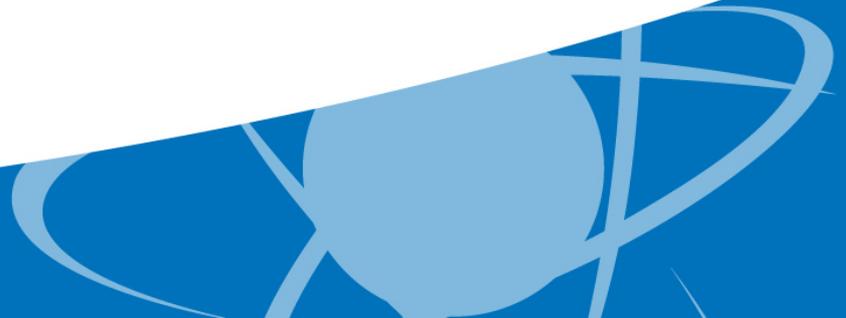


# **Presentation to the Drug Testing Advisory Board (HHS/SAMHSA)**

## **Operating Experience in 2018 and Policy Considerations**

10 CFR Part 26, Fitness-for-Duty Programs  
*"A Direct Contribution to Safety and Security"*

***June 11, 2019***



## Disclaimer

***The information in this presentation is provided as a public service and solely for informational purposes and is not, nor should be deemed as, an official NRC position, opinion or guidance, or "a written interpretation by the General Counsel" under 10 CFR 26.7, on any matter to which the information may relate. The opinions, representations, positions, interpretations, guidance or recommendations which may be expressed by the NRC technical staff during this presentation or responding to an inquiry are solely the NRC technical staff's and do not necessarily represent the same for the NRC. Accordingly, the fact that the information was obtained through the NRC technical staff will not have a precedential effect in any legal or regulatory proceeding.***

# Discussion Topics

- Fitness-for-Duty (FFD) Program Objective
- Individuals covered by the FFD Program
- Assuring Safety and Security through a Defense-in-Depth Strategy
- Industry Activities/Initiatives
- FFD Performance Data and Insights



# FFD Program Objective

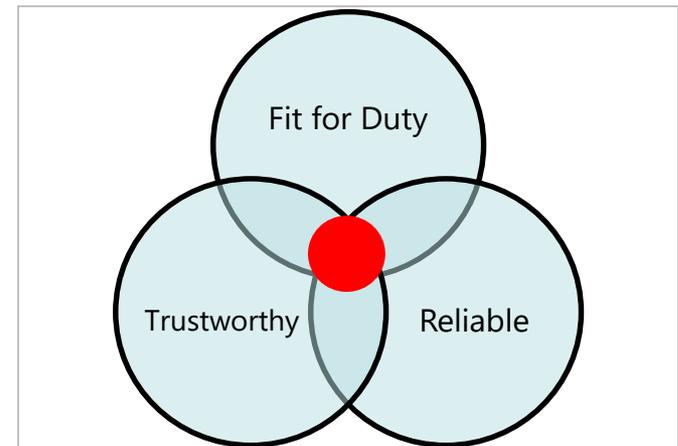
Provide reasonable assurance that nuclear power plant personnel are trustworthy, reliable, and not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform assigned duties or be afforded unescorted access to the protected areas of nuclear power plants, sensitive information, or strategic special nuclear material (SSNM).

An FFD program developed under 10 CFR Part 26 is intended to create an environment which is free of drugs and alcohol, and the effects of such substances.



# Individuals Covered by the FFD Program

- Security Officers
- Control Room Operators
- Maintenance & Surveillance (craft & supervisors)
- Health Physics, Chemistry, & Emergency Response
- Construct or Direct the Construction of Reactor Plants
- All other persons who have unescorted access
- FFD Program Personnel\*



\* FFD Program Personnel include the managers, technicians, collectors, Medical Review Officers, and Substance Abuse Experts who implement the program

# Assuring Safety and Security through a Defense-in-Depth Strategy

- People
  - ❑ Education, experience, training, qualification, etc.
  - ❑ Drug and Alcohol Testing (pre-access, random, for cause, follow-up, and post-event)
  - ❑ Behavioral Observation
  - ❑ Fatigue Management
- Access Requirements (e.g., background checks, fingerprinting, psychological testing)
- Physical Protection (e.g., vehicle barriers, blast walls, blast resistant enclosures, etc.)
- Detection (e.g., cameras, infra-red, motion, explosive vapors, x-ray, etc.)
- Programs for Insider Mitigation, Cyber Protection, and Information Controls



# Items of Interest

- Oral fluid testing
- Expanded panel testing
- Marijuana Rescheduling
- Auditing of HHS-certified laboratories
- Blind performance testing
- 10 CFR Part 26, "Fitness for Duty Programs," staff-proposed rulemaking

