offices.
- Decrease in management can impact enforcement actions that need to be reviewed by multiple offices.

FY19 Budget

For the first time in a long time, the
Department of Labor enters the fiscal year
with a full-year budget. Although the Trump
Administration proposed significant changes
to the budgets of the various labor agencies,
the final Congressional budget effectively
continues last year's appropriation and
provides small increases.

Current OSHA Budget

- Last Fall, OSHA got a new budget for FY 2019 (Oct. 2018 –Sept. 2019) -\$557,787,000. \$5M increase over FY18
- \$9M more than Pres. Trump requested
- Allocates \$103M to OSHA for State OSH Programs(a \$2M increase over FY18 –1st increase since FY14)

House Oversight

- As of Jan. 1, 2019 House of Representatives controlled by the Democrats (235 Democrats vs. 199 Republicans)
- House Committee on Education and Labor, particularly its Workforce Protection Subcommittee, exercises oversight of OSHA –now also controlled by Democrats
- Many Democrats vying for position on the Ed. & Labor Committee (now chaired by Rep. Bobby Scott (D-VA))
- Already signaled plans to hold extensive oversight hearings:
 - Implementation of De-Regulatory Agenda
 - Publication of Injury & Illness Data
 - Perceived decrease in enforcement activity

Rollback of Major Existing OSHA Rules?

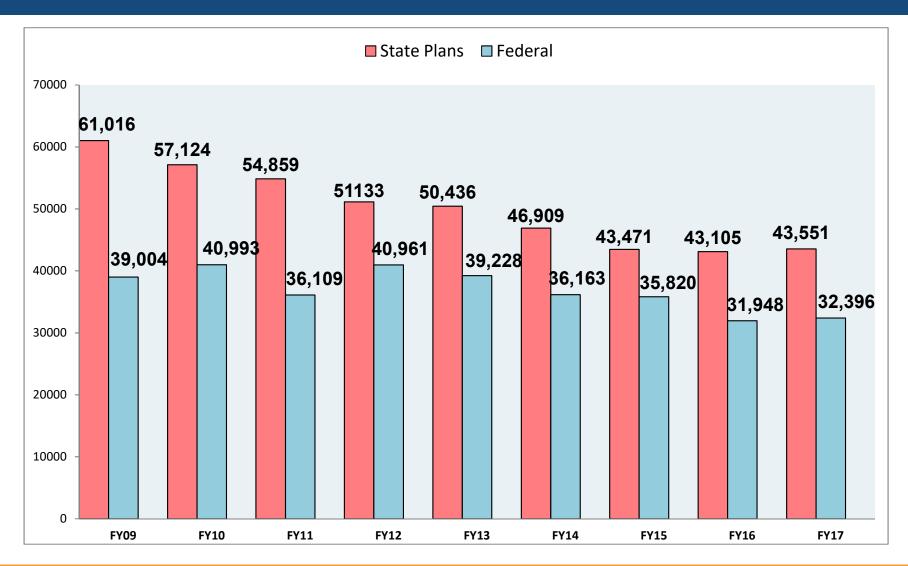
- E-Recordkeeping Rule Final Rule Stage
- HazCom Standard Proposed Rule Stage
- Silica Rule Prerule Stage
- Beryllium Standard
- Proposed Rule (Gen. Industry); Final Rule (Construction & Shipyard)
- Lockout/Tagout
- Prerule Stage (Updates); Final Rule Stage (SIP IV)

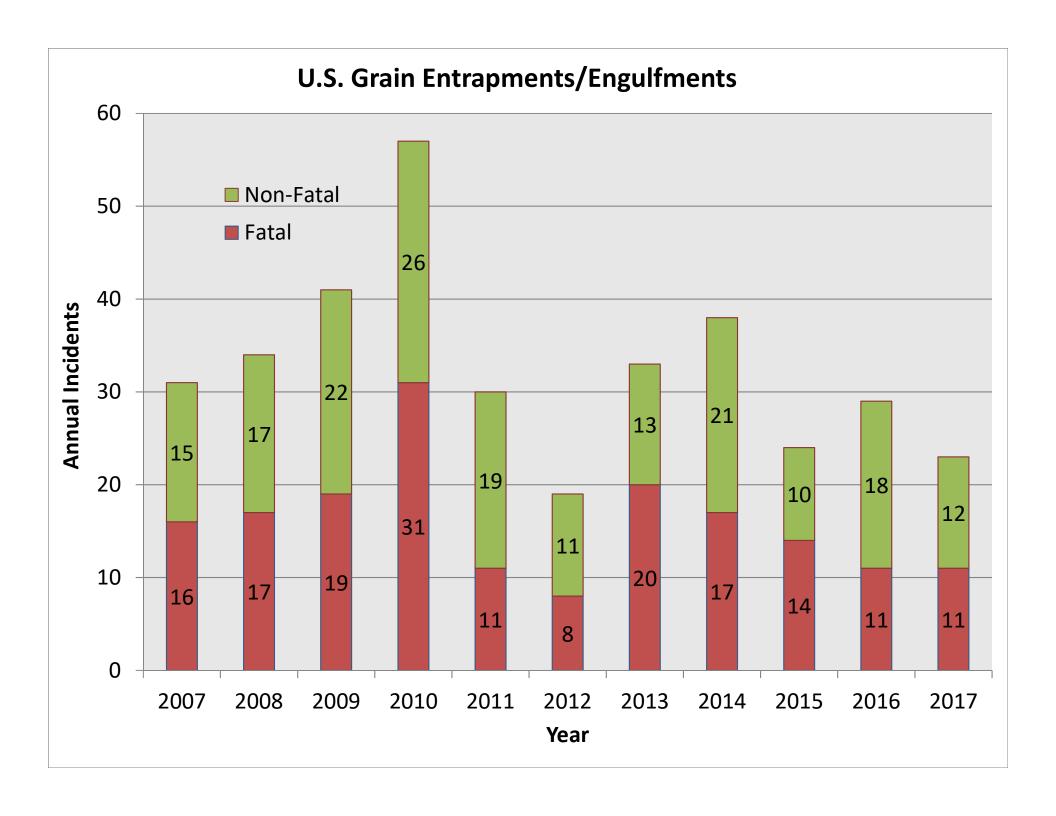
OSHA Enforcement, Inspection Data and Programs

Regional and Local Emphasis Programs FY19

- Local Emphasis Programs
 - Region V (IL, IN, WI, MI, OH) 10/01/2017
 - Region VII (IA, KS, MO, NE) 12/04/2017
 - Region VIII (CO, MT, ND, SD, UT, WY) 10/01/2018
 - Region X (AK, ID, OR, WA) 12/31/17
- Combustible Dust NEP
 - Region IX LEP 10/1/2015

Total Fed/State OSHA Inspections





Current OSHA Enforcement Policy

- OSHA continues to implement the same number of enforcement emphasis programs as at the end of the Obama Administration:
 - 150 Local and Regional Emphasis Programs
 - 9 National Emphasis
 Programs (+ new Chem/Ref PSM NEP)
 - Announced new Site-Specific Targeting Program

National Emphasis Programs:

- Combustible Dust
- Federal Agencies
- Hazardous Machinery
- Hexavalent Chromium
- Lead
- Primary Metal Industries
- Chem/Ref PSM NEP
- Shipbreaking
- Trenching and Excavation

Top 10 Most Frequently Cited OSHA Standards in FY2018

1. Fall Protection, Construction 7,216 violations

2. Hazard Communication 4,537 violations

3. Scaffolds, Construction 3,319 violations

4. Respiratory Protection 3,112 violations

5. Lockout/Tagout 2,923 violations

6. Ladders, Construction 2,780 violations

7. Powered Industrial Trucks 2,281 violations

8. Fall Protection, Training 1,978 violations

9. Machine Guarding 1,969 violations

10. PPE – Eye and Face Protection 1,528 violations

Impact of Government Shutdown on OSHA

- Is OSHA enforcement impacted by Government Shutdown?
- No. Dept. of Labor (including federal OSHA) is fully funded through September 2019 = business as usual at OSHA
- However, Chemical Safety Board is shutdown, and more than 13,000 EPA employees are not working
- Federal Register is also shutdown, so official regulatory actions can not be published (e.g., annual increase of OSHA's max civil penalty authority)

Increased OSHA Citation Penalties

Characterization	Historical Max Penalties	Aug. 2016 (after "catch-up")	Jan. 2019 (latest annual bump)
Other than Serious	\$7,000	\$12,471	\$13,260
Serious	\$7,000	\$12,471	\$13,260
Willful	\$70,000	\$124,709	\$132,589
Repeat	\$70,000	\$124,709	\$132,589
Failure to Abate	\$7,000 per day	\$12,471 per day	\$13,260 per day
Criminal (willful violation causes worker death)		\$250,000 for Individual and 6 Months in Prison \$500K for Corporate Defendants	

FY18 OSHA Inspection Data

Nationwide Federal Inspection Data – Number of Inspections FY16-FY18					
NAICS	FY18	FY17	FY16		
*311119 – Animal Feed Manufacturing	80	94	95		
311211 – Flour Milling 311212 – Rice Milling	21 11	19 8	19 8		
493130 – Farm Product			-		
Warehousing and Storage 424510 – Grain and Field	25	32	32		
Bean Merchant Wholesalers	133	108	128		
Total	270	261	282		

^{*}NAICS - 311119 - Other Animal Food Manufacturing is not part of the Regional and Local Emphasis Programs but 311111 - Pet Food Manufacturing is.

