

**Presentation for the
Drug Testing Advisory Board
HHS/SAMHSA**

**10 CFR Part 26
Fitness for Duty Programs**

“A Direct Contribution to Safety and Security”

Paul Harris, Senior Program Manager

Paul.Harris@nrc.gov 301-287-9294

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



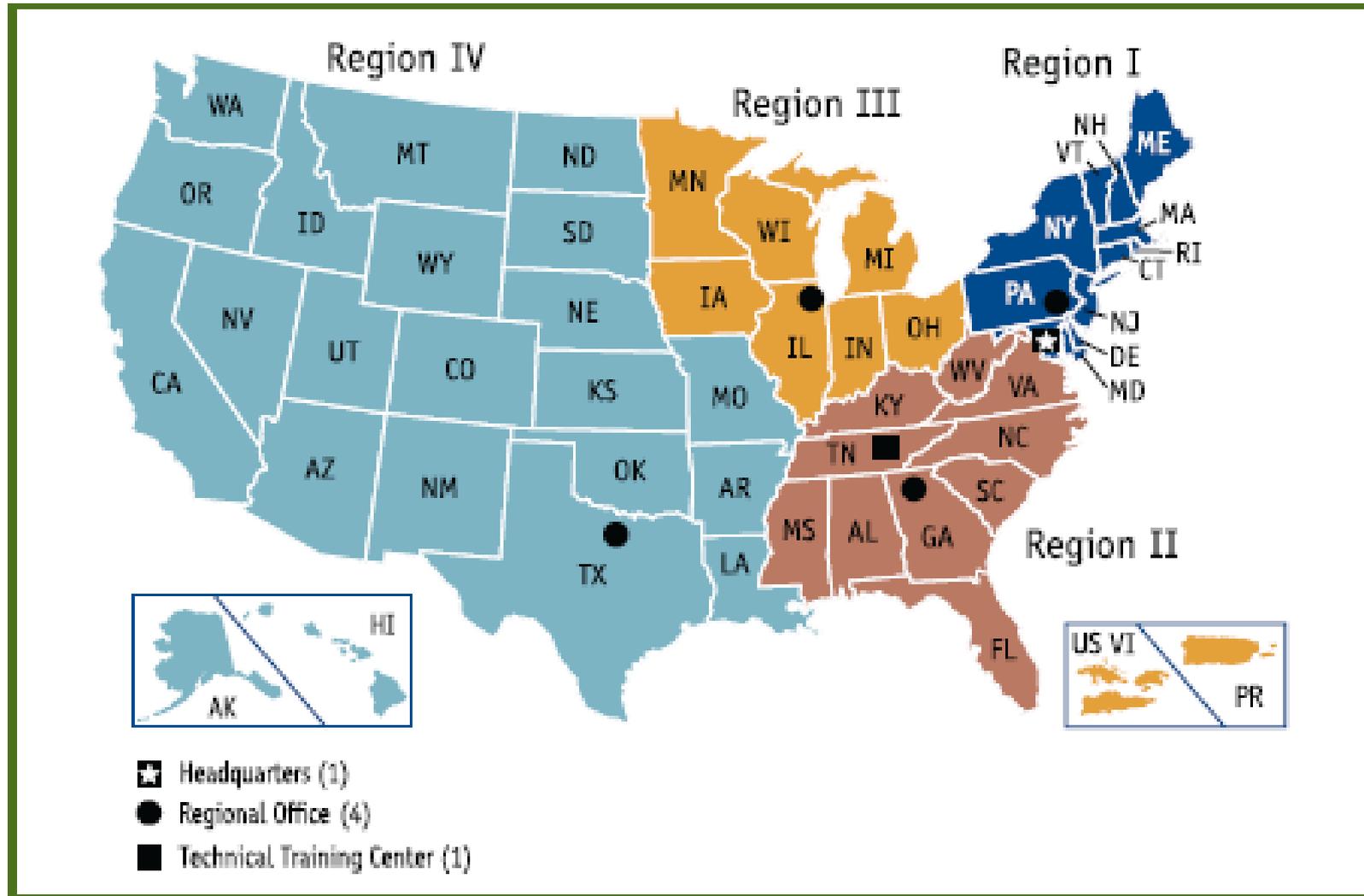
Mission

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.

