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Protecting People and the Environment

Presentation for the American Medical Review Officers Association

10 CFR Part 26
Fitness for Duty Program Performance in 2014

"A Direct Contribution to Safety and Security"
September 12, 2015

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Discussion Topics

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- Generic performance
- Results by Test Category and Employment Type
- Historical positive rates (Pre-Access, Random, For Cause tests)
- Substances
  - Historical presentation of substances detected
  - Results by employment type
  - Alcohol positives
  - Multi-substance positives
- Subversions
- Limit of Detection Testing (Dilute specimens)
- Laboratory Performance

Generic Industry Performance – 2014
10 CFR Part 26 Test Results

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75 **Licensees and other entities with an FFD program**

166,590 **Individuals drug & alcohol tested** *(up 3% from 2013)*

1,133 **Individuals that tested positive for a drug, alcohol, or refused a test**

67% identified at Pre-access testing
19% identified at Random testing

0.68% **Industry positive rate, all tests** *(up from 0.62% in 2013)*
0.23% licensee employee positive rate *(down from 0.25% in 2013)*
0.88% contractor/vendor positive rate *(up from 0.81% in 2013)*

0.34% **Industry random testing positive rate** *(up from 0.31% in 2013)*
0.14% licensee employee positive rate *(same as in 2013)*
0.62% contractor/vendor positive Rate *(up from 0.57% in 2013)*

Results by Test and Employment Categories 2014

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Test Category	Licensee Employees			Contractor/Vendors			Total		
	Number Tested	Number Positive	Percent Positive	Number Tested	Number Positive	Percent Positive	Number Tested	Number Tested Positive	Percent Positive
Pre-Access	9,545	27	0.28%	82,823	736	0.89%	92,368	763	0.83%
Random	37,545	53	0.14%	27,144	167	0.62%	64,689	220	0.34%
For Cause	215	23	10.70%	479	61	12.73%	694	84	12.10%
Post-Event	241	1	0.41%	656	12	1.83%	897	13	1.45%
Followup	3,382	14	0.41%	4,560	39	0.86%	7,942	53	0.67%
Total	**50,928**	**118**	**0.23%**	**115,662**	**1,015**	**0.88%**	**166,590**	**1,133**	**0.68%**

- 90% of positives and testing refusals from contractor/vendors (C/Vs)
- Positives and testing refusals by employment type is very different by test category
  - C/Vs (73% at Pre-access; 16% at Random, 6% at For Cause)
  - Licensee employees (23% at Pre-access, 45% at Random, 20% at For Cause)

Positive Rates by Employment Category (Pre-access, Random, and For Cause Testing)