FY18 OSHA Inspection Data

Violations Specific to the Grain Handling Industry				
Standard	Total Violations Issued	Avg Penalty Per Serious Violations Issued		
1910.28(b)(1)(i) – Unprotected side or edge below 4 ft.	20	\$ 6,522		
1910.212(a)(1) – Machine guarding	17	\$ 5,090		
1910.219(d)(1) – Guarding - pulleys	15	\$ 3,496		
1910.272(j)(1) – Implement housekeeping program	12	\$54,068		
1910.272(g)(1)(i)– Grain Bin Entry permit	10	\$14,953		
1910.272(g)(4) – Equipment for rescue operations	9	\$4,086		
1910.178(I)(1)(i) – Powered Industrial Truck training	8	\$ 4,889		
1910.219(c)(4)(i) – Projecting shaft ends	8	\$ 3,104		
1910.272(m)(3) – Certification of dust inspection	8	\$ 843		
OSH Act Section 5 (a)(1) – General Duty Clause	8	\$ 23,265		

FY18 OSHA Inspection Data

Violations Specific to the Grain Handling Standard - 1910.272					
	Total Violations	Avg Penalty Per Serious Violations			
Standard	Issued	Issued			
1910.272(j)(1) – Written	12				
housekeeping program		\$ 54,068			
1910.272(g)(1) – Grain Bin Entry	10				
procedures	10	\$ 14,953			
1910.272(g)(4) – Equipment for	9				
rescue operations	J	\$ 4,086			
1910.272(m)(3) – Certification of	8				
dust inspection	· ·	\$843			
1910.272(e)(1) – Annual training to	7				
employees	•	\$ 2,646			
1910.272(m)(1)(i) – Lubrication and	7				
appropriate maintenance	,	\$58,012			
1910.272(g)(1)(ii) – De-energize	6				
hazardous equipment in bin	U	\$ 22,665			
1910.272(g)(1)(iii) – Atmospheric	6				
testing before bin entry	U	\$ 2,221			
1910.272(j)(2) – Fugitive grain dust	6				
accumulation	U	\$ 3,906			
1910.272(d) – Emergency Action Plan	5				
5		\$ 26,764			

Is a Hopper Truck a PRCS?

The alleged violations below (1a, 1b and 1c) have been grouped because they involve similar or related hazards that may increase the potential for injury or illness.

Citation 1 Item 1 a Type of Violation: Serious

29 CFR 1910.146(c)(1): The employer did not evaluate the workplace to determine if any spaces were permit-required confined spaces:

(a)

LOCATIONS - Employees were required to clean the insides of the hopper trucks used to haul grain products to prevent cross product contamination, and the employer had not evaluated the task to determine that the hoppers in the trucks were permit required confined spaces, on or about, November 5, 2018.

Abatement certification required within 10 days after abatement date. The certification shall include a statement that abatement is complete, date and method of abatement, and states employees and their representatives were informed of this abatement.

ABATEMENT DOCUMENTATION REQUIRED FOR THIS ITEM

Date By Which Violation Must be Abated: 01/18/2019
Proposed Penalty: \$3880.00

See pages 1 through 4 of this Citation and Notification of Penalty for information on employer and employee rights and responsibilities.

Citation and Notification of Penalty Page 6 of 17 OSHA-2



OSHA and Local Inspection Authority

- Is it possible for an establishment to pass a federal/state OSHA inspection but then be cited and fined by the local inspection authority such as a county and/or state fire marshal?
- In principle, the answer is "yes." An
 establishment that passes an OSHA inspection
 could be cited and fined by the local inspection
 authority, such as a state or county fire marshal.
 Conversely, compliance with local codes may
 result in violations of OSHA standards.

OSHA and Drones

- Last year OSHA issued a memo authorizing inspectors to use camera-carrying drones to collect evidence during inspections of certain workplace settings.
- According to the OSHA guidance memo, inspectors must "obtain express consent from the employer" prior to using a drone.
- Was used in 2018 to investigate combustible dust incidents.
- In other words be prepared.

U.S. Department of Labor

Occupational Safety and Health Administration Washington, D.C. 20210

MAY 1 8 2018

MEMORANDUM FOR: REGIONAL ADMINISTRATORS

THROUGH:

RICHARD MENDELSON
Acting Deputy Assistant Secretary

FROM:

THOMAS GALASSI, Director Directorate of Enforcement Programs

SUBJECT:

OSHA's use of Unmanned Aircraft Systems in Inspections

This memorandum addresses the use of Unmanned Aircraft Systems ("UAS" or "drones") by OSHA. UAS may be used to collect evidence during inspections in certain workplace settings, including in areas that are inaccessible or pose a safety risk to inspection personnel. UAS may also be used for technical assistance in emergencies, during compliance assistance activities, and for training. As a Federal agency, there are currently two legal frameworks available to OSHA under Federal Aviation Administration (FAA) rules for the use of UAS, either as a Public Aircraft Operator (PAO) flying missions that meet the governmental functions listed in the Public Aircraft Statute (49 U.S.C. §§ 40102(a)(41) & 40125), or as a Civil Operator under the civil rules (14 CFR part 107).

OSHA is exploring the option of obtaining a Blanket Public COA to operate UAS nationwide. In the interim, OSHA UAS operations must adhere to the following guidance.

Any Region using UAS will designate a Regional UAS Program Manager (UPM) that will oversee all program elements. The UPM shall ensure that OSHA UAS operations follow all 14 CFR part 107¹ rules which include, but are not limited to, the following:

- Remote Pilot in Command (RPIC) shall pass an FAA Aeronautical Knowledge Test and obtain a Remote Pilot Certificate with UAS rating.
- ii. Register all UAS.
- Apply and obtain approval for FAA part 107, subpart D, waiver when unable to operate under part 107 rules.
- iv. Establish and maintain logbooks for RPICs and all UAS.
- v. Report accidents to FAA (see §107.9).



NGFA/OSHA Alliance

Hazards of The Industry

Determined SHA Has

1

← Engulfments

2

◆ Falls

3

◆ Electric

4

← Entanglement

5

← Struck by

Dust Explosion

NGFA and **OSHA** Alliance

- NGFA has signed a joint agreement with OSHA focusing on outreach and communication.
- Goal is to enhance communication between NGFA-members, State/Regional affiliates and Regional/Area offices.
 - Accomplished through speaking engagements, facility tours, Web pages and newsletters.
- Option to renew Alliance after 5 years and to then focus on substantive issues/projects.

Alliance Activities

- Gathering and sharing of recommended practices or effective approaches;
- Participating in industry and/or OSHA conferences, meetings and events;
- Host awareness events Grain Stand Up Engulfment Prevention Week
- Encouraging future collaborations among NGFA affiliates and OSHA

OSHA-NGFA-GEAPS at Kick Off Event

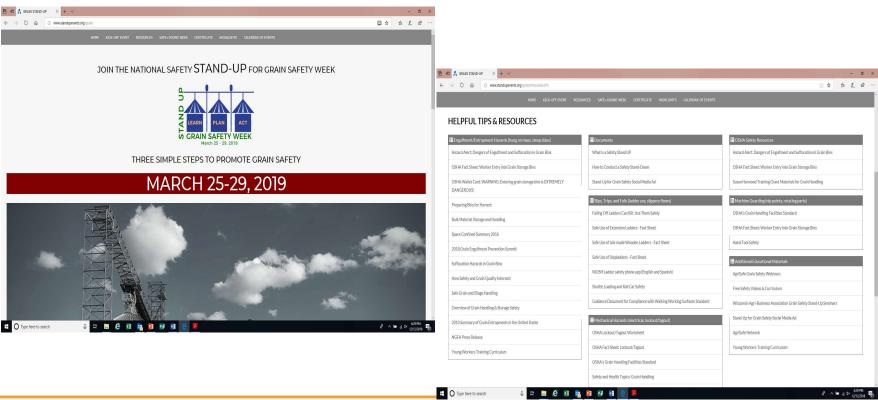


Stand Up for Grain Safety Week 2019

- The NGFA and OSHA are hosting a major safety outreach effort, the "Stand-Up for Grain Safety Week" from March 25-29, to help raise awareness about grain handling and storage hazards, provide education and training, and convey safety best practices.
- The event will focus on grain bin entry, machine guarding, respiratory protection, falls, heat, lockout/tagout, and other industry issues.
- The National Stand-Up for Grain Safety Week Kick-Off Event will be held at the Asmark Institute Agricenter on March 25 in Bloomington, IL. The Deputy Assistant Secretary of OSHA, Loren Sweatt is confirmed to attend.

Stand Up for Grain Safety Week 2019

 A website has been developed by NGFA and OSHA that provides resources for companies to use when they are conducting "Stand Ups" to promote safety.



Stand Up for Grain Safety Week 2019



OSHA and Grain Handling Issues for 2019

Top Grain Handling Issues for 2019

- Regulations
 - Emergency Preparedness and Response
 - OSHA Enforcement Policy on PELs
 - Injury and Illness Electronic Reporting
 - December 31 was the deadline for 2016 300A
 - July 1 was the deadline for 2017 300A
 - Powered Industrial Trucks
 - Globally Harmonized System for Labelling
 - Walking Working Surfaces
 - Rolling Stock Fall Protection
 - Combustible Dust

 OSHA intends to update / replace existing 29 CFR 1910.156, <u>Fire Brigades standard</u>.

