

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

## Operating Experience in 2017

Fitness for Duty Programs – 10 CFR Part 26  
*“A Direct Contribution to Safety and Security”*

***March 20, 2018***



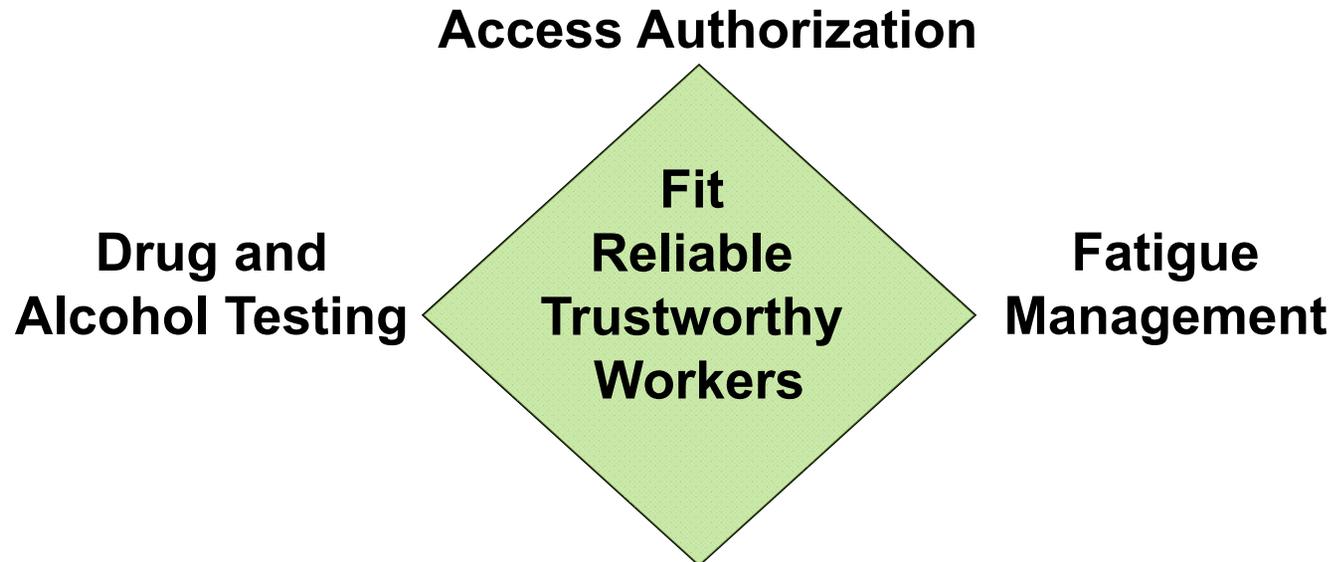
# Discussion Topics

- What is “Fitness for Duty”?
- Program Objective
- Defense-in-Depth Measures
- FFD Performance/Operating Experience
- Laboratory Testing Errors
- FFD Electronic Reporting System



**DISCLAIMER:** Because the annual reporting cycle for 2017 test results closed on February 28, 2018, the NRC has yet to perform the standard quality assurance and quality control process to validate the information received. Therefore, all results for 2017 are DRAFT.

# Fitness for Duty A Strategy of Defense in Depth



**Behavioral  
Observation**



# 10 CFR Part 26

## FFD Program General 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 Part 26 is intended to create an environment which is free of drugs and alcohol, and the effects of such substances.



# FFD Program Defense-in-Depth Elements



1. Integrated with access authorization (i.e., employment screening)
2. Test categories (pre-access, random, for-cause, post-event, followup)
3. Testing
  - Permit lower cutoff levels for drugs
  - Time-dependent alcohol limits for BACs of 0.02 and 0.03 percent
  - 50% annual random testing rate for drugs & alcohol
  - Permit drug testing to Limit of Detection for dilute specimens
  - Permit testing for additional drugs (local use trends, MRO directed)
4. Behavior observation program (both on and offsite)
5. Minimum sanctions for violations & industry tracks in a database
6. Policy & procedures training (initial & annual refresher)
7. 24-hour and 30-day reportable events  
(10 CFR 26.719)