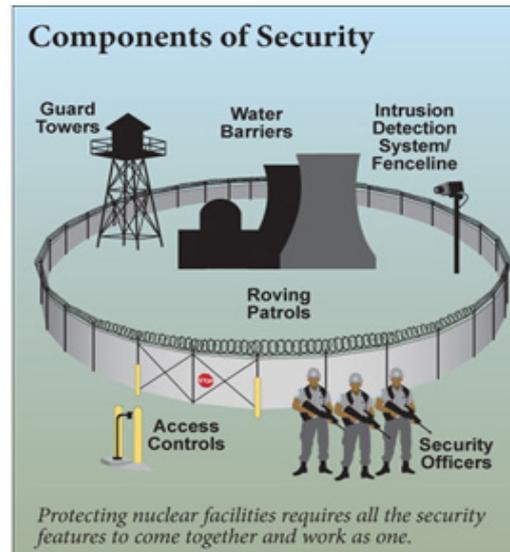
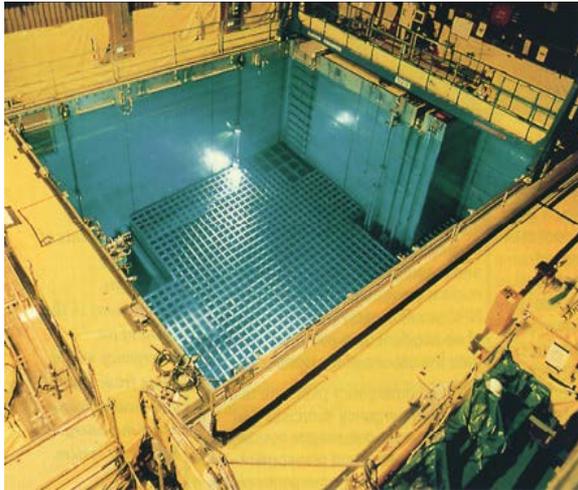
We do this by:

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

NRC Regional Offices



Power Plant Features



Fitness for Duty Programs

FFD Mission

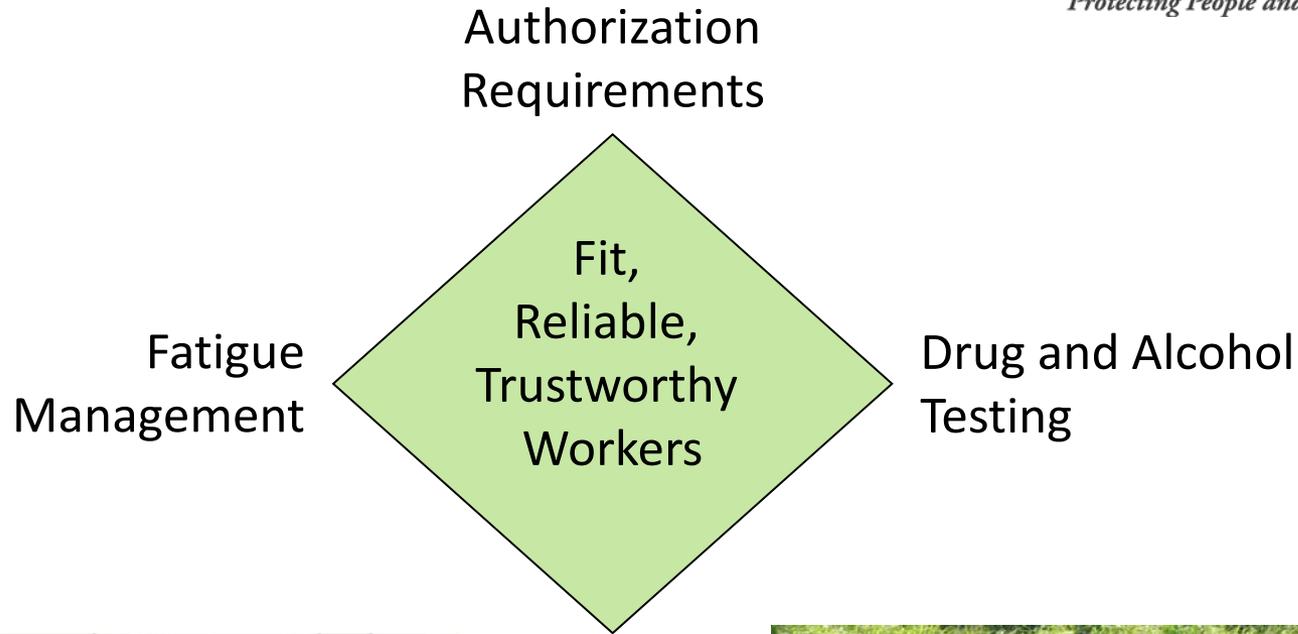
The mission of the FFD Program is to provide a direct contribution to safety and security through the effective regulatory oversight (policy development in support of licensing, rulemaking, and inspection) of licensees and other affected entities that implement the drug and alcohol provisions of 10 CFR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