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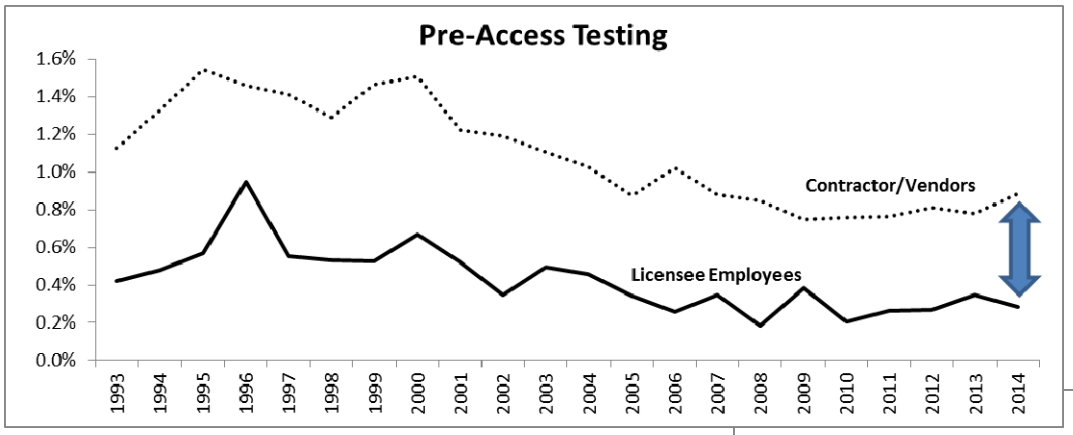