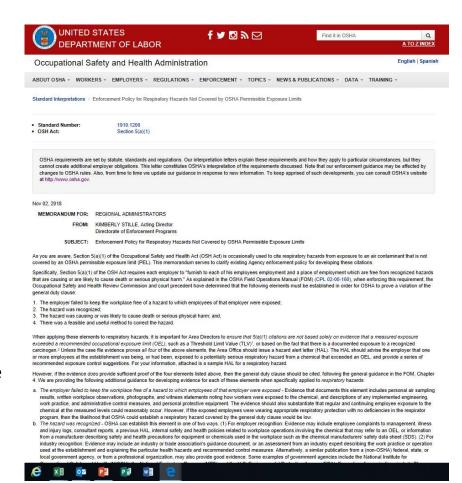
 New standard would be called <u>Emergency</u> <u>Response</u>.

 The primary concern is that whatever requirements are placed upon the ERP, it is certainly going to carry over to organizations that they work with such as grain handling facilities. Some examples include: 1) additional paperwork burdens related to preincident planning; 2) responder preparedness e.g. training and certification and facility; and 3) equipment preparedness, to name a few.

 OSHA's agenda indicates that the agency plans to convene several Small Business Advocacy Review (SBAR) (also known as SBREFA) panels in 2019, including the Emergency Response and Preparedness. Several members of the SHEQ committee have already volunteered to serve as a small entity representatives (SER) with this panel when it is formally convened by the agency to review and provide comments on the draft rule.

OSHA Enforcement Policy on PELs

- Last year, OSHA's Directorate of Enforcement Programs issued a <u>memorandum</u> that clarifies its existing policy for developing citations under the general duty clause for respiratory hazards from exposure to an air contaminant that is <u>not</u> covered by an OSHA permissible exposure limit (PEL).
- The following elements must be established for OSHA to prove a violation of the general duty clause:
 - The employer failed to keep the workplace free of a hazard to which employees of that employer were exposed;
 - The hazard was recognized;
 - The hazard was causing or was likely to cause death or serious physical harm; and,
 - There was a feasible and useful method to correct the hazard.



Powered Industrial Trucks

OSHA to Rewrite PIT?

- On March 11, 2019, OSHA issued a Request for Information (RFI) in the Federal Register seeking comments and information from stakeholders regarding the use of powered industrial trucks (PITs) for maritime (1915.120, 1917.43, 1918.65) construction, (1926.602(c), (d)), and general industries (1910.178).
- OSHA is considering revising current standards regarding PITs and this information will assist the agency in determining what actions, if any, it will take in revising these standards. Comments are due on June 10.

OSHA to Rewrite PIT?

Specifically, the RFI seeks information in various categories and outlines specific questions for each category of information requested such as:

- Types of Powered Industrial Trucks
- Truck Operations, Maintenance, and Training
- Incidents and Injuries
- Consensus Standards
- Compliance Issues

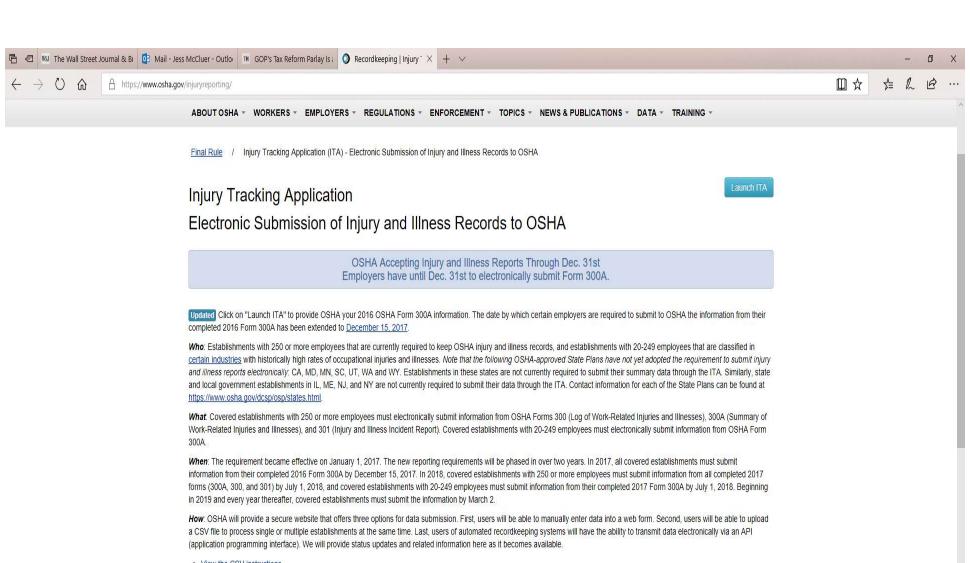
Injury and Illness Recordkeeping and Reporting

OSHA's Electronic Recordkeeping Final Rule

- Electronic Submission
 - Employers with 250 or more (includes part-time, seasonal, and/or temporary workers) in each establishment to electronically submit their 300, 300A, and 301 forms to OSHA annually
 - Employers with more than 20 but less than 250 employees in certain identified industries to electronically submit their 300A form annually
 - Employers who receive notification from OSHA to electronically submit their 300, 300A, and 301 forms to OSHA
- OSHA was originally intending to post the data from employer submissions on a publically accessible website – not to include an information that could be used to identify individual employees. The rationale for publishing the collected injury and illness data is that public exposure would result in improved safety and health.

Effective Dates in the Final Rule (cont.)

Submission Deadline	Number of Employees	
	250 or more	Between 20 and 249
December 31, 2017	Form 300A	Form 300A
July 1, 2018	Forms 300A, 300, 301	Form 300A
March 2 (2019 and beyond)	Forms 300A, 300, 301	Form 300A



- View the CSV instructions
- Download a CSV file template
- Download a CSV sample file
- View the API technical specifications

ITA Job Aids: These instructions are available to support users through the submission process.

- Getting started in ITA
- Setting up an account
- Create an establishment
- Add 300A summary data
- Submit establishment data
- Upload a file
- View API token
- View an establishment or edit an establishmen

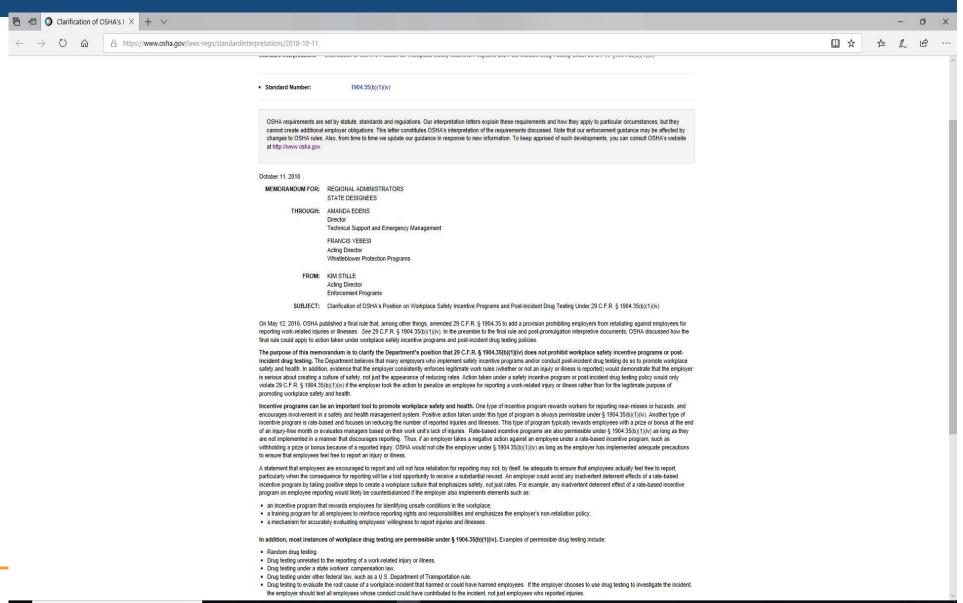




OSHA's Electronic Recordkeeping Final Rule

- Post-accident drug testing
 - "Should limit post-accident testing to situations in which employee drug use is likely to have contributed to the accident and for which the drug test can accurately identify impairment caused by drug use"
 - "Blanket post-injury drug testing policies deter proper reporting"
- Incentive Programs
 - Be careful that program doesn't incentivize underreporting – e.g. bonus for team of employees if no one is injured over defined period of time vs. bonus for employees participating in safety committee

OSHA Memo on Safety Incentive and Post Incident Drug Testing

























OSHA Memo on Safety Incentive and Post Incident Drug Testing

Safety Incentive Programs

 According to the memorandum, OSHA acknowledges that some safety incentive programs promote workplace safety and health. The memorandum clarifies that not only are safety incentive programs that reward employees for reporting near-misses or hazards, or encourage involvement in a safety and health management system permissible but so are ratebased safety incentive programs, which focus on reducing the reducing number of reported workrelated injuries and illnesses.

OSHA Memo on Safety Incentive and Post Incident Drug Testing

Drug Testing Programs

OSHA also clarified that most drug testing policies are permissible, including post-accident drug testing. OSHA specifically noted that the following types of drug testing policies were not in violation of OSHA's requirements:

- Random drug testing.
- Drug testing unrelated to the reporting of a work-related injury or illness.
- Drug testing under a state workers' compensation law.
- Drug testing under other federal law, such as a U.S. Department of Transportation rule.
- Drug testing to evaluate the root cause of a workplace incident that harmed or could have harmed employees. If the employer chooses to use drug testing to investigate the incident, the employer should test all employees whose conduct could have contributed to the incident, not just employees who reported injuries.