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 st Offense | 14-day denial |
| 2 nd Offense | 5-year denial |
| 3 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 1st 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 = mgt/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

Drug & Alcohol Test Results (CY 2013)

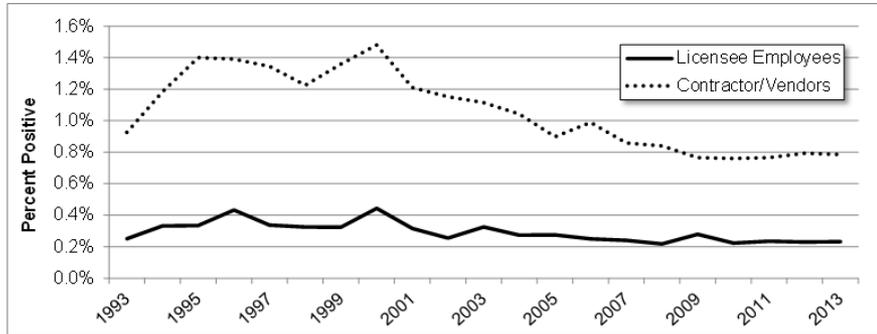
Test Results by Test Category [DRAFT]

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

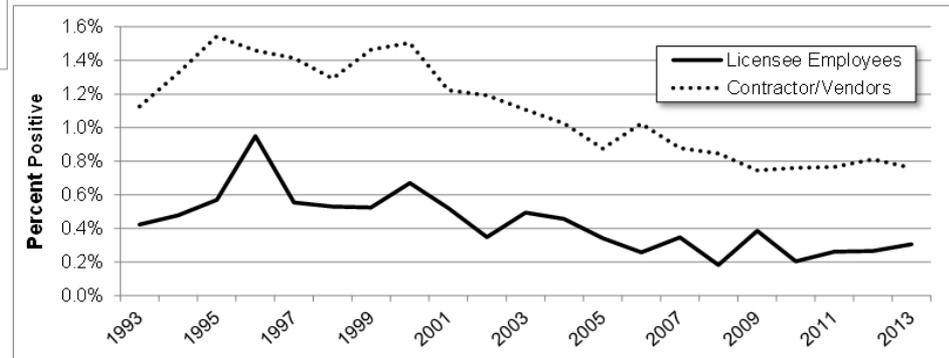
Test Results by Test and Employment Categories [DRAFT]

| Test Category | Licensee Employees | | | C/Vs | | |
|-----------------|--------------------|-----------------|------------------|----------------|-----------------|------------------|
| | Number Tested | Number Positive | Percent Positive | Number Tested | Number Positive | Percent Positive |
| Pre-Access | 10,143 | 31 | 0.31% | 79,044 | 601 | 0.76% |
| Random | 39,140 | 49 | 0.13% | 24,538 | 140 | 0.57% |
| For-Cause | 187 | 19 | 10.16% | 440 | 61 | 13.86% |
| Post-Event | 226 | 0 | 0.00% | 492 | 5 | 1.02% |
| <u>Followup</u> | 3,781 | 25 | 0.66% | 3,706 | 44 | 1.19% |
| Total | 53,477 | 124 | 0.23% | 108,220 | 851 | 0.79% |