# Overall Industry Performance, 2017 [Draft]



<b>148,357</b>	<b>Individuals drug &amp; alcohol tested</b>	<i>(down 3.6% from 2016)</i>
<b>1,143</b>	<b>Individuals tested positive for a drug, alcohol, or refused a test</b>	
	64.0% identified at pre-access testing	<i>(65.1% in 2016)</i>
	22.7% identified at random testing	<i>(22.3% in 2016)</i>
<b>0.77%</b>	<b>Industry overall positive rate</b>	<i>(0.76% in 2016)</i>
	0.24% LE positive rate	<i>(0.22% in 2016)</i>
	1.01% C/V positive rate	<i>(1.00% in 2016)</i>
<b>0.44%</b>	<b>Industry random positive rate</b>	<i>(0.42% in 2016)</i>
	0.14% LE positive rate	<i>(0.16% in 2016)</i>
	0.84% C/V positive rate	<i>(0.80% in 2016)</i>

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

# Results by Test and Employment Categories, 2017

**[DRAFT]**



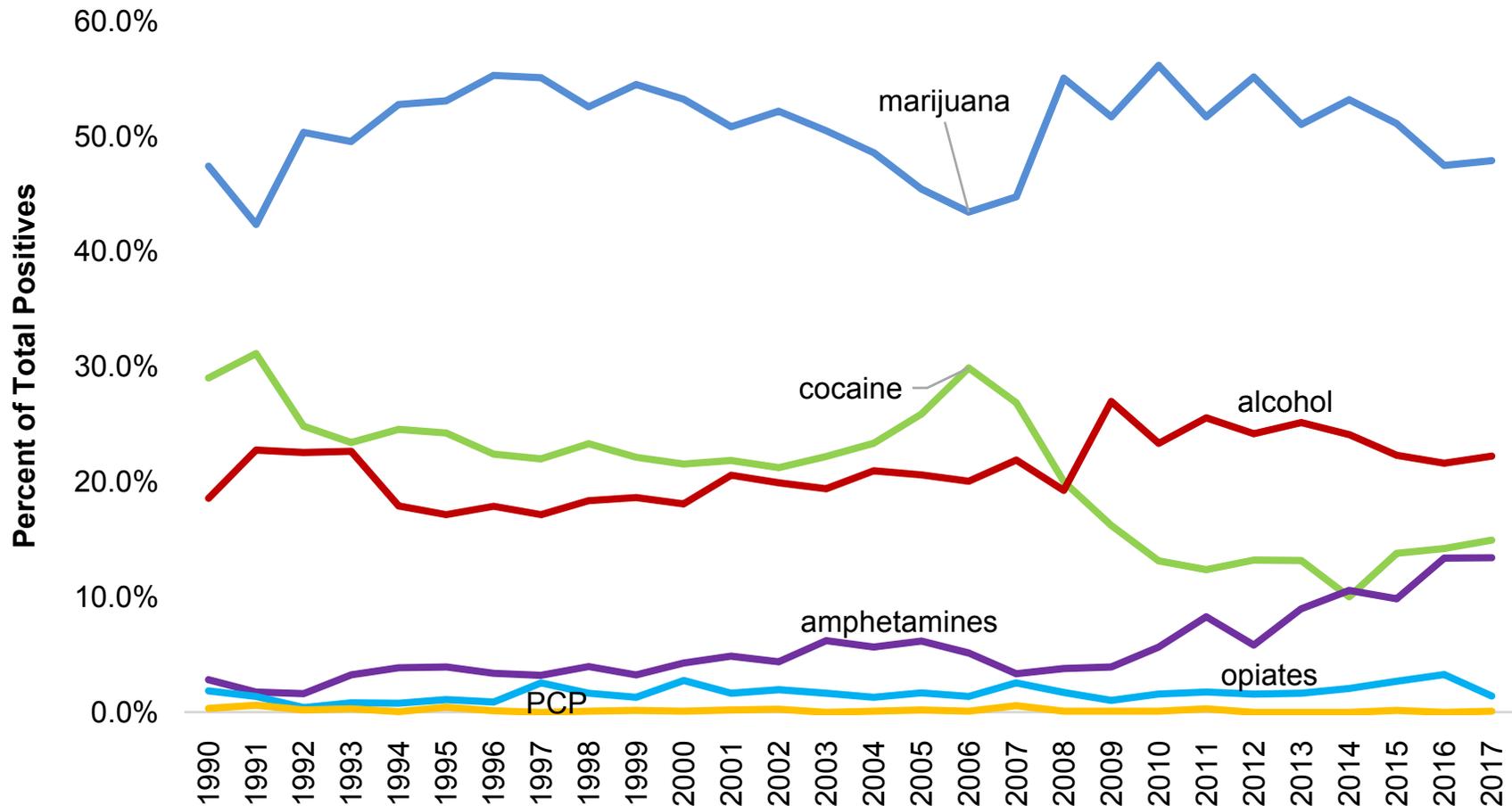
Test Category	Licensee Employees			Contractor/Vendors (CVs)			Total			% of Total Positives
	Tested	Positive	Percent Positive	Tested	Positive	Percent Positive	Tested	Positive	Percent Positive	
Pre-Access	8,513	36	0.42%	71,586	695	0.97%	80,099	731	0.91%	64.0%
Random	34,624	48	0.14%	25,100	212	0.84%	59,724	260	0.44%	22.7%
For Cause	111	14	12.61%	757	64	8.45%	868	78	8.99%	6.8%
Post-Event	136	-	0.00%	492	11	2.24%	628	11	1.75%	1.0%
Followup	3,044	13	0.43%	3,994	50	1.25%	7,038	63	0.90%	5.5%
<b>Total</b>	<b>46,428</b>	<b>111</b>	<b>0.24%</b>	<b>101,929</b>	<b>1,032</b>	<b>1.01%</b>	<b>148,357</b>	<b>1,143</b>	<b>0.77%</b>	<b>100.0%</b>