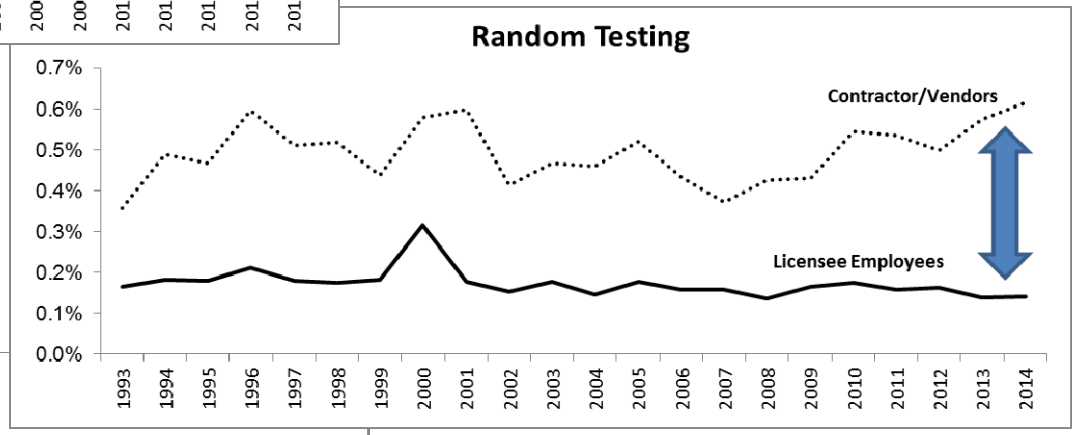
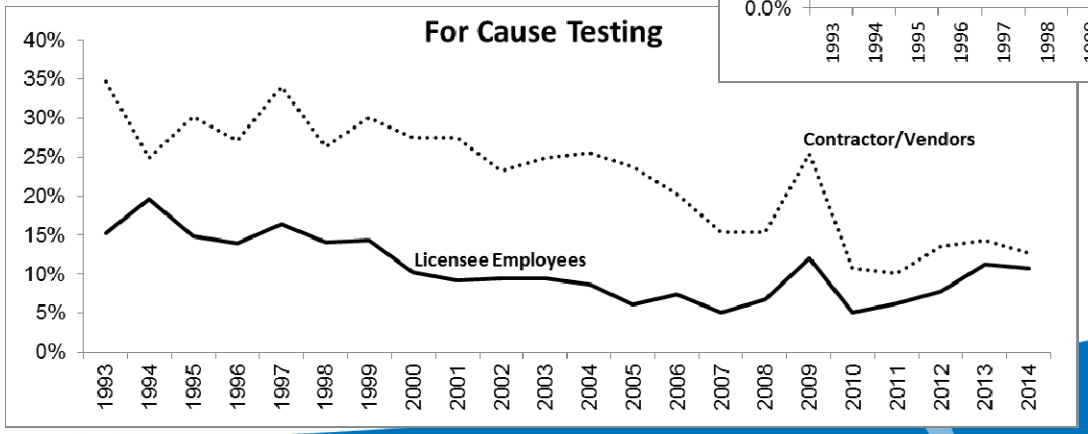
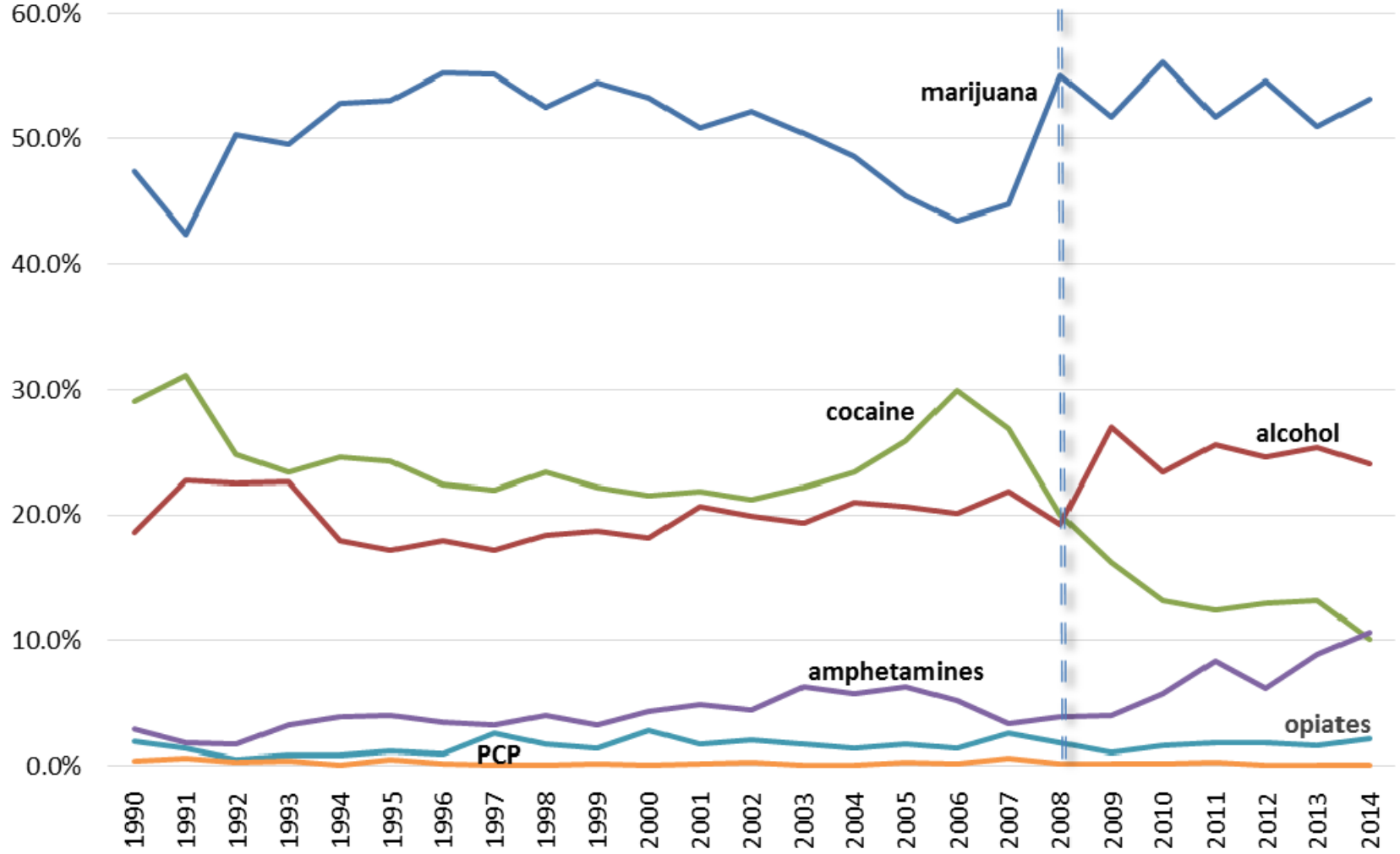