# Operating Experience in 2018

# Overall Industry Performance, 2018 [Draft]

**145,798**    **Individuals drug & alcohol tested**    (*down ~2% from 2017*)

**1,185**    **Individuals positive for drug(s), alcohol, or refused a test**

69.8% identified at pre-access testing    (64.3% in 2017)

17.7% identified at random testing    (22.5% in 2017)

**0.81%**    **Industry overall positive rate**    (*0.78% in 2017*)

0.28% LE positive rate    (*0.24% in 2017*)

1.06% C/V positive rate    (*1.04% in 2017*)

**0.37%**    **Industry random positive rate**    (*0.44% in 2017*)

0.17% LE positive rate    (*0.14% in 2017*)

0.68% C/V positive rate    (*0.89% in 2017*)

- LE = licensee employee; C/V = contractor/vendor
- All results in this presentation are MRO verified

# Results by Test and Employment Categories, 2018

**[DRAFT]**

Test Category	Licensee Employees			Contractor/Vendors (C/Vs)			Total			% of Total Positives
	Tested	Positive	Percent Positive	Tested	Positive	Percent Positive	Tested	Positive	Percent Positive	
Pre-Access	8,291	36	0.43%	72,934	791	1.08%	81,225	827	1.02%	69.8%
Random	34,676	59	0.17%	22,221	151	0.68%	56,897	210	0.37%	17.7%
For Cause	132	11	8.33%	302	65	21.52%	434	76	17.51%	6.4%
Post-Event	148	-	0.00%	348	2	0.57%	496	2	0.40%	0.2%
Follow-up	2,859	21	0.73%	3,887	49	1.26%	6,746	70	1.04%	5.9%
<b>Total</b>	<b>46,106</b>	<b>127</b>	<b>0.28%</b>	<b>99,692</b>	<b>1,058</b>	<b>1.06%</b>	<b>145,798</b>	<b>1,185</b>	<b>0.81%</b>	<b>100.0%</b>

## Where were the most tests conducted in 2018 (>90% of tests)?

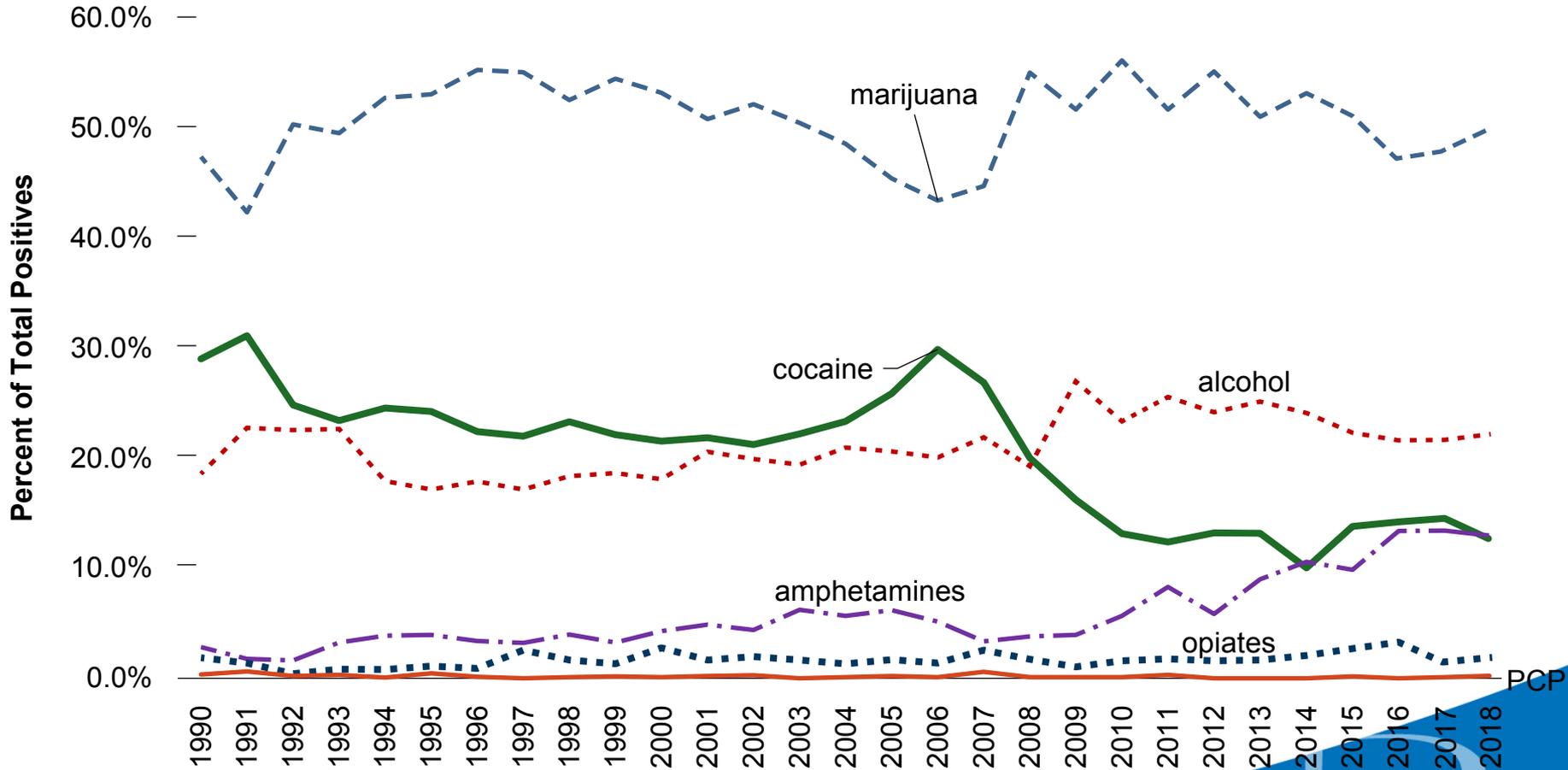
Licensee Employees		Contractor/Vendors	
Pre-access	18.0%	Pre-access	73.2%
Random	75.2%	Random	22.3%
Follow-up	6.2%	Follow-up	3.9%
<hr/>		<hr/>	
99.4%		99.3%	