Where were the most tests conducted in 2017 (>90% of tests)?			
<u>Licensee Employees</u>		<u>Contractor/Vendors</u>	
Pre-access	18.3%	Pre-access	70.2%
Random	74.6%	Random	24.6%
Followup	6.6%	Followup	3.9%
99.5%		98.8%	
Where were most drug and alcohol testing violations identified in 2017 (>90% of positives)?			
<u>Licensee Employees</u>		<u>Contractor/Vendors</u>	
Pre Access	32.4%	Pre-access	67.3%
Random	43.2%	Random	20.5%
For Cause	12.6%	For Cause	6.2%
Followup	11.7%	94.1%	
100.0%			

# Detection Trends – NRC Testing Panel

## Percentage of Total Positives by Substance Tested

[Draft]



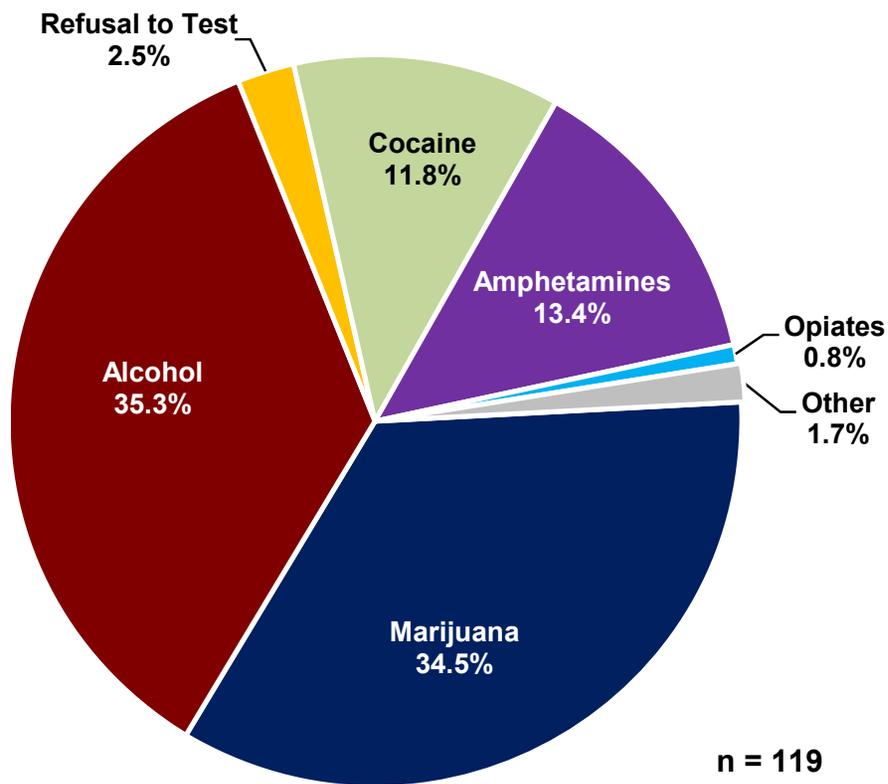
Since at least 2014, this chart under reports the substances used by individuals with a drug testing violation. This is because of the high number of subversion attempts each year, and because in at least 60% of these subversion attempts, no specimens were tested.