NRC Drug and Alcohol Testing Panel (10 CFR Part 26)
Percentage of Total Positives by Substance Tested (1990 - 2014)



Results by Employment Type, 2014

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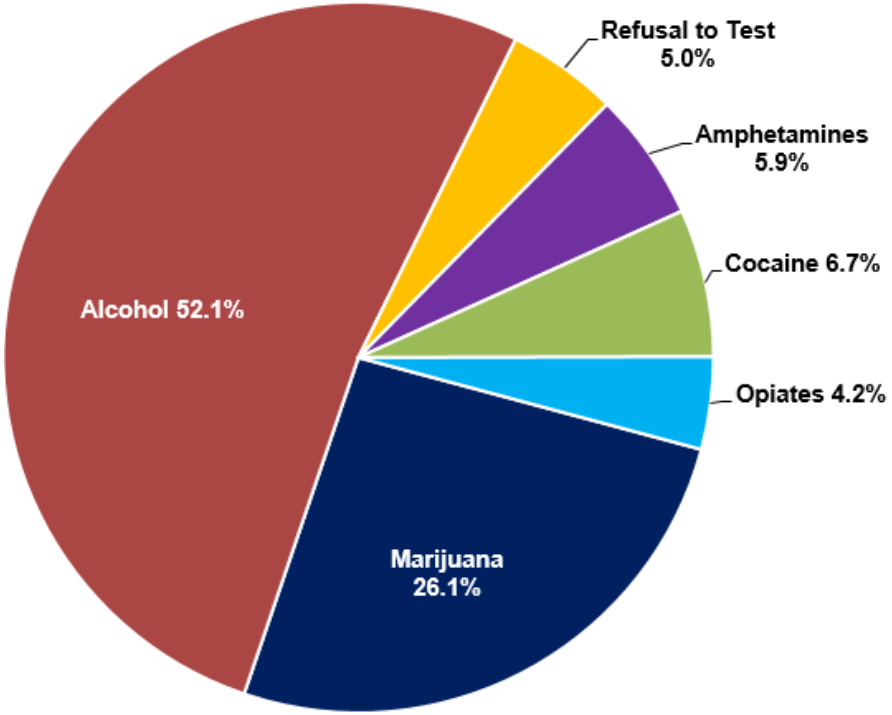
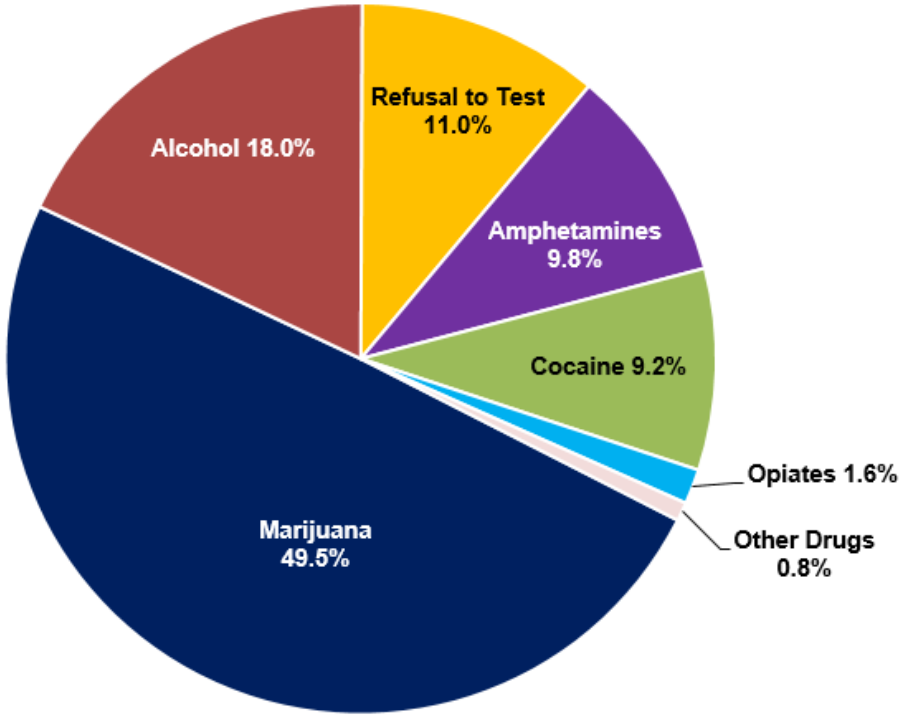
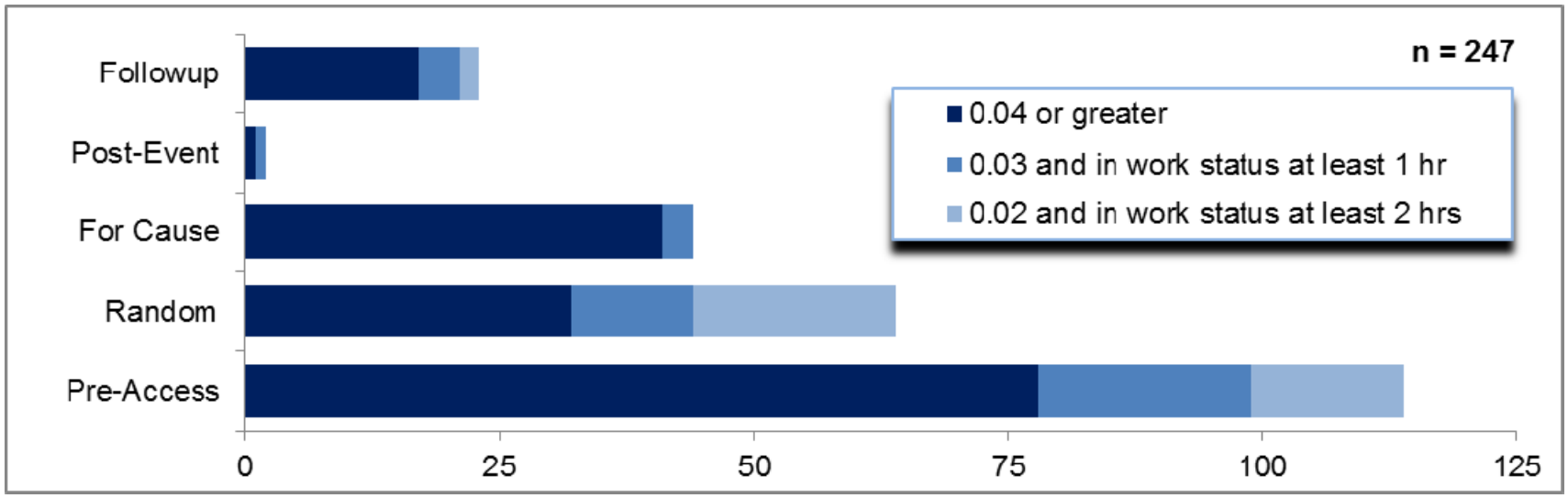
Licensee Employees
(50,928 tested, 118 individuals positive)



