Presentation for the
Drug Testing Advisory Board
HHS/SAMHSA

10 CFR Part 26
Fitness for Duty Programs

“A Direct Contribution to Safety and Security”
Introduction

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Organization

Security Programs and Support Branch
Division of Security Policy
Office of Nuclear Security and Incident Response
U.S. Nuclear Regulatory Commission
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Discussion Topics

• The Nuclear Regulatory Commission

• 10 CFR Part 26, Fitness for Duty Programs
  – The Defense-in-Depth FFD Strategy
  – Being “fit for duty”
  – Sanctions
  – Time-dependent alcohol limits

• Drug and Alcohol Trends

• Programmatic Discussion

• Subversions and Adulteration
  – Identification
  – Data and Trend

• Temperature Profile
Mission

The mission of the NRC is to license and regulate the Nation’s civilian use of byproduct, source, and special nuclear materials to ensure the adequate protection of public health and safety, promote the common defense and security, and protect the environment.

We do this by:

1. Establishing requirements, standards, and guidance
2. Licensing facilities and possession, use, and disposal of nuclear materials
3. Inspecting facilities and of users to ensure compliance
4. Providing emergency response and assessment
5. Assessing security threat conditions
6. Providing liaison with Federal, State, and Local partners
Power Plant Features

Components of Security

- Guard Towers
- Water Barriers
- Intrusion Detection System/Fenceline
- Roving Patrols
- Access Controls
- Security Officers

Protecting nuclear facilities requires all the security features to come together and work as one.
Fitness for Duty Programs

FFD Mission

The mission of the FFD Program is to provide a direct contribution to safety and security through the effective regulatory oversight (policy development in support of licensing, rulemaking, and inspection) of licensees and other affected entities that implement the drug and alcohol provisions of 10 CFR Part 26, Fitness for Duty Programs.

FFD Vision

Establish and maintain a regulatory framework that effectively and efficiently enables NRC-licensees to meet or exceed the FFD performance objectives listed in 10 CFR 26.23. In particular, FFD programs must provide reasonable assurance that:

- Persons are trustworthy and reliable;
- Persons are not under the influence of any legal or illegal substance or physically impaired from any cause;
- Licensees can provide for early detection of persons who are not fit for duty or indicate untrustworthiness or unreliability;
- Licensee facilities are free from the adverse effects of drugs, alcohol, and other substances; and,
- Persons are not fatigued or in a state of diminished mental or physical capacity.
The Defense-in-Depth FFD Strategy

Authorization Requirements

Fit, Reliable, Trustworthy Workers

Fatigue Management

Drug and Alcohol Testing

Behavioral Observation
Being Fit for Duty

Being fit for duty is part of the NRC’s defense-in-depth regulatory framework that helps provide assurance that persons who have unescorted access to the protected areas at commercial nuclear power reactors and Category I fuel cycle facilities, or who conduct certain activities, can safely and competently perform assigned duties.

From the requirements in 10 CFR Part 26, being fit for duty means that a person is:

a) not under the influence of any legal or illegal drug or substance as defined by testing cutoffs and MRO determination;

b) mentally and physically capable to safely and competently perform assigned duties; and,

c) not impaired by acute or cumulative fatigue.

Being FFD also means that the person is trustworthy and reliable.
NRC Sanctions – for alcohol or drug test results

Three Strikes

1\textsuperscript{st} Offense  14-day denial
2\textsuperscript{nd} Offense  5-year denial
3\textsuperscript{rd} Offense  Permanent denial

Special Cases

1. Licensee-administered sanctions
2. Administrative actions allowed on validity screening or initial validity testing results for marijuana and cocaine; others drugs allowed if determined by an SAE
3. Withdrawal of employment application after 1\textsuperscript{st} test = 5-year denial
4. Use of drugs/alcohol within the Protected Area = 5-year denial
5. Subversion/Adulteration/Refusal-to-Test = Permanent denial
6. Reporting of offsite drug use = mgmt/SAE review with a D&A test
Time-Dependent Alcohol Limits

Initial Test

- < 0.02 BAC: negative test result

Confirmatory Test

- ≥ 0.04 BAC: positive test result
- ≥ 0.03 BAC: at work for at least 1 hour before the initial test
- ≥ 0.02 BAC: at work for at least 2 hours before the initial test