# Results by Employment Category, 2017

[DRAFT]

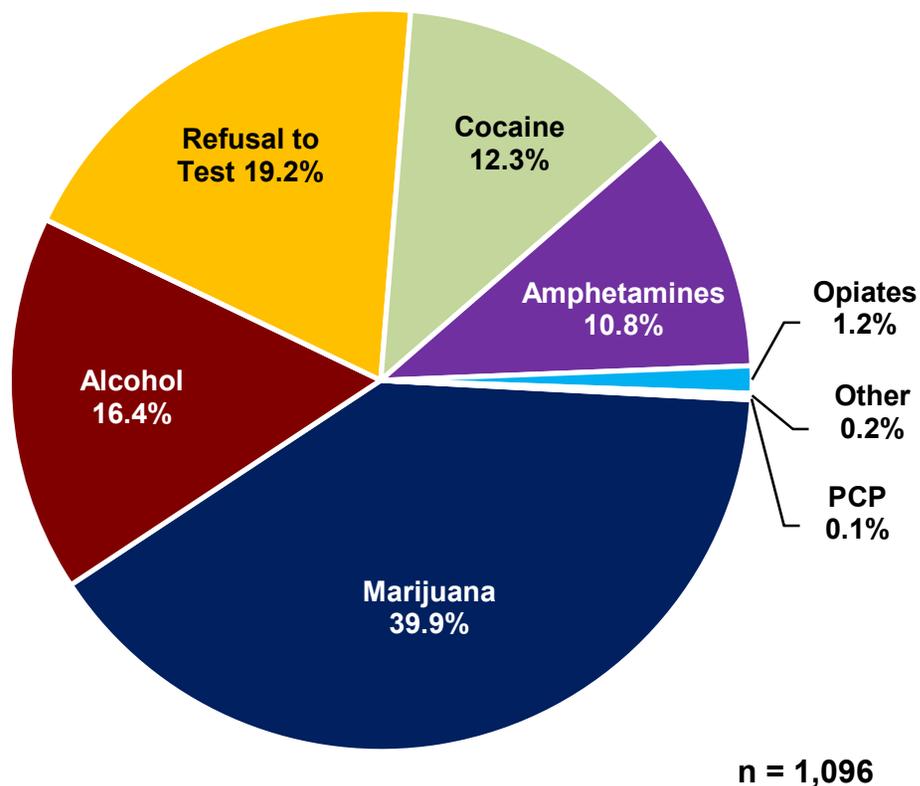
## Licensee Employees

(46,428 tested; 111 individuals positive)



## Contractors/Vendors

(101,929 tested; 1,032 individuals positive)



# Additional Substance Testing



- 10 CFR 26.31(d)(1)(i) permits a licensee or other entity to account for local drug use trends that may affect the workforce in a specific region or locality by expanding the drug testing panel.
- 10 CFR 26.31(d)(1)(ii) permits a licensee or other entity to test for any substance(s) that an individual is suspected of having abused, when performing follow-up, for-cause, and post-event tests.

In order to test for any additional substance, a forensic toxicologist first must review and validate the testing assays and cutoff levels the HHS-certified laboratory will use to perform the tests.