## Where were most drug and alcohol testing violations identified in 2018 (>90% of positives)?

Licensee Employees		Contractor/Vendors	
Pre Access	28.3%	Pre-access	74.8%
Random	46.5%	Random	14.3%
For Cause	8.7%	For Cause	6.1%
Follow-up	16.5%		95.2%
<hr/>		<hr/>	
100.0%			

# Detection Trends 1990-2018, NRC Testing Panel Percentage of Total Positives by Substance Tested

[Draft]



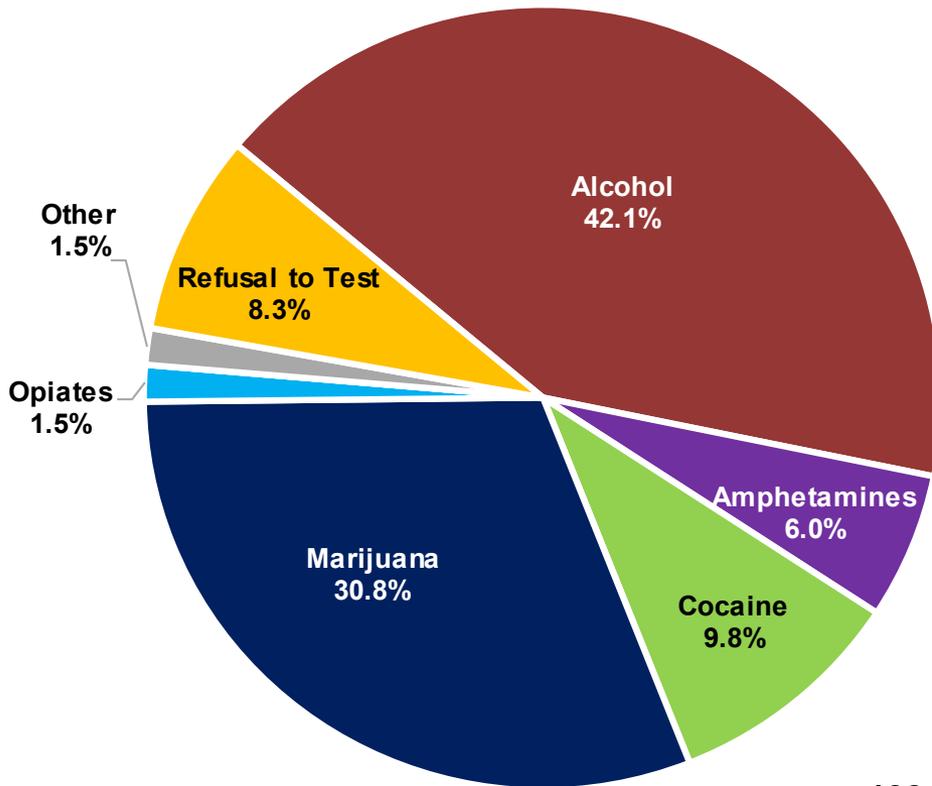
Since at least 2014, this chart under reports the substances used by individuals with a drug testing violation. This is because of the high number of subversion attempts each year, and because in at least 60% of these subversion attempts, no specimens were tested.