Future of the E-Recordkeeping and Anti-Retaliation Rule

- President Trump's 2017 and 2018 Regulatory Agendas included initiating new rulemaking to rescind/amend the E-Recordkeeping Rule
- Industry was anticipating the following:
 - Injury data limited to only 300A Annual Summaries for all employers in all years
 - Increase threshold trigger for "High Hazard Industries"
 - Increase threshold for smaller employers to be covered
 - Eliminate the Anti-Retaliation provisions

New Rulemaking for Recordkeeping Rule

- In September NGFA, along with 60 other trade groups submitted comments to the agency on their proposed revisions which raised several points critical of the proposal, including:
 - OSHA wants to retain collection of the 300A annual summaries which contain confidential business information but gives no indication of trying to protect this information from disclosure; employers are concerned that these forms would be subject to FOIA requests and that a future administration would not hesitate to release these forms;
 - OSHA wants to add Employer Identification Numbers (EINs) to these forms which seems unjustified and gives employers concerns that this sensitive information will be released inappropriately, even if EINs may be available from other sources;
 - OSHA has not addressed the many problems associated with the antiretaliation provision.

Revised Recordkeeping Rule

- On Jan. 25 OSHA issued a final rule that eliminates the requirement for establishments with 250 or more employees to electronically submit information from OSHA Form 300 and OSHA Form 301 to OSHA each year. These establishments are still required to electronically submit information from OSHA Form 300A (Summary of Work-Related Injuries and Illnesses).
- Employers with more than 20 but less than 250
 employees in each establishment are still required to
 electronically submit their 300A form annually
 (includes part-time, seasonal, and/or temporary
 workers).

Revised Recordkeeping Rule

- OSHA has determined that this rule will benefit worker privacy by preventing routine government collection of sensitive information, including descriptions of workers' injuries and the body parts affected, thereby avoiding the risk that such information might be publicly disclosed under the Freedom of Information Act or through OSHA's Injury Tracking Application. The rule does not alter an employer's duty to maintain OSHA Forms 300 and 301 on-site, and OSHA will continue to obtain these forms as needed through inspections and enforcement actions.
- OSHA is also amending the recordkeeping regulation to require covered employers to electronically submit their Employer Identification Number with their information from Form 300A.

Electronic Recordkeeping: Site Specific Targeting

- On October 16, 2018, OSHA published Site Specific Targeting 2016 (SST-16)inspection plan
- Outlines OSHA's strategy for targeting establishments for inspection based on 300A injury data collected under new E-Recordkeeping Rule



J.S. DEPARTMENT OF LABOR Occupational safety and

SUBJECT: Site-Specific Targeting 2016 (SST-16)

ABSTRACT

Purpose: This Notice implements OSHA's Site-Specific Targeting 2016 (SST-16) inspection plan. This program does not include construction worksites.

OSHA-wide

References: OSHA Instruction CPL 02-00-025 Scheduling System for Programmed

Inspections, January 4, 1995; OSHA Instruction CPL 02-00-160, Field Operations Manual (FOM), August 2, 2016; OSHA Instruction CSP 01-00-004, State Plan Policies and Procedures Manual, September 22, 2015, and Interim Enforcement Procedures for Failure to Submit Electronic Illness and Injury Records under 29 CFR 1904.41(a)(1) and (a)(2).

February 21, 2018.

Cancellations: None

Action Offices:

Expiration Date: One year from the effective date, unless replaced by a new Notice. Upon

the expiration or replacement of this Notice, inspection cycles already underway must be completed as described in paragraph XI.B.

State Impact: Notice of Intent and Equivalency required. State Plan documentation of

targeting system required if not current. See paragraph VII, State Plan

National, Regional, and Area Offices

Originating Office: Directorate of Enforcement Programs

Abstract - 1

Electronic Recordkeeping: Site Specific Targeting

- SST-16 Plan selects individual establishments for inspection based on CY 2016 300A injury data
- Establishments covered by SST-16include: Establishments w/ DART rate above currently unpublished threshold
 - NOTE -Different DART rate trigger for manufacturing and non-manufacturing establishments
- Random set of establishments OSHA believes were required to submit 2016 300A injury data under E-Recordkeeping Rule but did not;
- Random sample of establishments w/ unusually lowinjury rates (for quality control purposes and to identify possible under-recording)

Electronic Recordkeeping: Site Specific Targeting

- Inspections will be comprehensive in scope
- Coordinated with NEPs —i.e. if an establishment that is covered by a NEP and happens to be selected for inspection under SST-16 Plan, the SST and NEP inspections will run concurrently (classified separately)
- Targeted establishments will be deleted from list if: No longer in business
- Received a comprehensive safety/health inspection w/in 36 months of creating current inspection cycle list;
 - VPP or SHARP participant
 - Public sector employer (federal, state, or local gov.)



Overview of OSHA Final Rule on Electronic Reporting

By Jess McCluer, NGFA Vice President of Safety and Regulatory Affairs

National Grain and Feed Association

September 2016

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National Fire Protection Association/ Chemical Safety Board

Overview of 652 Content

- NFPA 652: Standard on the Fundamentals of Combustible Dust, 2016 edition, was created to promote and define hazard analysis, awareness, management and mitigation.
- The standard also issues a new term, Dust Hazard Analysis to differentiate this analysis from the more complex forms of process hazard analysis methods currently found in industry.
- NFPA 652 takes this requirement further by making this requirement retroactive to existing installations with a deadline.
- A DHA is now required for new installations and upgrades to existing installations. The standard allows three years to complete this DHA. To illustrate the importance of this hazard analysis, many OSHA citations regarding combustible dust hazards list the lack of a hazard analysis at the top of the citation.

Overview of 652 Content

- NFPA 652 is now the starting point for defining a combustible dust and its hazards. Its purpose is to clarify the relationship between the shared standards and the industry-specific standards such as NFPA 484 for metals, NFPA 664 for wood, NFPA 655 for sulfur, and NFPA 61 for agricultural and food processing.
- These standards require that a facility processing or handling combustible dust perform a hazard analysis and risk assessment for each operation that handles combustible dust. DHA differs from the more complex Process Hazard Analysis (PHA) used by industries such as refineries and chemical manufacturing. It is not the intent of the NFPA to force all manufacturers to undergo strict hazard analysis procedures that are necessary for industries such as these.

Impact on NFPA 61

- The Technical Committee made this update such that users of NFPA 61 would not need to use NFPA 652 as a starting point.
- Other notable updates include:
 - The exemption from protection and monitoring devices on small, low speed bucket elevators has been removed from the standard.
 - Flame-arresting and particulate retention vent systems are now explicitly allowed to be utilized for explosion venting on bucket elevators.
 - Exceptions on explosion protection for smaller cyclones are now provided, with certain conditions.
 - The standard lists a completion date of June 2021 for facilities with existing equipment, but the DHA must be completed sooner for any new process or existing processes being significantly changed. Then it must be completed as part of the project.

NFPA 61 2020 Edition

- The committee met earlier this year to review the first draft of comments to modify the existing version.
- Many of the suggested changes were to further incorporate NFPA 652 into 61.
 Concern amongst industry is that many of the changes are being pursued by consultants.
 - A DHA is now required for new installations and upgrades to existing
 installations. The standard allows three years to complete this DHA. To
 illustrate the importance of this hazard analysis, many OSHA citations
 regarding combustible dust hazards list the lack of a hazard analysis at the top
 of the citation. The committee is developing an industry specific checklist.
- The committee accepted proposal to incorporate the results of the study, funded by the National Grain and Feed Foundation, regarding the explosibility of particular types of grain dust.

Combine All Combustible Dust Standards into One Document

- NFPA Standards Council has requested that NFPA Combustible Correlating Committee weigh the pros and cons of combining all of the combustible dust standards into one document. This is the first step in creating one standard.
- Overall, the grain, feed, processing and milling reps on the NFPA 61 committee believe that NFPA 61 should not be combined, either in substance or in form, with other combustible dust standards and that it should remain a free-standing standard.
- As a result, one size does not fit all because many new concepts and operational practices cannot be applied to existing facilities or new construction without great costs and design changes that are not even necessary.

Call to Action: Combustible Dust

- In October, the U.S. Chemical Safety and Hazard Investigation Board, as part of its investigation into the May 2017 Didion Mill explosion, issued a <u>"Call to Action:</u> <u>Combustible Dust"</u> to gather comments on the management and control of combustible dust from companies, regulators, inspectors, safety training providers, researchers, unions, and the workers affected by dustrelated hazards.
- The agency seeks input on a variety of complex issues, including: recognizing and measuring "unsafe" levels of dust in the workplace, and the methods for communicating the low-frequency but highconsequence hazards of combustible dust in actionable terms for those working and overseeing these environments.



Call to Action: Combustible Dust

Didion Milling & Others

Request for Comments

The CSB asks for comment from companies, regulators, inspectors, safety training providers, researchers, unions, and the workers of dust-producing operations themselves on some very fundamental questions. Please add to our understanding by answering any or all of the following questions:

- In real-world working conditions, where dust is an inherent aspect of the operation, can a workplace be both dusty and safe?
- In such working environments where the amount of ambient/fugitive dust cannot be wholly eliminated 100 percent of the time — how does an individual or organization distinguish between an acceptable or safe dust level and one that has been exceeded? How often does judgment or experience play a role in such decisions? Should it?
- How are hazards associated with combustible dust communicated and taught to workers? What systems have organizations successfully used to help their employees recognize and address dust hazards?
- What are some of the challenges you face when implementing industry guidance or standards pertaining to dust control/management?
- If companies/facilities need to use spearate or different approaches in order to comply with both santation standards for product qualify or food safety and those associated with dust explosion prevention, then how do you determine what takes priority? Is the guidance clear?