## Additional Substance Testing



- In 2017, 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) (four facilities, one FFD program).
- Typically, a few facilities each year will 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, 2011-2017

[Draft]

	2011	2012	2013	2014	2015	2016	2017	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			4
Oxymorphone		1	1	1	1			4
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>31</b>

The 31 test results in this table reflect positive results for 24 individuals. That is, some individuals tested positive for more than one of the substances in the same testing event

# Additional Substance Results by Test Category (2011-2017) [Draft]



Substances	Pre-Access	Random	For Cause	Followup	Total
Amphetamine; Marijuana; Hydrocodone; Hydromorphone	1				1
Amphetamine; Methamphetamine; Marijuana; Benzodiazepines			1		1
Amphetamine; Methamphetamine; Benzodiazepines			2		2
Amphetamine; Methamphetamine; Hydrocodone; Hydromorphone			1		1
Benzodiazepines		1	1	2	4
Buprenorphine	1				1
Buprenorphine; Norbuprenorphine			1		1
Cocaine; Benzodiazepines			1		1
Fentanyl; Oxycodone; Oxymorphone			1		1
Hydrocodone			1		1
Hydrocodone; Oxycodone; Oxymorphone			1		1
Marijuana; Benzodiazepines			1		1
Marijuana; Benzodiazepines; Methadone	1				1
Marijuana; Propoxyphene	1				1
Methadone		1	1		2
Oxycodone; Oxymorphone			2		2
Tramadol			2		2
<b>Total</b>	<b>4</b>	<b>2</b>	<b>16</b>	<b>2</b>	<b>24</b>

- 66% of individuals (16 of 24) tested positive on for-cause testing
- 25% of individuals (6 of 24) tested positive for one or more of the semi-synthetic opiates in the updated HHS Guidelines (i.e., hydrocodone, hydromorphone, oxycodone, oxymorphone)
- 57% of individuals that tested positive for an additional substance, also tested positive for a substance in the NRC-required testing panel (i.e., amphetamine, methamphetamine, cocaine, marijuana)

# Subversion Attempt Trends [Draft]

**Subversion attempt** – 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:** Permanent denial of unescorted access (10 CFR 26.75)

## Subversion Attempt Trends

2012 – 177 of 1,114 violations (15.8% subversions)  
2013 – 148 of 1,007 violations (14.7% subversions)  
2014 – 187 of 1,133 violations (16.5% subversions)  
2015 – 232 of 1,200 violations (19.3% subversions)  
2016 – 304 of 1,164 violations (26.1% subversions)  
2017 – 298 of 1,143 violations (26.1% subversions)



## Subversion Attempts in 2017:

- 45 facilities with at least 1 subversion attempt
- 67% identified at Pre-Access testing (200 of 298)
- 98% by contractor/vendors

## HHS-Certified Laboratory Testing Errors (2017) 10 CFR 26.719 (30-day event reports)



- Specimen validity tests not performed on two donor specimens. The laboratory determined the data entry operator entered the incorrect testing profile, which resulted in the inconsistencies in the tests performed. The laboratory also reported that incorrect initial testing cutoff levels for marijuana and opiates were used in the tests performed.
- Two BPTS formulated to return “substituted” validity test results, were reported as negative. The laboratory reported that while specimen aliquotting is normally performed via an automated process, manual aliquotting was performed for these specimens. The event was determined to be human error in the manual aliquotting step.
- A BPTS formulated to test positive for marijuana was reported as negative. The laboratory determined that the THC screening reagent for one of the initial testing instruments was improperly prepared. The testing supervisor had directed the staff to discard the reagent, but staff inadvertently missed the supervisor’s direction.

## HHS-Certified Laboratory Testing Errors (2017) 10 CFR 26.719 (30-day event reports)



- A BPTS formulated to test positive for marijuana was reported as negative. The laboratory determined that when the specimen was injected on the mass spectrometer, a series of strong peaks to the far right of the chromatogram interfered with the visual display of the peaks. This unusual presentation was misinterpreted as a negative result. The confirmation assay was not interpreted accurately by the Certifying Scientist and should have been set up for re-extraction.
- A BPTS formulated to test positive for amphetamine and methamphetamine was reported as positive only for amphetamine. The laboratory determined that the specimen had also tested positive for methamphetamines, but that an administrative error had occurred in the recording of the results in the report sent to the MRO. The scientist conducting the testing had failed to enter the data into the necessary computer reporting field for methamphetamine, which prevented the result from being recorded as positive.

# 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. 3155-0146 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 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 report 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 fields for additional information**

Submission Update  Delete Submission

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. 3155-0146 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 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 report 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 form fields to view additional information**  
**4) Use of Adobe Reader 8 or later is required**

Submission Update  Delete Submission

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



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