# Results by Employment Category, 2018

[DRAFT]

## Licensee Employees

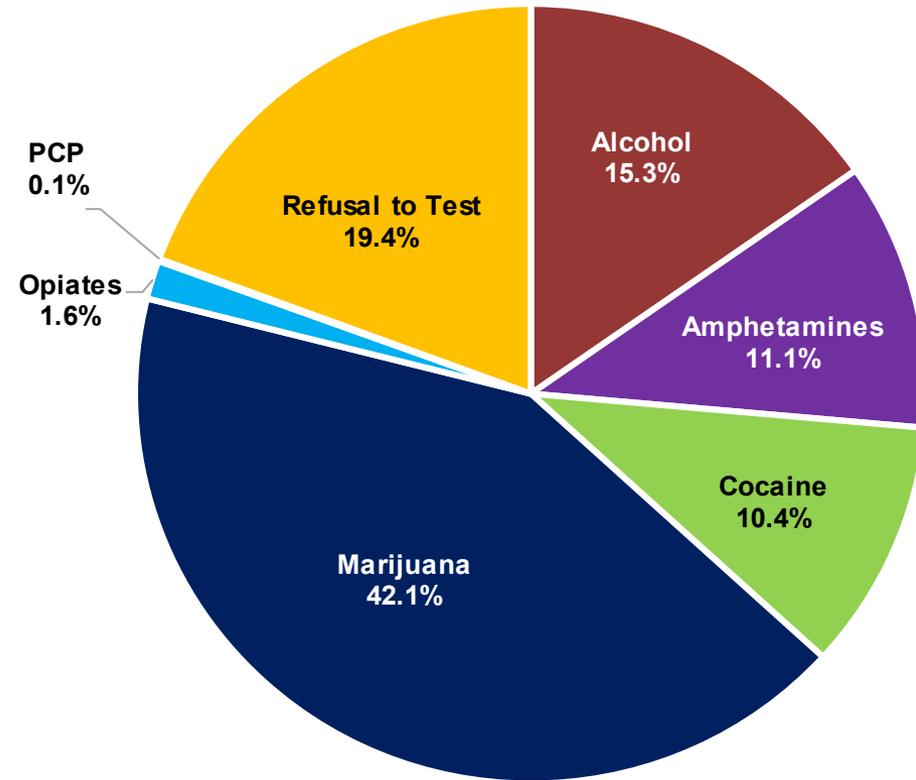
(46,106 tested; 127 individuals positive)



n = 133

## Contractors/Vendors

(99,692 tested; 1,058 individuals positive)



n = 1,125

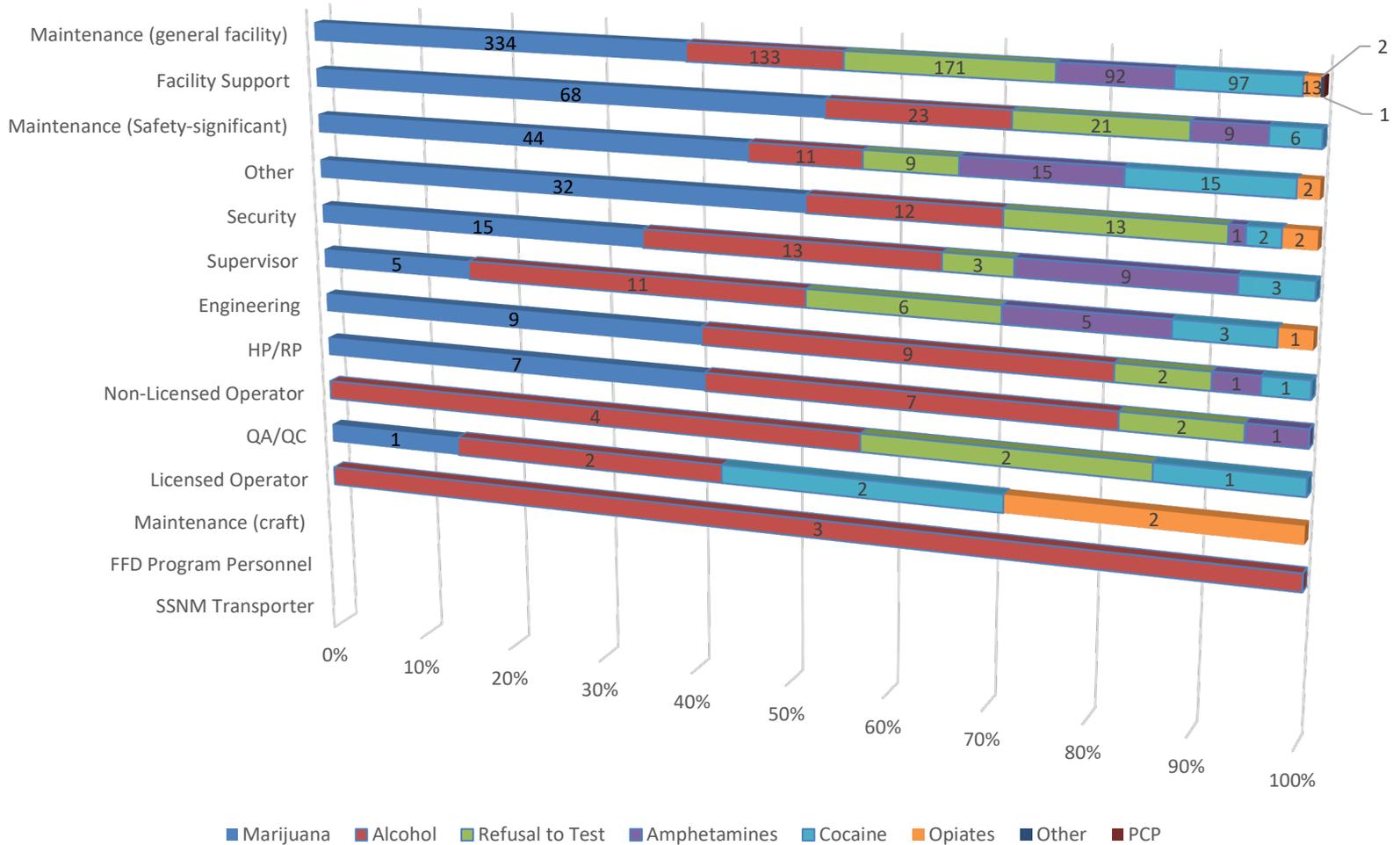
# Substances Detected by Labor Category, 2018