- How should the effectiveness of housekeeping be measured? What methods work best (e.g., cleaning methods, staffing, schedules)?
- As equipment is used and ages, it requires mechanical integrity to maintain safe and efficient operability. How does inspection, maintenance, and overall mechanical integrity efforts play a role in dust accumulations, and how are organizations minimizing such contributions in the workolace?
- What are some of the challenges to maintaining effective dust collection systems?
- How common are dust fires in the workplace that do not result in an explosion? Does this create a false sense of security?
- Are workers empowered to report issues when they feel something needs to change with regard to dust accumulation? What processes are in place to make these concerns known?
- How can combustible dust operators, industry standard organizations, and regulators better share information to prevent future incidents?

The CSB will review all responses submitted by November 26, 2018, and use the information provided to explore the conditions that influence the control and management of combustible dust in order to seek out a deeper understanding of the real-world challenges to preventing dust explosions and, more importantly, new opportunities for safety improvements.

Background

To date, the CSB has issued four recommendations to OSHA calling for the issuance of a comprehensive general industry standard for combustible dust, and combustible dust safety is on the agency's Drivers of Critical Chemical Safety Change list. Yet development of a general industry standard has not come to fruition. With

and control of combustible dust beyond regulatory promulgation.

In 2006, the CSB identified 281 combustible dust incidents between 1980 and 2005. One hundred and nineteen workers were fatally injured, 718 more were hurt, and industrial facilities were extensively damaged. The incidents occurred

Call to Action: Combustible Dust

- The American Feed Industry Association, the Corn Refiners Association, the National Oilseed Processors Association, the North American Millers Association and the U.S. Beet Sugar Association joined in signing the NGFA-authored letter.
- Effects of our industry's self-initiated and self-funded actions, including significant facility, equipment and technology improvements, extensive education and research efforts, and improved commodity handling, storage, and shipping practices, is being reflected in substantially reduced risks of fires, explosions and associated injuries and fatalities.

New Source Performance Standard for Grain Elevators/ EPCRA Trier II Reporting – Combustible Dust

NSPS for Grain Elevators

- NSPS for Grain Elevators is on the EPA's list of inactive rules (presumably those that will not be addressed within the next year).
- NGFA and NOPA have met with senior officials in OAR to discuss the NSPS Subpart DD Coalition's request that EPA: 1) formally withdraw the NSPS DDa proposed rule, and 2) rescind NSPS DD prospectively for grain elevators constructed or reconstructed in the future.
- According to OAR senior political appointee, OAR is "still working on the legal and technical" issues related to our requests and will follow-up with the Coalition in early 2019 with an update on the next steps.

EPCRA Tier II Reporting – Combustible Dust

- EPA recently updated its safety standards regarding hazardous chemicals, including combustible dust.
- As part of a Tier II inventory report, a facility must designate the physical or health hazard associated with each hazardous chemical. Now facilities must choose from among 13 possible physical hazards and 11 possible health hazards. Combustible Dust is classified as a physical hazard.

EPCRA Tier II Reporting – Combustible Dust

- The reporting threshold for combustible dust and grains is 10,000 pounds on-site at any one time during the reporting year
- The EPA's clarification on combustible dust (<u>Combustible-food-dust-and-EPCRA-311-312-reporting</u>) also specifies that if a facility "accumulates" 10,000 pounds of dust, may imply that the presence of dust entrained in grain is not counted towards the threshold.
- An <u>article</u> posted by EPA described how to report combustible dust in a Tier II: "Facility owners and operators can use their best professional judgment or engineering calculations to determine the amount of dust present at their facility when making threshold determinations and when calculating amounts to include on the Tier II chemical inventory form (e.g., maximum amount and average amount on site)."

EPCRA Tier II Reporting – Combustible Dust



Tier II Reporting Guidance for Whole Grains and Grain Dust

What are the Tier II reporting requirements?

The Environmental Protection Agency's (EPA) Tier II reporting is required for all facility types if, at any time during the last calendar year, they had any material requiring a Safety Data Sheet (SDS) on-site in quantities over:

- 10,000 pounds¹, or
- if it is an Extremely Hazardous Substance (EHS) such as aluminum phosphide or ammonia, 500
 pounds or the threshold planning quantity (TPQ), whichever is lower.

Some of the commonly reported materials at grain elevators and feed mills are fuels, fertilizer and pesticides. Facilities are required to report this information using their <u>state's reporting system</u> by March 1 of each year. The Tier II reports assist Local Emergency Planning Committees (LEPCs) in developing and managing local emergency response plans.

Significantly, section 311(e) of the Emergency Planning and Community Right-to-Know Act (EPCRA) excludes from the reporting requirement any food, food additive, color additive, drug, or cosmetic regulated by the Food and Drug Administration (FDA).² This exemption applies to both human and animal food (feed) products regulated by FDA.

Do I need to report grain and grain dust?

In 2012, the Occupational Safety and Health Administration (OSHA) changed its Hazard Communication standard to make it consistent with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). OSHA also took that opportunity to add combustible dust as a hazard category. This addition impacted the classification of grain and grain dust and is related to the EPA's Tier II reporting. Grain and grain dust may require safety data sheets as discussed in Section 4 of the NGFA's Guidance: Hazard Communication Program at Grain Handling, Feed, Ingredient and Processing Facilities.

As previously stated, the EPA's Tier II reporting requirements still exempt food and food additives regulated by the FDA, which typically includes grain and grain dust. However, if the grain or grain dust was not sold or



To assist in determining whether to report grain or grain dust in a Tier II report, the NGFA has prepared the following flowcharts³:

Flowchart for Tier II Reporting of Grain Yes Was all the grain used as food or feed⁴? No At any time, last year, did the facility store over 10,000-pounds of grain that was not used as

Flowchart for Tier II Reporting of Grain Dust

Yes Was the grain dust used

food or feed5?

No

You are not required to

report the grain for the

previous year.



Globally Harmonized Standard for Labelling

More Updates to HazCom Coming?

- 2012 HazCom update aligned OSHA's rule w/ GHS Rev.
 3 (2009)
- Since HCS 2012, GHS up to Rev. 7 (2017)
- Where there is conflict, reliance on GHS is a violation
- OSHA is working on proposed revisions to HazCom again:
- Realign HazCom w/ more current version of GHS
- Address issues identified in 2-4 years of HCS 2012 implementation
- Not de-regulatory (enhance or maintain current protections)

Walking Working Surfaces

Walking Working Surfaces

- On November 18, 2016 OSHA issued a new final rule that updates and revises the general industry Walking-Working Surfaces and Personal Protective Equipment (Fall Protection Systems) standards on slip, trip, and fall hazards
- Includes revised and new provisions addressing
 - fixed ladders;
 - rope descent systems;
 - fall protection systems and criteria (including personal fall protection systems); and
 - training on fall hazards and fall protection systems
- Adds requirements on the design, performance and use of personal fall protection systems

Frequency of Slips, Trips and Falls

- Overwhelming majority of general industry accidents stem from slips, trips and falls
- Statistics: Approx. 15% of accidental deaths are from slips, trips, and falls
- Approx. 20% of workplace fatalities disabling injuries and days away injuries in general industry result from slips, trips and falls
- Walking Working Surfaces Standard among most frequently cited standards every year

Top 8 Most Cited Sections

# of Citations	Section	Subject	
291	1910.22(a)(1)	General housekeeping	
205	1910.28(b)(1)(i)	Fall protection for unprotected sides & edges	
122	1910.22(a)(2)	Clean and dry floors	
55	1910.28(b)(11) subparts	Fall protection for stairways	
53	1910.22(a)(3)	WWS free of hazards	
49	1910.28(b)(3) subparts	Fall protection for holes	
45+	1910.29(b) subparts	Specifications for guardrail systems	
26	1910.28(b)(6) subparts	Fall protection around dangerous equipment	

Final Subpart D Re-Organizations

With the revision of Subpart D OSHA changed most of the titles for each of the standards that appear in it. As a result, information that was previously found under the old standard number are now found under a completely different standard number. This table shows the previous standard titles versus the new titles.

PREVIOUS SUBPART D	NEW SUBPART D	
1910.21 Definitions	1910.21 Scope and Definitions	
1910.22 General Requirements	1910.22 General Requirements	
1910.23 Guarding Floor and Wall Openings and Holes	1910.23 Ladders	
1910.24 Fixed Industrial Stairs	1910.24 Step Bolts and Manhole Steps	
1910.25 Portable Wood Ladders	1910.25 Stairways	
1910.26 Portable Metal Ladders	1910.26 Dockboards	
1910.27 Fixed Ladders	1910.27 Scaffolds and Rope Descent Systems	
1910.28 Safety Requirements for Scaffolding	1910.28 Duty to Have Fall Protection and Falling Object Protection	
1910.29 Manually Propelled Mobile Ladder Stands and Scaffolds (Towers)	1910.29 Fall Protection Systems and Falling Object Protection – Criteria and Practices	
1910.30 Other Working Surfaces	1910.30 Training Requirements	

Effects of New Rule

- Adds consistency b/n General Industry and Construction standards (1926, subparts L, M & X)
- Harmonizes w/ national consensus standards
 - ANSI A1264.1 (surfaces, floor, wall and roof openings / stairs and guardrail systems)
 - ANSI Z359.1 (personal fall arrest systems)
 - ANSI I-14.1 (window cleaning)
- Gives flexibility to use personal fall protection systems (e.g., personal fall arrest, travel restraint, and work positioning systems) in lieu of guardrail systems

Walking Working Surfaces – Training

 Any time a new method or system of protection is introduced at your organization, all employees that will be working in and around this system must be adequately trained – in each specific device and/or method. General fall protection training will not suffice. The training will need to be specific and needs to be done immediately prior to implementation of any new systems.