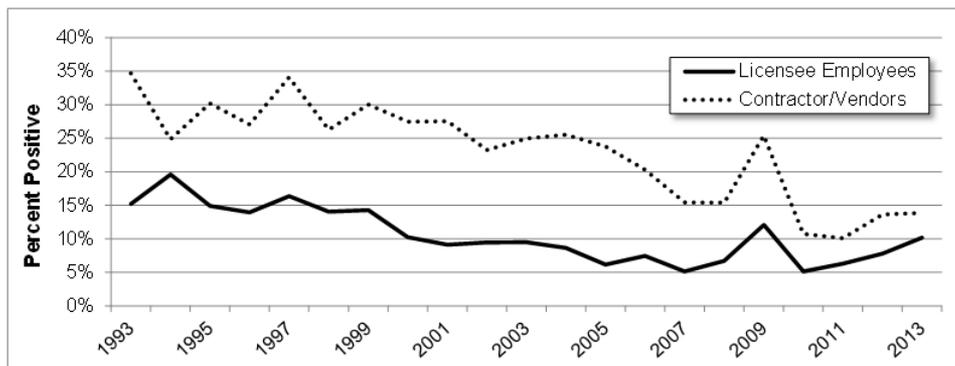
Graph 1: Positive Pre-Access Testing Rates by Employment Category



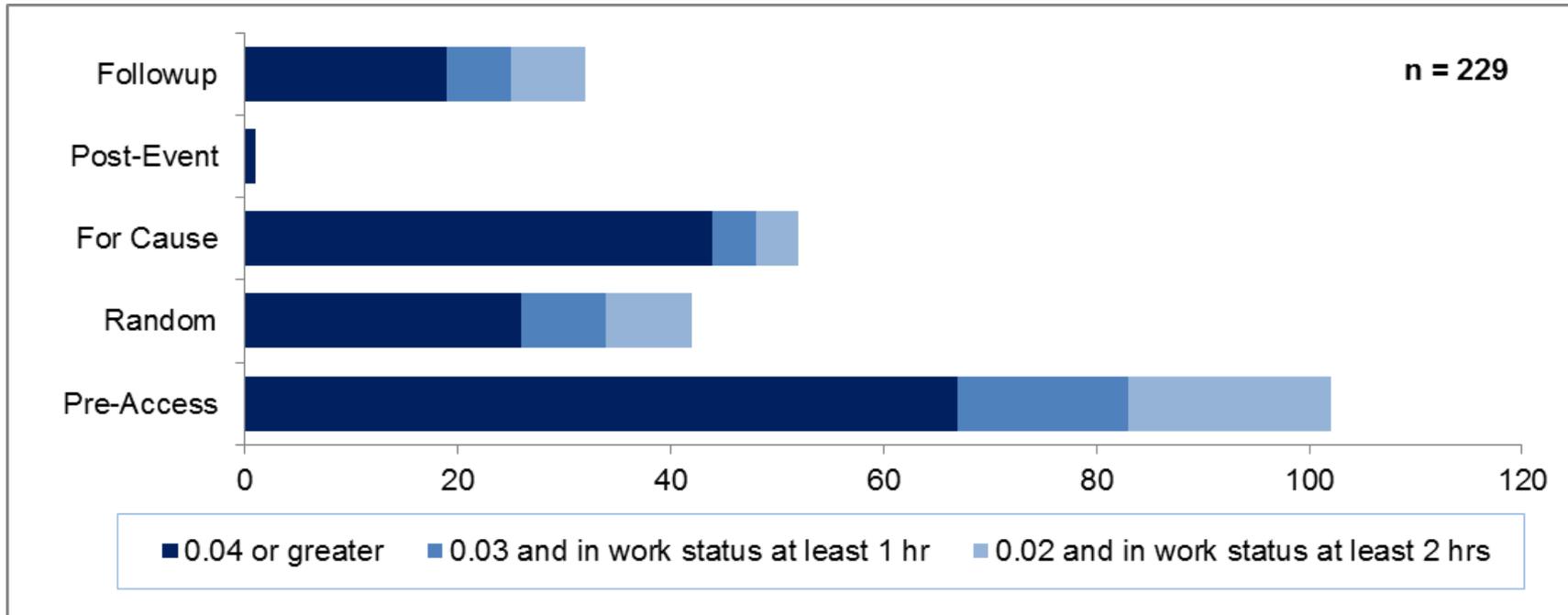
Graph 2: Positive Random Test Rates by Employment Category