Contractor/Vendors
(115,662 tested, 1,015 individuals positive)



Alcohol Test Results by Test Type, 2014



	Pre-Access	Random	For Cause	Post-Event	Followup	Grand Total
0.04 or greater	78	32	41	1	17	169
0.03 and in work status at least 1 hr	21	12	3	1	4	41
0.02 and in work status at least 2 hrs	15	20			2	37
Grand Total	**114**	**64**	**44**	**2**	**23**	**247**

Multi-Substance Positive Results 2014

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	Pre-Access	Random	For Cause	Followup	Grand Total
Amphetamines; Alcohol				1	1
Amphetamines; Cocaine		1	1		2
Amphetamines; Cocaine; Marijuana		1			1
Amphetamines; Marijuana	4				4
Amphetamines; Methamphetamines	12	6	1		19
Amphetamines; Methamphetamines; Cocaine	1				1
Amphetamines; Methamphetamines; Marijuana	3				3
Amphetamines; Methamphetamines; Other: Hydrocodone			1		1
Amphetamines; Opiate: Codeine			1		1
Methamphetamines; Marijuana		1			1
Cocaine; Marijuana	5				5
Cocaine; Opiate: Morphine	1				1
Marijuana; Alcohol	1	1	1		3
Opiate: Codeine; Opiate: Morphine		2			2
Other: Benzodiazepines; Other: Methadone; Marijuana	1				1
Other: Hydrocodone; Other: Oxycodone; Other: Oxymorphone			1		1
Other: Propoxyphene; Marijuana	1				1
Grand Total	**29**	**12**	**6**	**1**	**48**

Of the 1,133 individuals with a drug and/or alcohol testing violation in 2014, 48 individuals tested positive for more than one substance

Subversion Attempts – 2012-2014

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Subversion attempt is any act or attempted act to subvert the testing process, including but not limited to, refusing to provide a specimen and providing or attempting to provide a substituted or adulterated specimen.