[DRAFT]

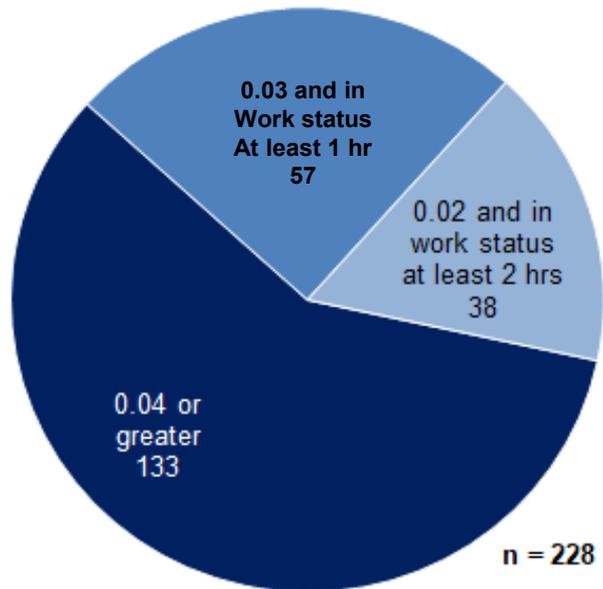
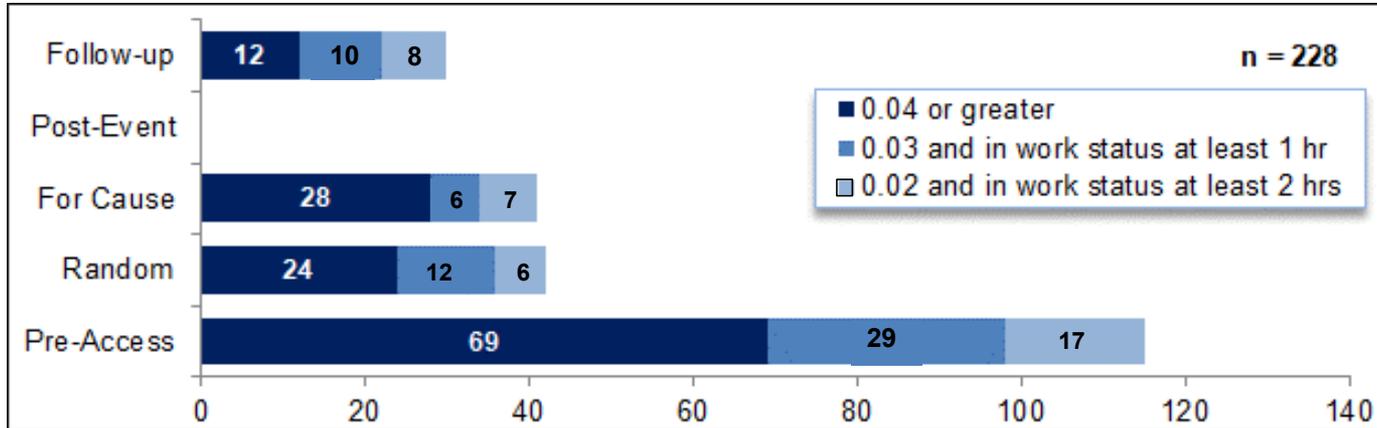