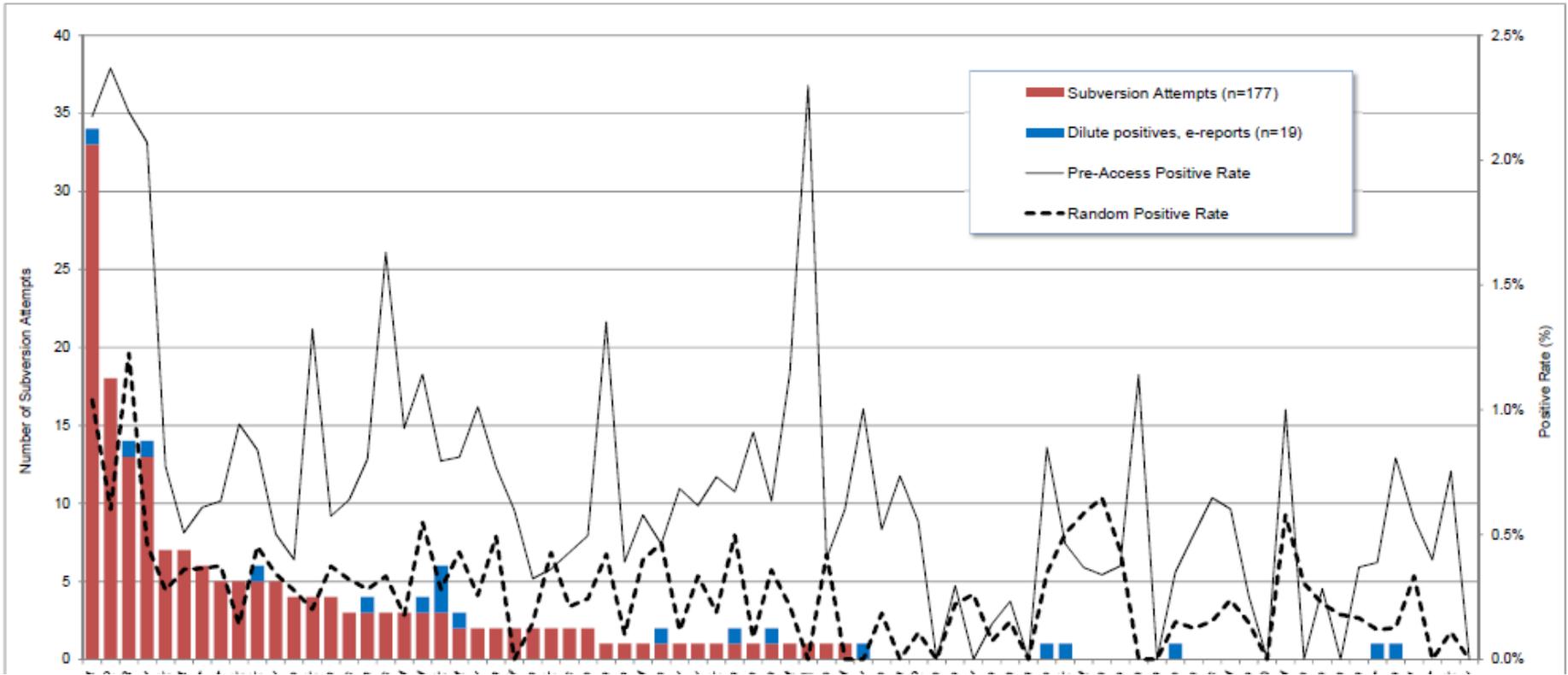
Positive For-Cause Testing Rates by Employment Category