Administrative Actions

- ≥ 0.01 to < 0.02 BAC: at work for at least 3 hours before the initial test
  - no sanctions applied
  - SAE fitness determination required
### Test Results by Test Category [DRAFT]

<table>
<thead>
<tr>
<th>Test Category*</th>
<th>Number Tested</th>
<th>Number Tested Positive</th>
<th>Percent Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Access</td>
<td>89,187</td>
<td>632</td>
<td>0.71%</td>
</tr>
<tr>
<td>Random</td>
<td>63,678</td>
<td>189</td>
<td>0.30%</td>
</tr>
<tr>
<td>For-Cause</td>
<td>627</td>
<td>80</td>
<td>12.76%</td>
</tr>
<tr>
<td>Post-Event</td>
<td>718</td>
<td>5</td>
<td>0.70%</td>
</tr>
<tr>
<td>Followup</td>
<td>7,487</td>
<td>69</td>
<td>0.92%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>161,697</strong></td>
<td><strong>975</strong></td>
<td><strong>0.60%</strong></td>
</tr>
</tbody>
</table>

### Test Results by Test and Employment Categories [DRAFT]

<table>
<thead>
<tr>
<th>Test Category</th>
<th>Licensee Employees</th>
<th>C/Vs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number Tested</td>
<td>Number Positive</td>
</tr>
<tr>
<td>Pre-Access</td>
<td>10,143</td>
<td>31</td>
</tr>
<tr>
<td>Random</td>
<td>39,140</td>
<td>49</td>
</tr>
<tr>
<td>For-Cause</td>
<td>187</td>
<td>19</td>
</tr>
<tr>
<td>Post-Event</td>
<td>226</td>
<td>0</td>
</tr>
<tr>
<td>Followup</td>
<td>3,781</td>
<td>25</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>53,477</strong></td>
<td><strong>124</strong></td>
</tr>
</tbody>
</table>
Graph 1: Positive Pre-Access Testing Rates by Employment Category

Graph 2: Positive Random Test Rates by Employment Category

Positive For-Cause Testing Rates by Employment Category
Alcohol Positives (CY 2013) - DRAFT

- n = 229

- Followup: 0.04 or greater (20), 0.03 and in work status at least 1 hr (10), 0.02 and in work status at least 2 hrs (5)
- Post-Event: 0.04 or greater (2), 0.03 and in work status at least 1 hr (1), 0.02 and in work status at least 2 hrs (1)
- For Cause: 0.04 or greater (90), 0.03 and in work status at least 1 hr (10), 0.02 and in work status at least 2 hrs (3)
- Random: 0.04 or greater (15), 0.03 and in work status at least 1 hr (10), 0.02 and in work status at least 2 hrs (5)
- Pre-Access: 0.04 or greater (11), 0.03 and in work status at least 1 hr (30), 0.02 and in work status at least 2 hrs (10)
Performance by Site – Subversions, Pre-Access & Dilute (CY 2012)