An individual identified as having attempted to subvert the testing process is permanently denied unescorted access.

Subversion attempts 2012 – 2014

2012 – 177 of 1,114 violations (15.8% subversion rate)
2013 – 148 of 1,007 violations (14.7% subversion rate)
2014 – 187 of 1,133 violations (16.5% subversion rate)

In 2014

72% of subversion attempts occurred at Pre-Access testing
96% of subversion attempts were made by contractor/vendors

How were individuals identified as subverting the testing process in 2014?

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- Of the 187 individuals identified as subverting the testing process:
  - 120 refused to provide a 1st or 2nd specimen for testing
  - 63 tested positive (i.e., observed 2nd specimen collection)

	Pre-Access	Random	For Cause	Followup	Grand Total
Amphetamines	2				2
Amphetamines; Marijuana	1				1
Amphetamines; Methamphetamines	1				1
Cocaine	4	4	1		9
Marijuana	38	6	1	1	46
Marijuana; Other: Methadone; Other: Benzodiazepines	1				1
Marijuana; Other: Propoxyphene	1				1
Methamphetamines		1			1
Opiate: Morphine	1				1
Grand Total	**49**	**11**	**2**	**1**	**63**

  - 4 of 187 individuals identified by validity testing (1 adulterated & 3 substituted test results)

- 63% of subversion events were associated with out of temperature specimens (118 of 187)

How do we collect such specific subversion attempt data?

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Started in 2009 using voluntary electronic reporting form (PDF-based), single event reporting for each result

Subversion Attempts - 26.717(b)(7) and 26.75(b)

If this result relates to a subversion attempt, select one or more of the following choices as applicable.
If not a subversion attempt, do not select any of the four boxes.

Physical Evidence ☐	Observed Actions/Behaviors ☐
Refusal to Cooperate ☒	Other ☐

Please elaborate on the choice(s) selected:

Subject presented a preaccess specimen with a temperature of 106.3 degrees F. Subject admitted to providing a surrogate sample. When advised an observed collection would be required subject refused to submit to the collection.

After two years of use, updated the e-form to include more specific and standardized checkboxes to improve characterization of events.

Subversion Attempts - 26.717(b)(7) and 26.75(b)

Did this collection involve a subversion attempt (Yes/No)? Yes

☐ Refused to provide initial specimen	☐ Specimen characteristics (e.g., color, odor, precipitant)
☒ Refused to provide second specimen	☐ Invalid test result (initial specimen collected) - 26.185(f)
☐ Specimen temperature (out of range)	☐ Refused to follow directions
☒ Specimen paraphernalia identified	☐ Other

Please elaborate on the choice(s) selected:

Specimen paraphernalia identified after completion of 1st collection, to include an electronic thermometer, small heating pad, and empty bottle with residual urine inside. Donor admitted substitution and refused to provide a sample under observed collection.

Methods used that may account for improved detection of subversion attempts

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- **Highly trained collectors at dedicated collection sites**.
  A small number of staff perform collections at each licensee facility (primarily nuclear power plants).

- **Most licensees do not solely rely upon the 90-100°F temperature strip on the specimen collection cup** (e.g., use infrared temperature device with a much wider temperature range). An expanded temperature range can provide sufficient evidence to stop a collection (e.g., an 85°F or 115°F specimen).

- **MROs have made subversion determinations based on**:

  – Significant temperature differences between initial (unobserved) and second (observed) specimens collected.

  – Differences in specimen pH and creatinine levels between the initial and second (observed) specimens collected.