Walking-Working Surfaces

- The employer must train each employee in at least the following topics:
 - The nature of the fall hazards in the work area and how to recognize them;
 - The procedures to be followed to minimize those hazards;
 - The correct procedures for installing, inspecting, operating, maintaining, and disassembling the personal fall protection systems that the employee uses

Employer Training Requirements

- 1910.30 Training Requirements: Ensure workers who use fall protection and work in high hazard areas are trained and retrained (as needed) about fall hazards and equipment, and the proper use of FPSs.
- Trainer must be a qualified person and is responsible for training employees how to:
 - Identify and minimize fall hazards
 - Use personal FPSs and RDSs
 - Maintain, inspect, & store fall protection equipment or systems
- May overlap with 1910.132 PPE Training Requirements but training will be sufficient to satisfy both standards.

Timeline

Most of the rule became effective January 17, 2017, 60 days after publication in the *Federal Register*, but some provisions have delayed effective dates, including:

- Ensuring exposed workers are trained on fall hazards (May 17, 2017),
- Ensuring workers who use equipment covered by the final rule are trained (May 17, 2017),
- Inspecting and certifying permanent anchorages for rope descent systems (November 20, 2017),
- Installing personal fall arrest or ladder safety systems on new fixed ladders over 24 feet and on replacement ladders/ladder sections, including fixed ladders on outdoor advertising structures (on and after November 19, 2018),
- Ensuring existing fixed ladders over 24 feet, including those on outdoor advertising structures, are equipped with a cage, well, personal fall arrest system, or ladder safety system no later than (November 19, 2018) and,
- Having ladder safety or personal fall arrest systems installed on all fixed ladders over 24 feet by (November 18, 2036).

More Simple General Requirements

- Housekeeping -1910.22(a)
 - Workplaces must be kept clean, orderly, and sanitary
 - Workroom floors must be clean and as dry as possible
- Load Limit –1910.22(b)
 - Must ensure each walking-working surface can support "maximum intended load" for surface
 - No more requirement for plate indicating max load
- Aisle and Passageways –1910.22(c)
 - Must provide and ensure employees use safe means of access and egress to and from walking-working surfaces
- Inspection Requirement –1910.22(d)
 - Must inspect / maintain walking-working surfaces in safe condition

Grandfathering In the New Rule

- Unlike most building and other codes, WWS has no consistent grandfathering rule.
- Grandfathering is allowed for:
 - Construction of stairs (interpretation letter)
 - Stair rail height (preamble)
 - Fall protection for fixed ladders (until Nov. 2036) (standard)
- Grandfathering not allowed for:
 - Guardrail height (preamble)
- Unclear whether grandfathering allowed:
 - Ladders (dimensions)
 - Step bolts

Fixed Ladder Fall Protection Change

Major change – cages and wells no longer acceptable fall protection on fixed ladders higher than 24'

- Grandfather Provisions and Phase-In of New Provisions for Ladders that extend more than 24' above a lower level
- Employer must ensure:
 - Fixed ladder installed before 11/19/2018 is equipped w/ personal fall arrest system, ladder safety system, cage, or well;
 - Fixed ladder installed on and after 11/19/2018 is equipped w/ personal fall arrest system or a ladder safety system;
 - When replacing fixed ladder, cage or well (or any portion), personal fall arrest system or ladder safety system is installed; and;
 - On and after 11/18/2036, all fixed ladders to be equipped w/ personal fall arrest system or ladder safety system

Additional and Anticipated Guidance

- 11/20/17 Enforcement Guidance for RDS Systems – Provides flexibility on timing for completing inspections of anchorages.
- Submitted Numerous requests for interpretations
- Frequently Asked Questions from OSHA
- Anticipated –Compliance Directive

Notable FAQs

- Multi-Section Ladder and Fall Arrest/Ladder Safety Systems:
 - If a multiple section or side-step ladder extends more than 24 feet above ground, the employer must equip the entire ladder with personal fall arrest or ladder safety systems throughout all ladder sections

Walking Working Surfaces

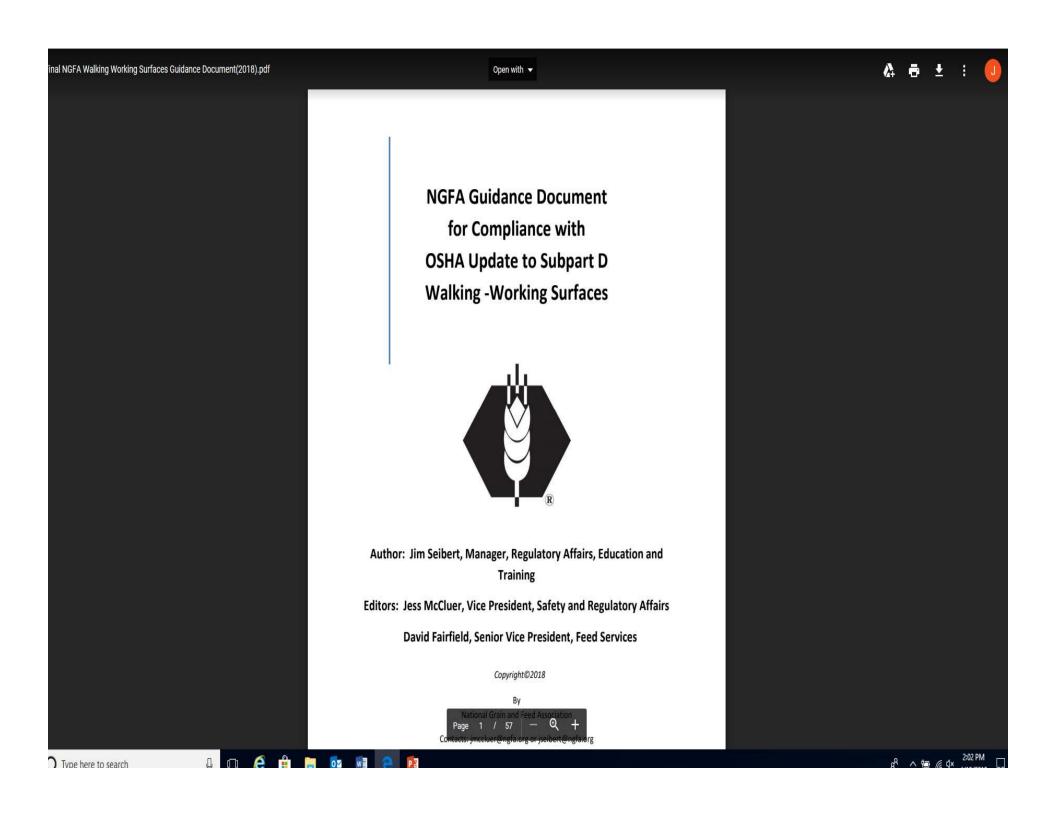
 On May 24, 2010, OSHA issued a proposed rule on fall protection and requested separate comments on whether specific regulations are needed to address falls from rolling stock and commercial motor vehicles. In the proposal, the agency states that the 1996 Miles Memo "...did not result in clear direction to the public or to OSHA's field staff."

Walking Working Surfaces (cont.)

- In our comments, we highlighted the effectiveness of the Miles Memo and opposed any additional regulatory burden that would have an operational and economic impact on industry.
- In the final rule, the Agency states that since it did not propose any specific fall protection requirements in the 2010 proposal then it will not include any in this final rule.
- Under the Obama Administration OSHA has completely ignored the 1996 Miles Memo and instead has been citing facilities for not conducting a proper PPE hazard assessment when allowing workers to be on top of rolling stock without fall protection.

Walking Working Surfaces (cont.)

 In the final rule, OSHA will continue to regulate combustible dust hazards on walking working surfaces. Even though the term "combustible dust" was not included in the final language under section 1910.22(a)(1), the Agency contends in the preamble that they continue to "interpret" combustible dust as a walking working surfaces hazard since excessive accumulation is a slip, trip or fall hazard.



FSMA Update

Food Safety Modernization Act of 2011

- Signed into law on Jan. 4, 2011
- Amended Federal Food Drug and Cosmetic Act and greatly expanded FDA's authority to regulate the U.S. food supply
 - Mandated that FDA create a <u>new prevention-based regulatory system</u> to ensure the safety

of food products



Scope of FSMA

- U.S. Law: Feed (Animal Food) is Food
 - Section 201(f) Federal Food, Drug and Cosmetic Act:

"The term "food" means (1) articles used for food or drink for man <u>or other animals</u>, (2) chewing gum, and (3) articles used for components of any such article."