United States Nuclear Regulatory Commission  
Protecting People and the Environment

Substances Detected by Labor Category, 2018



# Measuring Effectiveness of Lower Cutoff Levels for Alcohol, 2018 [DRAFT]



- 42% of alcohol positives (BAC < 0.04) are the result of time dependent cutoff levels, which have been required since 2008
- 32-60% of positive alcohol results per test category were BAC < 0.04

# Testing for Additional Substances

A licensee or other entity can:

- Expand the drug testing panel to account for local drug use trends that may affect the workforce -- 10 CFR 26.31(d)(1)(i)
- Test for any substance(s) that an individual is suspected of having abused, when performing follow-up, for cause, and post-event tests -- 10 CFR 26.31(d)(1)(ii)

A forensic toxicologist must first review and validate the testing assays and cutoff levels used by the HHS-certified laboratory, unless already in use in the current HHS Guidelines -- 10 CFR 26.31(d)(1)(i)(D)

# Testing for Additional Substances

In 2018, eight facilities conducted expanded panel testing in two ways:

- Tested all specimens collected for barbiturates, benzodiazepines, methadone, and propoxyphene (four facilities, one FFD program)
- Tested follow-up, for-cause, and post-event testing specimens for benzodiazepines (i.e., alprazolam, clonazepam, and lorazepam), and hydromorphone, hydrocodone, and oxycodone (four facilities, one FFD program)

Typically, a few facilities each year conduct testing for one or more additional substances when ordered by the MRO (e.g., for-cause or follow-up test).

# Additional Substance Test Results, 2011-2018

**[Draft]**

Substance	2011	2012	2013	2014	2015	2016	2017	2018	Total
Benzodiazepines	1	2	1	1	1	1			7
Buprenorphine		1			1		1		3
Fentanyl					1				1
Hydrocodone				1	1		1		3
Hydromorphone				1			1		2
Methadone	1	1	1	1					4
Norbuprenorphine							1		1
Oxycodone		1	1	1	1			1	5
Oxymorphone		1	1	1	1			1	5
Propoxyphene				1					1
Tramadol					1				1
<b>Total</b>	<b>2</b>	<b>6</b>	<b>4</b>	<b>7</b>	<b>7</b>	<b>1</b>	<b>4</b>	<b>2</b>	<b>33</b>

The 33 test results in this table reflect positive results for 25 individuals (see next slide). That is, some individuals test positive for more one of substance in the same testing event

# Additional Substance Results by Test Category (2011-2018) [Draft]

Substances	Pre-Access	Random	For Cause	Follow-up	Total
Benzodiazepines		1	1	2	4
Benzodiazepines; Amphetamine; Methamphetamine			2		2
Benzodiazepines; Amphetamine; Methamphetamine; Marijuana			1		1
Benzodiazepines; Cocaine			1		1
Benzodiazepines; Marijuana;			1		1
Benzodiazepines; Methadone; Marijuana	1				1
Buprenorphine	1				1
Buprenorphine; Norbuprenorphine			1		1
Hydrocodone			1		1
Hydrocodone; Hydromorphone; Amphetamine; Marijuana	1				1
Hydrocodone; Hydromorphone; Amphetamine; Methamphetamine			1		1
Hydrocodone; Oxycodone; Oxymorphone			1		1
Methadone		1	1		2
Oxycodone; Oxymorphone			3		3
Oxycodone; Oxymorphone; Fentanyl			1		1
Propoxyphene; Marijuana	1				1
Tramadol			2		2
<b>Total</b>	<b>4</b>	<b>2</b>	<b>17</b>	<b>2</b>	<b>25</b>

- 68% of individuals (17 of 25) tested positive on for cause testing
- 36% of individuals (9 of 25) also tested positive for a substance in the NRC-required testing panel

# Subversion Attempt Trends [Draft]

**Subversion attempt** is any willful act or attempted act to cheat on a required test (e.g., refuse to provide a specimen, alter a specimen with an adulterant, provide a specimen that is not from the donor's body)

**Sanction for a subversion attempt** is a permanent denial of unescorted access (10 CFR 26.75)

## Subversion Attempt Trends (last 5 years)

- 2014 – 187 subversions (21.2% of drug testing violations)
- 2015 – 232 subversions (21.2% of drug testing violations)
- 2016 – 305 subversions (32.4% of drug testing violations)
- 2017 – 301 subversions (33.5% of drug testing violations)
- 2018 – 298 subversions (31.0% of drug testing violations)



## Subversion Attempts in 2018:

- 70.0% facilities with at least 1 subversion attempt (50 of 71)
- 77.5% identified at Pre-Access testing (231 of 298)
- 95.6% by contractor/vendors (285 of 298)