Nuclear Sites by Name
### Geographic Prevalence

#### Regional Commercial Power Reactors

<table>
<thead>
<tr>
<th>Map Pt</th>
<th>Site Name</th>
<th>Licensee</th>
<th>CVs</th>
<th>Average Site Population Total</th>
<th>Random Testing Rate</th>
<th>Positive Rate (CY 2012)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Vogtle 1&amp;2</td>
<td>1,080</td>
<td>712</td>
<td>1,792</td>
<td>55.7</td>
<td>2.37</td>
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<tr>
<td></td>
<td>Vogtle 3&amp;4</td>
<td>368</td>
<td>2,368</td>
<td>2,736</td>
<td>70.2</td>
<td>2.18</td>
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<tr>
<td></td>
<td>Vogtle 1&amp;2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.60</td>
</tr>
<tr>
<td></td>
<td>Vogtle 3&amp;4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.04</td>
</tr>
<tr>
<td></td>
<td>Vogtle 1&amp;2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.74</td>
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<tr>
<td></td>
<td>Vogtle 3&amp;4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.86</td>
</tr>
<tr>
<td>B</td>
<td>V.C. Summer 1</td>
<td>982</td>
<td>656</td>
<td>1,638</td>
<td>54.8</td>
<td>0.56</td>
</tr>
<tr>
<td></td>
<td>V.C. Summer 2&amp;3</td>
<td>0</td>
<td>1,642</td>
<td>1,642</td>
<td>54.6</td>
<td>2.19</td>
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<tr>
<td></td>
<td>Hatch</td>
<td>997</td>
<td>530</td>
<td>1,527</td>
<td>54.8</td>
<td>0.63</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>0.36</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>0.58</td>
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<tr>
<td>D</td>
<td>Catawba</td>
<td>1,193</td>
<td>820</td>
<td>2,013</td>
<td>60.5</td>
<td>0.77</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>0.49</td>
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<td></td>
<td></td>
<td>0.65</td>
</tr>
<tr>
<td>E</td>
<td>McGuire</td>
<td>1,324</td>
<td>995</td>
<td>2,319</td>
<td>59.0</td>
<td>0.14</td>
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<td></td>
<td></td>
<td>0.07</td>
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<td>0.17</td>
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<td>F</td>
<td>Brunswick</td>
<td>890</td>
<td>1,075</td>
<td>1,966</td>
<td>54.3</td>
<td>0.79</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>0.28</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>0.61</td>
</tr>
<tr>
<td>G</td>
<td>Shearon Harris</td>
<td>875</td>
<td>833</td>
<td>1,708</td>
<td>55.4</td>
<td>0.43</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.21</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.31</td>
</tr>
<tr>
<td>H</td>
<td>Watts Bar</td>
<td>1,465</td>
<td>3,363</td>
<td>4,828</td>
<td>51.3</td>
<td>0.61</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.36</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.68</td>
</tr>
</tbody>
</table>
Programmatic Discussion

1. Performance-based auditing of HHS-certified labs
2. HHS/SAMHSA-NLCP review of NRC-related laboratory problems
3. Medical Review Officer guidance on semi-synthetic opiates
4. Voluntary announcement of all medications, and mental and physical ailments
5. Use of the hair specimens for “pre-access authorization” and follow-up testing
6. Use of oral fluid for short-duration pre-access, for-cause, and post-event testing
7. Conduct of a security-related search for “prohibited items” during a collection
8. Enable engineering and biological detection devices for illegal drugs
9. Minimum volume requirements – no volumetric latitude and too much?
10. Use of mirrors for direct-observed collections
11. Leaving the collection site in an emergency
12. In-situ Cup adulterant testing upon collection
Vigilance at the collection site is very important
  – Most subversions are temperature based
  – Some subversions are determined by hearing sounds or seeing paraphernalia
  – Very few subversions are identified through lab testing

Securing non-essential items prior to collection
  – Security and maintenance personnel work uniforms and equipment
  – Evaluation of specimen characteristics (e.g., color, odor, precipitate, etc.)

Refusing to following direction – intimidation, delay, etc
  – Security-related searches for prohibited items (slide 18, bullet 7)

Alcohol subversions, do they exist?

Unknown adulterants?

Synthetic urine detection?

Are we effective at identifying subversions?
### Identification of Adulterants

#### Table 8. Non-Negative Rates By Specimen Validity Test (SVT)² Category – Urine Drug Tests

(For Federally Mandated, Safety-Sensitive Workforce, as a percentage of all such tests)

<table>
<thead>
<tr>
<th>SVT Category</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acid-Base</td>
<td>0.02%</td>
<td>0.03%</td>
<td>0.03%</td>
<td>0.03%</td>
<td>0.03%</td>
</tr>
<tr>
<td>Invalid</td>
<td>0.11%</td>
<td>0.09%</td>
<td>0.09%</td>
<td>0.09%</td>
<td>0.11%</td>
</tr>
<tr>
<td>Oxidizing Adulterants</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Substitution</td>
<td>0.05%</td>
<td>0.06%</td>
<td>0.06%</td>
<td>0.06%</td>
<td>0.05%</td>
</tr>
</tbody>
</table>

#### Table 9. Non-Negative Rates By Drug/SVT Category – Urine Drug Tests

(For General U.S. Workforce, as a percentage of all non-negatives)

<table>
<thead>
<tr>
<th>SVT Category</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acid-Base</td>
<td>0.002%</td>
<td>0.001%</td>
<td>0.001%</td>
<td>0.001%</td>
<td>0.001%</td>
</tr>
<tr>
<td>Invalid</td>
<td>0.12%</td>
<td>0.12%</td>
<td>0.13%</td>
<td>0.14%</td>
<td>0.15%</td>
</tr>
<tr>
<td>Oxidizing Adulterants</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Substitution</td>
<td>0.01%</td>
<td>0.02%</td>
<td>0.02%</td>
<td>0.01%</td>
<td>0.01%</td>
</tr>
</tbody>
</table>