 Definition of food includes grains, oilseeds, animal feed, feed ingredients, pet food

FSMA Rules and Compliance Dates

Final Rule	Compliance Date - Large Business	Compliance Date - Small Business	Compliance Date - Very Small Business	
CGMP Preventive Controls - Human Food	Sept. 19, 2016	Sept. 18, 2017	Sept. 17, 2018	
CGMP Preventive Controls - Animal Food	Sept. 19, 2016 (CGMP) Sept. 18, 2017 (PCs)	Sept. 18, 2017 (CGMP) Sept. 17, 2018 (PCs)	Sept. 17, 2018 (CGMP) Sept. 17, 2019 (PCs)	
Foreign Supplier Verification Program	May 30, 2017	Not applicable	Not applicable	
Third Party Accreditation	Requirements go into effect after FDA publishes Model Accreditation Standards – Issued Dec. 6, 2016			
Sanitary Transportation - Human and Animal Food	April 6, 2017	April 6, 2018	Not applicable	
Food Defense/ Intentional Adulteration	July 26, 2019	July 26, 2020	July 26, 2021	



Applicability of FSMA Rules

- Who's In, Who's Out ...
 - Generally, FSMA rules apply to facilities required to register as a "food facility" with FDA under Bioterrorism Act requirements
 - Exception: Foreign Supplier Verification Programs;
 Carriers under rule for Sanitary Transportation of Human and Animal Food
 - Farms (operations meeting FDA's definition of a "farm") are exempt
 - Individual rules also specify certain exemptions and modified requirements

Applicability of FSMA Rules

1-2. Human Food and Animal Food CGMP and Preventive Controls

- Facilities "<u>solely engaged</u>" in storing grain and oilseeds [e.g., a facility consisting <u>only</u> of a grain elevator] <u>exempt</u> from both rules
 - Different treatment for elevators handling "fruits" [e.g., lentils, kidney beans, pinto beans, lima beans, coffee beans, cocoa beans, peas, peanuts, tree nuts, seeds for direct consumption]
 - Elevators solely engaged in storing, handling such "fruits" exempt from CGMP requirements, but <u>not</u> exempt from the preventive controls
 - Grain elevator exemptions apply <u>only</u> when storing grain/oilseeds is the <u>only</u> food-related operation subject to FSMA that occurs within the <u>entire</u> facility
- Grain millers, processors potentially covered by both human, animal food rules
- Animal feed and pet food facilities covered by animal food rule

Congress of the United States Washington, DC 20515

September 28, 2018

Stephen Ostroff, M.D. Deputy Commissioner for Foods and Veterinary Medicine Office of Foods and Veterinary Medicine Food and Drug Administration 10903 New Hampshire Ave White Oak Building 1 Silver Spring, MD 20993

Dear Dr. Ostroff,

We write to express strong concern over the approach the U.S. Food and Drug Administration (FDA) has used in implementing regulations under the Food Safety Modernization Act (FSMA) pertaining to the agency's classification of pulse raw agricultural commodities (such as dry peas, lentils, chick peas and dry beans) as "fruits or vegetables."

FDA's FSMA-related human food and animal food rules currently include exemption provisions for facilities that store and distribute raw agricultural commodities that FDA classifies as "grain," because they pose an extremely low risk to human and animal health. However, the same exemptions do not apply when FDA classifies a raw agricultural commodity as a "fruit or vegetable."

By diverging from a common-sense reading of the statute, FDA has veered away from the science, and risk-based approach to food safety that is the very foundation of FSMA, and in so doing imposed significant and unnecessary compliance costs and created irrational regulatory disparities among operations within the industry. We urge FDA to act expeditiously and revise its current position.

Being required to comply with the human and animal food rules of FSMA is of substantial consequence and cost. The National Grain and Feed Association's economic analysis of these requirements estimates actual annualized costs of compliance to be \$57,000 to \$127,000 per facility - which would be several orders of magnitude greater if FDA's current interpretations

Currently, FDA defines "grains" to mean the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion).

Contrary to FDA's current classification, pulses indeed are the edible hard seeds of plants from the legume family, which makes their origin consistent with the terminology used by FDA to

define "grains." In addition, pulses are processed prior to consumption, which makes their use consistent with the terminology used by FDA to define "grains."

Finally, the absence of incidents of foodborne illness associated with holding (storage) of pulses does not warrant additional FDA requirements for such commodities. For these reasons, FDA should classify pulse raw agricultural commodities (e.g., dry peas, lentils, chick peas, and dry beans) as "grains."

Therefore, we urge FDA to act quickly to reclassify pulses as "grains" under its FSMA rules for human and animal food. The current interpretations by FDA are contrary to a science- and riskbased approach to protect public and animal health.

Sincerely,

Member of Congress

Collin C. Peterson Member of Congress

Mike Bishop Member of Congress

Kristi Noem Member of Congress Member of Congress

Cathy McMorris Rodgers Member of Congress

Member of Congress

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Applicability of FSMA Rules

3. Foreign Supplier Verification Programs

- Generally applies to importers of grains and oilseeds, feed ingredients, human food. Covered importers are to:
 - Analyze the hazards for the foods they import
 - Evaluate the performance of their potential foreign suppliers and the risk posed by the foods to be imported
 - Determine and conduct appropriate foreign supplier verification activities, such as onsite auditing of foreign suppliers, sampling and testing, and review of supplier food safety records
- Current FDA Policy: FDA will use enforcement discretion for:
 - Importers of grain RACs that are solely engaged in the storage of grain intended for further distribution or processing (e.g., grain elevators)
 - Importers of grain that do not take physical possession of the grain they import but instead arrange for the delivery of the grain to others for storage, packing or manufacturing/processing (e.g., brokers)

Applicability of FSMA Rules

4. Accreditation of Third-Party Auditors

 Applies to foreign food in certain circumstances; i.e., high-risk designation by FDA or participation in Voluntary Qualified Importer Program (VQIP)

5. Sanitary Transportation of Human and Animal Food

Applies to grain and feed facilities; truck and rail transportation

6. Food Defense/Intentional Adulteration

 Applies to human food, animal food exempt; grain elevators exempt

21 CFR PART 507 – Current Good Manufacturing Practice, Hazard Analysis, and Risk–Based Preventive Controls

- Subpart A: General Provisions
- Subpart B: Current Good Manufacturing Practice
- Subpart C: Hazard Analysis and Risk-Based Preventive Controls
- Subpart D: Withdrawal of a Qualified Facility Exemption
- Subpart E: Supply-Chain Program
- Subpart F: Requirements Applying to Records That Must Be Established and Maintained



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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 11, 16, 117, et al.

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; Final Rule

21 CFR PART 507 – Current Good Manufacturing Practice

- FSMA CGMPs Baseline conditions and practices that FDA believes are needed to ensure animal food safety
 - FDA Animal Food Guidance:
 - https://www.fda.gov/downloads/AnimalV eterinary/GuidanceComplianceEnforceme nt/GuidanceforIndustry/UCM499200.pdf

21 CFR PART 507 – Preventive Controls

- A written food safety plan is required
- Hazard evaluation is the cornerstone of the PC requirements
 - Assess the severity of the illness or injury to man and/or animals if the hazard were to occur
 - Assess the probability that the hazard will occur <u>in</u> the absence of preventive controls

RISK = Severity x Probability

21 CFR PART 507 – Preventive Controls

- FDA Draft Animal Food Preventive Controls Guidance:
 - <u>Draft Guidance for Industry #245: Hazard Analysis</u> and Risk-Based Preventive Controls for Food for <u>Animals</u>
 - <u>Draft Guidance for Industry #246: Hazard Analysis</u> and Risk-Based Preventive Controls for Food for <u>Animals: Supply-Chain Program</u>

Inspections – Inspections – Inspections

- FDA initial enforcement and compliance approach: "Educate Before and While We Regulate"
- Small "cadre" of federal and state investigators trained to perform initial inspections
- Issuance of FDA Form 483's (Notice of Observations), if any, are made in consultation with FDA headquarters

PART 507 Animal Food Inspections

- CGMP inspections began first quarter 2017 for "large businesses" (500 employees or more company wide)
- About 300 CGMP inspections conducted during F'18 (ended Sept. 30, 2018)
- Routine PC inspections to begin Oct. 2018 at "large businesses"
 - Expect inspections to last 3-4 days
- Routine PC inspections to begin Oct. 2019 at "small businesses" (less than 500 employees company wide)





Menu 🔻

FSPCA Preventive Controls for Animal Food

Training

FSPCA Preventive Controls for Animal Food Course
FSPCA Preventive Controls for Animal Food Lead Instructor Training
FSPCA Preventive Controls for Animal Food Course AND Lead Instructor Training
Selection Criteria for Lead Instructor
Animal Food Lead Instructor Course Schedule

FSPCA PREVENTIVE CONTROLS FOR ANIMAL FOOD

COURSE DESCRIPTION

The Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Animal Food regulation (referred to as the Preventive Controls for Animal Food regulation) is intended to ensure safe manufacturing/processing, packing and holding of food products for human consumption in the United States. The regulation requires that certain activities must be completed by a "preventive controls qualified individual" who has "successfully completed training in the development and application of risk-based preventive controls, or is otherwise qualified through job experience to develop and apply a food safety system". This course

« FSPCA HOME

- + THE ALLIANCE
- COURSES
 - FOREIGN SUPPLIER VERIFICATION PROGRAMS (FSVP)
 - INTENTIONAL ADULTERATION
 - FSPCA PREVENTIVE CONTROLS FOR ANIMAL FOOD
 - FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD
- LEAD INSTRUCTOR
- TECHNICAL ASSISTANCE NETWORK (TAN) DATABASE
- + RESOURCES
- + FAO
- INTERNATIONAL
- INTENTIONAL ADULTERATION
- + COMMITTEES
- + NEWS
- RETURN TO IFSH