# Subversion Attempts, 2018 (draft)

## Positive Results for Specimens Collected under Direct Observation

Test Result	Pre-Access	Random	For Cause	Follow-up	Total
Marijuana	39	5	2	1	47
Cocaine	3		1	2	6
Amphetamine; Methamphetamine	3				3
Cocaine; Marijuana	3				3
Amphetamine; Marijuana	1	1			2
Amphetamine; Methamphetamine; Marijuana	2				2
Amphetamine	1				1
Amphetamine; Methamphetamine; Cocaine	1				1
Cocaine; 6-AM; Codeine; Morphine; PCP	1				1
Methamphetamine		1			1
Morphine			1		1
<b>Total</b>	<b>54</b>	<b>7</b>	<b>4</b>	<b>3</b>	<b>68</b>

- 298 individuals identified as subverting a test in 2018
- 68 provided specimens under direct observation (68/298 = 22.8%)

# Limit of Detection (LOD) Testing of Dilute Specimens

10 CFR 26.163(a)(2) permits a licensee to require the HHS-certified laboratory to conduct confirmatory drug testing to LOD for a substance if:

1. Validity test result = Dilute, and
2. Immunoassay response is equal to or greater than 50% of cutoff

- 66 of 71 sites maintained the optional LOD testing policy in 2018
- 422 dilute specimens were tested to LOD in 2018, with 17 individuals testing positive
- 35% sites (23 of 66) conducted at least one 26.163(a)(2) test in 2018

# LOD Testing of Dilute Specimens (2010-2018) – 10 CFR 26.163(a)(2)

	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total
<b>Pre-Access</b>										
Marijuana	15		6	8	6	2	6	3	11	57
Cocaine	2						2	2		6
Amphetamine; Methamphetamine					1		1		1	3
Amphetamine; Marijuana					1					1
Cocaine; Marijuana							1			1
<b>Total</b>	<b>17</b>		<b>6</b>	<b>8</b>	<b>8</b>	<b>2</b>	<b>10</b>	<b>5</b>	<b>12</b>	<b>68</b>
<b>Random</b>										
Marijuana	1		1					1	3	6
Cocaine		1			1	1			1	4
Methamphetamine									1	1
<b>Total</b>	<b>1</b>	<b>1</b>	<b>1</b>		<b>1</b>	<b>1</b>		<b>1</b>	<b>5</b>	<b>11</b>
<b>For Cause</b>										
Marijuana					1					1
<b>Total</b>										<b>1</b>
<b>Post-Event</b>										
Marijuana		1								1
Follow-up										
Cocaine	1									1
<b>Total</b>	<b>1</b>									<b>1</b>
<b>Total</b>	<b>19</b>	<b>2</b>	<b>7</b>	<b>8</b>	<b>10</b>	<b>3</b>	<b>10</b>	<b>6</b>	<b>17</b>	<b>82</b>

# HHS-Certified Laboratory Testing Errors, 2018

## 10 CFR 26.719 (30-day event reports)

- A blind performance test sample (BPTS) formulated to return an adulterated validity test result (due to low pH) was reported with negative drug test results. The forensic processing technician did not properly aliquot all of the original specimen to the correct sample cup, which caused the incorrect result.
- A donor specimen was reported as “negative dilute.” Two days later, the laboratory updated the result to “negative.” It was determined that the Screening Technician did not load the specimen on the refractometer consistent with the Standard Operating Procedure, which resulted in an incorrect specific gravity value. A second aliquot of the sample consistent with the applicable procedure determined the specimen was not dilute.

# HHS-Certified Laboratory Testing Errors, 2018

## 10 CFR 26.719 (30-day event reports)

- A BPTS formulated to return an adulterated validity test result was submitted for testing. Initial validity testing indicated general oxidants were above normal and required confirmation. However, the laboratory's confirmatory oxidant testing equipment (ion chromatograph instrument) was out of service. The laboratory sent the specimen to a second HHS-certified laboratory for additional adulterant testing, but that laboratory was not the licensee's authorized backup laboratory. That specimen was then sent to the licensee's authorized backup laboratory, but the specimen was empty upon receipt and was reported as invalid.
- A BPTS formulated to test positive for marijuana was reported by the HHS-certified laboratory as negative. The BPTS was a false negative challenge sample formulated at between 130 and 155 percent of the initial testing cutoff concentration for marijuana). The licensee determined the unexpected results were related to the BPTS supplier's preparation and/or preservation of the samples.

# HHS-Certified Laboratory Testing Errors, 2018

## 10 CFR 26.719 (30-day event reports)

- A licensee sent two donor specimens for testing to the HHS-certified laboratory, and both specimens were reported as "rejected for testing" due to the Bottle B specimens being switched. The licensee and the laboratory conducted investigations, with conflicting conclusions reached.
  - The laboratory reported the accessioner identified a switch in the bottle B specimens for the two donors and the accessioner's supervisor verified the bottle switch.
  - The licensee concluded that it was likely that the Bottle B specimens were switched at the laboratory because the licensee only allows for one collection to be performed at a time and that the donor certifies the Bottle A and B specimens and observes the sealing of the specimens in the tamper-evident bag. In addition, in one of the two cases, the specimen was monitored by another member of management that observed the process from beginning to end, including sealing of the tamper evident bag.