- **Random security checks during plant access occasionally identify subversion paraphernalia**

Expanded Drug Testing Panel

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10 CFR 26.31(d)(1)(i)(A) ". . . The licensee or other entity may add other drugs . . . to the panel of substances for testing, but only if the additional drugs are listed in Schedules I through V of section 202 of the Controlled Substances Act [21. U.S.C. 812]"

A limited number of licensees have expanded the drug testing panel to include testing for substances such as:

- barbiturate
- benzodiazepines
- hydromorphone
- hydrocodone
- methadone
- oxymorphone
- oxycodone
- methadone
- propoxyphene
- suboxone

Limit of Detection Testing of Dilute Specimens – 10 CFR 26.163(a)(2)

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- 26.163(a)(2) permits a licensee to require the HHS-certified laboratory to conduct confirmatory drug testing to the limit of detection for a substance if:
  1. Validity Test = Dilute, and
  2. Immunoassay response is equal to or greater than 50% of the cutoff level
- 69 of 75 licensees instituted the optional LOD testing policy in 2014
- 41 of 69 licensees conducted LOD testing on 834 urine specimens in 2014 (10 specimens tested positive)

Dilute Specimens with Positive Drug Test Results

	2012	2013	2014
LOD Testing Conducted = Yes	**7**	**8**	**10**
Pre-Access	**6**	**8**	**8**
Marijuana	6	8	6
Amphetamines; Marijuana			1
Amphetamines; Methamphetamines			1
Random	**1**		**1**
Cocaine			1
Marijuana	1		
For Cause			**1**
Marijuana			1
LOD Testing Conducted = No	**12**	**8**	**5**
Pre-Access	**10**	**3**	**3**
Marijuana	9	3	2
Cocaine	1		1
Random	**2**	**5**	**2**
Marijuana	2	3	2
Amphetamines		1	
Cocaine		1	
Total	**19**	**16**	**15**

HHS-Certified Laboratory Testing – Unsatisfactory Performance - 10 CFR 26.719(c)

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- A report must be made to the NRC within 30-days of a licensee completing an investigation into unsatisfactory laboratory performance. A summary of 4 of the 5 reports for 2014 is as follows:
  - A blind performance test sample (BPTS) formulated as "dilute and negative" was reported only as negative. The laboratory (Clinical Reference Laboratory) determined that bubbles in the chamber of the automated refractometer can cause erroneously elevated specific gravity readings (i.e., bubbling can occur if the sample probe is not fully immersed in the specimen due to low aliquot volume). The laboratory changed its SOP to require the operator to verify the specimen aliquot volume prior to testing.
  - A BPTS formulated as positive for PCP was reported only as negative. The laboratory (LabCorp) concluded that an inappropriate amount of sample was pipetted during the extraction process. LabCorp retrained its extraction technologists to carefully check the volume of urine aliquoted for the confirmation batch and to ensure consistent delivery of the internal standards in accordance with the SOP.
  - A BPTS formulated as "dilute and negative" was reported as "negative". The laboratory (LabCorp) determined the error was due to inadequate testing of a software upgrade made 18 days prior to the testing event (i.e., the specific gravity result was not included with the creatinine test result).

HHS-Certified Laboratory Testing – Unsatisfactory Performance (continued)

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– A BPTS formulated as positive for PCP was reported as negative. The laboratory (LabCorp) determined that shortly after the PCP test, the GC/MS instrument was taken out of service because the technologist was unable to achieve the daily auto-tune of the instrument (a crack in the GC/MS column caused leaking between the interface of the Gas Chromatograph and the Mass Spectrometer). Corrective actions included:

(1) Addition of a QC specimen injected as the last sample of each confirmation batch

(2) Extractors must complete a visual verification of volumes sheet for each batch

(3) Internal standard abundance criteria will be applied to NRC samples (any sample with an internal standard that is not within 50-200% of the calibrator and quality controls will be repeated in accordance with the HHS Guidelines

(4) An upfront dilution of 1:5 was added to the SOP for PCP when the initial test result is equal to or greater than 100 (this was instituted because samples with high PCP concentrations must be re-extracted due to column overloading; this method is already in place for THC and cocaine confirmation assays)

(5) NRC samples that initially test positive for PCP and confirm negative will be repeated and the entire batch held until the repeat is complete and is still negative. If the repeat does not correlate, the whole batch will be repeated (in accordance with HHS Guidelines and already done for THC and cocaine).

NRC Fitness for Duty Program Staff

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