21 CFR PART 1 – Sanitary Transportation of Human and Animal Food

Subpart O

- **General Provisions** 1.900 Who is subject?
- Vehicles and Transportation Equipment 1.906 What requirements apply to vehicles and transportation equipment?
- Transportation Operations 1.908 What requirements apply to transportation operations?
- Training 1.910 What training requirements apply to carriers engaged in transportation operations?
- Records 1.912 What record retention and other records requirements apply to shippers, receivers, loaders, and carriers engaged in transportation operations?
- Waivers



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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1 and 11

Sanitary Transportation of Human and Animal Food; Final Rule



21 CFR PART 1 – Sanitary Transportation of Human and Animal Food

- Generally applies to:
 - Intrastate and interstate food transportation, including grain and feed
 - Truck and rail transportation operations, not waterborne or air
- "Shippers" bear most of the regulatory burden under the rule
- Compliance dates
 - "Large Businesses" April 6, 2017: Businesses that are not "small" and is not otherwise excluded from coverage
 - "Small Businesses" April 6, 2018: Businesses (other than motor carriers that are not also shippers and/or receivers) employing fewer than 500 persons and motor carriers having less than \$27.5 million in annual receipts
- Inspections: Routine inspections to begin fall 2018

Requirements for Shippers

- Shippers must specify in writing to the carrier and, when necessary, to the loader, all sanitary specifications necessary for the carrier's vehicle and transportation equipment pursuant to the product to be transported
 - One time notification is sufficient, unless specifications change
- Shippers must develop and implement written procedures to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition
- Shippers of food transported in bulk must develop and implement written procedures to ensure that a previous cargo does not make the food unsafe
 - <u>NO</u> requirement for "Shipper" or "Loader" to know last load hauled <u>or</u> cleanout information, <u>but</u> "Shipper" needs to establish adequate written procedures to ensure a prior load does not cause food to become unsafe during transportation

More Information/Guidance

- NGFA FDA/FSMA Guidance
 - http://feed.ngfa.org/
- FDA
 - http://www.fda.gov/Food/GuidanceRegulation/FSMA

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NGFA Guidance on FDA Regulations Applicable to Grain, Feed and Processing Industry

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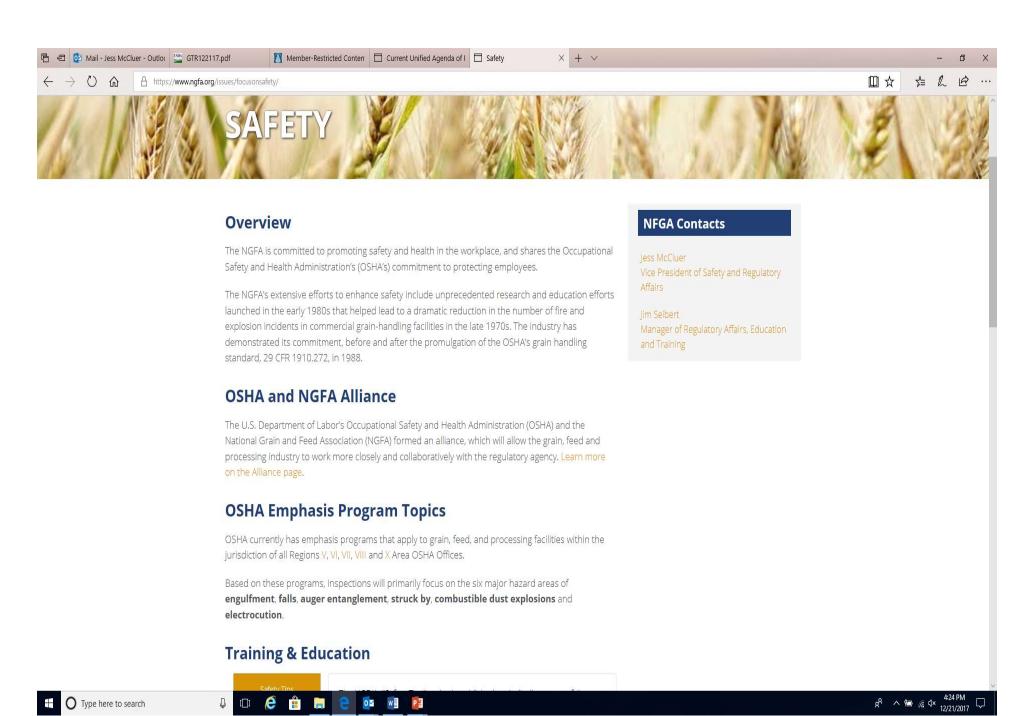


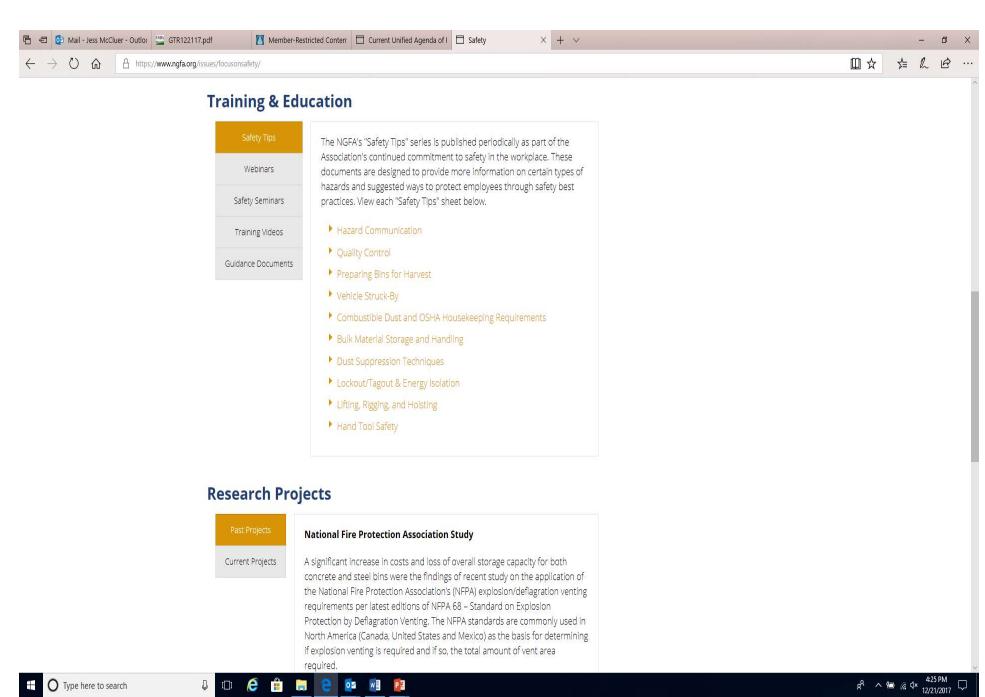






Education and Training









NGFA Safety Tips: Preparing Bins for Harvest

... Committed to promoting safety and health in the workplace...

Suggested Tasks Prior to and During Bin Entry

Incidents potentially can occur when a worker stands next to or underneath bridged or cliffed grain inside of a grain bin.

Therefore, as the fall harvest draws near, here are a few suggestions to prepare for a proper bin entry, if one is absolutely necessary, so as to prevent incidents such as entrapments from occurring.

Remember: do not enter a grain storage unit unless absolutely necessary.

If it is necessary to have employees enter a bin, silo or tank, commercial facilities are to follow the applicable practices, including the issuing of a bin entry

permit, found in OSHA's grain handling facilities standard [29 CFR 1910.272(g)], which took effect in 1988, to help minimize the risk.

Once it has been determined that a certain task must be completed inside the bin, then the facility can begin the pre-task planning and permitting process.

Pre-task planning process: A sit-down with employees to identify roles and responsibilities during the task and identify:

- equipment to be locked out
- · forms of communication
- · equipment needed for the work
- · emergency action plan



Before the bin entry process, train employees and supervisors in the following roles and responsibilities: Entry Supervisor; Attendant; and Entrant.

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NGFA Safety Program

- The NGFA is committed to promoting safety and health in the workplace, and shares the Occupational Safety and Health Administration's (OSHA's) commitment to protecting employees.
- The NGFA's extensive efforts to enhance safety include unprecedented research and education efforts launched in the early 1980s that helped lead to a dramatic reduction in the number of fire and explosion incidents in commercial grainhandling facilities.
- Each year, NGFA jointly sponsors regional safety seminars with affiliated state and regional grain and feed associations. The one-day conferences focus on keeping grain handling employees physically safe.

NGFA Education and Training (cont.)

NGFA Regional Safety Seminars

Conducted with our Regional/State Affiliates and is funded through the generosity of the National Grain and Feed Foundation.

- Kansas Grain and Feed Association, Jan. 15 in Manhattan, Kan.
- Nebraska Grain and Feed Association, Feb. 7 in Kearney, Neb.
- Texas Grain Elevator Association, Feb. 14 in Amarillo, Tex.
- North Dakota Grain Dealers Association and the Minnesota Grain and Feed Association, March 27 in Fargo, N.D.; and
- Pacific Northwest Grain and Feed Association, April 25 in Spokane, Wash.
- Established in 1965, the National Grain and Feed Foundation supports
 public education and research projects that benefit the grain, feed and
 processing industry, enhance the industry's presence to the public, and
 positions it for future growth. The Foundation is funded entirely by
 voluntary corporate and individual contributions. As a 501(c)(3) charitable
 organization, contributions to the Foundation are tax deductible.

Thank You

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