# Electronic Reporting

## FFD Program Performance Information



- Meets annual reporting requirements in 10 CFR 26.417(b)(2) and 26.717
- Available since 2009 (100% e-reporting since 2014)
- Provides uniform, robust, and event specific information permitting additional trending and analyses (NRC Summary Reports on industry performance available at: <https://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/performance-reports.html>)
- Reporting forms (PDF forms) available at: [www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/submit-ffd-reports.html](http://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/submit-ffd-reports.html)

### Annual Reporting Form

**FFD Program Performance Data Reporting System**  
**NRC Form 891, Annual Reporting Form for Drug and Alcohol Tests**  
 (EIE General Submission Portal)

APPROVED BY OMB: CLEARANCE NO. 3158-0146 EXPIRES: 11/30/2017  
 Estimated burden per response to comply with this collection request is 114 hours. This form is a voluntary means of reporting the information required under 10 CFR 26.717. The information is required by NRC to obtain on an annual basis site specific fitness-for-duty (FFD) program performance data on drug and alcohol programs from licensees and other entities. Send comments regarding burden estimate to the FOIA, Privacy and Information Collection Branch (15-F53), U.S. Nuclear Regulatory Commission, Washington DC 20555-0001, or by e-mail to [info@nrc.gov](mailto:info@nrc.gov), and to the Desk Officer, Office of Information and Regulatory Affairs, NRC-1020, (3150-0146), Office of Management and Budget, Washington DC 20503. If a means used to impose information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

**1) All fields required unless marked 'optional'**  
**2) Use of Adobe Reader 8 or later is required**  
**3) Mouse over icons for additional information**

Submission Update  Deletion

Unique Reference ID (License Supplied)

Select Facility

Period of Report

Reason for Testing	Total Number of Tests Conducted		Total Number of Positive, Adulterated, Substituted, and Refusal to Test Results
	Licensee Employees	Contractors/Vendors	
Pre-Access	<input type="text"/>	<input type="text"/>	<input type="text"/>
Random	<input type="text"/>	<input type="text"/>	<input type="text"/>
For Cause	<input type="text"/>	<input type="text"/>	<input type="text"/>
Post-Event	<input type="text"/>	<input type="text"/>	<input type="text"/>
Followup	<input type="text"/>	<input type="text"/>	<input type="text"/>
Total (Calculated)	<input type="text"/>	<input type="text"/>	<input type="text"/>

**FFD Program Random Testing Population and Rate**

Average number of licensee employees	Average number of contractors/vendors	Total size of the random testing pool throughout the period (Calculated)	Annual random testing percentage achieved for the testing pool
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

### Single Positive Test Form

**FFD Program Performance Data Reporting System**  
**NRC Form 890, Single Positive Test Form**  
 (EIE General Submission Portal)

APPROVED BY OMB: CLEARANCE NO. 3158-0146 EXPIRES: 11/30/2017  
 Estimated burden per response to comply with this collection request is 30 minutes. This form is a voluntary means of reporting the information required under 10 CFR 26.717. The information is required by NRC to obtain on an annual basis site specific fitness-for-duty (FFD) program performance data on drug and alcohol programs from licensees and other entities. Send comments regarding burden estimate to the FOIA, Privacy and Information Collection Branch (15-F53), U.S. Nuclear Regulatory Commission, Washington DC 20555-0001, or by e-mail to [info@nrc.gov](mailto:info@nrc.gov), and to the Desk Officer, Office of Information and Regulatory Affairs, NRC-1020, (3150-0146), Office of Management and Budget, Washington DC 20503. If a means used to impose information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

**1) All fields required except those marked 'optional'**  
**2) Entries in some fields auto-populate information in other fields**  
**3) Mouse over icons for additional information**  
**4) Use of Adobe Reader 8 or later is required**

Submission Update  Deletion

Unique Reference ID (License Supplied)

Select Facility

Date of Collection (mm/dd/yyyy)

Reason for Testing - 26.717(b)(5)

Employment Type - 26.717(b)(3)  Outage Worker (optional)?

Labor Category - 26.717(b)(3)

Is this a 24-hour reporting event? - 26.719(b)

Was this collection refused? - 26.717(b)(7) & 26.75

Test Results - 26.717(b)(4)  
 Test Type(s) for Result(s) Reported - 26.717(b)(2)

# NRC Fitness for Duty Program Staff



## U.S. Nuclear Regulatory Commission

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