Note: Tables 8 and 9 from the *Drug Testing Index™*, November 18, 2013, Quest Diagnostics®
Effectiveness of Specimen Validity Testing

Non-Negative Rates by Drug/SVT Category

Urine Drug Tests – For General U.S. Workforce, as a Percentage of All Non-Negatives

Note: Table from the Drug Testing Index™, November 18, 2013, Quest Diagnostics®
Things We Need

- Enhanced Medical Review Officer guidance on:
  - Evaluation of semi-synthetic opiates
  - Drug cocktailing

- Hair and Oral Fluids Guidelines

- Latitude on minimum urine volume requirements

- Enhanced detection of synthetic urine and adulterants

- Better evaluation of invalids

- Enhanced criteria to evaluate the 1st and 2nd collections
  - Differences in creatinine, pH, and temperature
  - Differences in metabolites
  - Differences in color
Subversion Data (CY 2013) - DRAFT

- For Cause
- Followup
- Random
- Pre-Access

Subversion attempts with positive, adulterated, or substituted test result vs. Refusals to test
The Subversion Matrix (CY2013) - DRAFT

First Collection
- No Specimen Collected
- Subversion Suspected*
  - Specimen temperature (104)
  - Specimen characteristics (7)
  - Paraphernalia discovered (22)
- Specimen Collected Appears Normal
- Specimen Collected Appears Normal, Invalid Test Result

Second Collection
- No Specimen Collected
- Directly Observed Specimen Collection

Subversion (145)
- 25 Donor refusal (23)
  - Collector stopped process (2)
- 71 Donor refusal (56)
  - Collector stopped process (15)
- 41 Drug Test Results
  - (1st spec negative/2nd spec positive)
- 4 Validity Test Results
  - Adulterated (0); Substituted (4)
- 2 Drug Test Results
  - (1st spec invalid/2nd spec positive)

*For some subversion cases, more than one indicator of subversion was reported.
# Temperature Profile

## Sample Bottle Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material</td>
<td>HD Polyethylene</td>
</tr>
<tr>
<td>Size</td>
<td>100 ml</td>
</tr>
<tr>
<td>Thickness</td>
<td>1.3 mm</td>
</tr>
<tr>
<td>Height</td>
<td>75 mm</td>
</tr>
<tr>
<td>Width</td>
<td>53 mm</td>
</tr>
<tr>
<td>Density</td>
<td>0.93 g/cm³</td>
</tr>
<tr>
<td>Specific Heat Capacity</td>
<td>1.55 J/(gK)</td>
</tr>
<tr>
<td>k</td>
<td>0.465 W/(mK)</td>
</tr>
<tr>
<td>Thermal Diffusivity</td>
<td>3.23E-03 cm²/s</td>
</tr>
<tr>
<td>k Table</td>
<td>0.25 W/(mK)</td>
</tr>
<tr>
<td>h Urine</td>
<td>500 W/(m²K)</td>
</tr>
<tr>
<td>h Air</td>
<td>60 W/(m²K)</td>
</tr>
<tr>
<td>k Urine</td>
<td>0.6 W/(mK)</td>
</tr>
<tr>
<td>k Air</td>
<td>0.025 W/(mK)</td>
</tr>
<tr>
<td>Specific Heat Capacity Urine</td>
<td>4.18 J/(gK)</td>
</tr>
<tr>
<td>Density Urine</td>
<td>0.985 g/cm³</td>
</tr>
</tbody>
</table>

## Thermal Resistance Calculations

- Thermal Resistance Wall: 8.984909712 K/W
- Thermal Resistance Top: 10.75787848 K/W
- Thermal Resistance Bottom: 40.13966359 K/W
- Total Thermal Resistance: 0.229165869 W/K
- Energy Losses: 11.6541046 W

## Contact Areas

- Total Contact Area of Sample: 0.004375989 m²
- Contact Area of Wall of Cup: 0.002380952 m²
- Contact Area of Top and Bottom of Cup (rt angle cylinder): 0.001995037 m²
Questions?