Alcohol Positives (CY 2013) - DRAFT

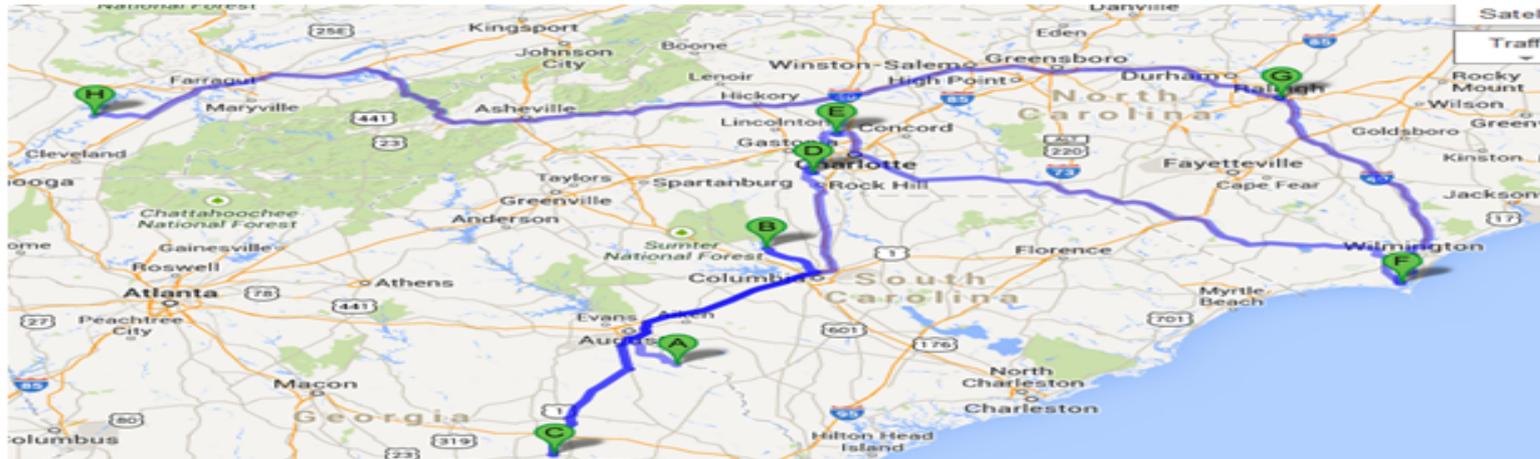


Performance by Site – Subversions, Pre-Access & Dilute (CY 2012)



Nuclear Sites by Name

Geographic Prevalence



Regional Commercial Power Reactors

| Map Pt | Site Name | Average Site Population | | Average Site Population Total | Random Testing Rate | Positive Rate (CY 2012) | | |
|--------|-----------------|-------------------------|-------|-------------------------------|---------------------|-------------------------|--------|-----------|
| | | Licensee | CVs | | | Pre Access | Random | All Tests |
| A | Vogtle 1&2 | 1,080 | 712 | 1,792 | 55.7 | 2.37 | 0.60 | 1.74 |
| | Vogtle 3&4 | 368 | 2,368 | 2,736 | 70.2 | 2.18 | 1.04 | 1.86 |
| B | V.C. Summer 1 | 982 | 656 | 1,638 | 54.8 | 0.56 | 0.33 | 0.55 |
| | V.C. Summer 2&3 | 0 | 1,642 | 1,642 | 54.6 | 2.19 | 1.23 | 1.91 |
| C | Hatch | 997 | 530 | 1,527 | 54.8 | 0.63 | 0.36 | 0.58 |
| D | Catawba | 1,193 | 820 | 2,013 | 60.5 | 0.77 | 0.49 | 0.65 |
| E | McGuire | 1,324 | 995 | 2,319 | 59.0 | 0.14 | 0.07 | 0.17 |
| F | Brunswick | 890 | 1,076 | 1,966 | 54.3 | 0.79 | 0.28 | 0.61 |
| G | Shearon Harris | 875 | 833 | 1,708 | 55.4 | 0.43 | 0.21 | 0.31 |
| H | Watts Bar | 1,465 | 3,363 | 4,828 | 51.3 | 0.61 | 0.36 | 0.68 |

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

Subversions and Adulteration

- 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)
More than 1.7 million tests from January to December 2012

| SVT Category | 2008 | 2009 | 2010 | 2011 | 2012 |
|-----------------------|-------|-------|-------|-------|-------|
| Acid-Base | 0.02% | 0.03% | 0.03% | 0.03% | 0.03% |
| Invalid | 0.11% | 0.09% | 0.09% | 0.09% | 0.11% |
| Oxidizing Adulterants | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |
| Substitution | 0.05% | 0.06% | 0.06% | 0.06% | 0.05% |

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

(For General U.S. Workforce, as a percentage of all non-negatives)
More than 5 million tests from January to December 2012

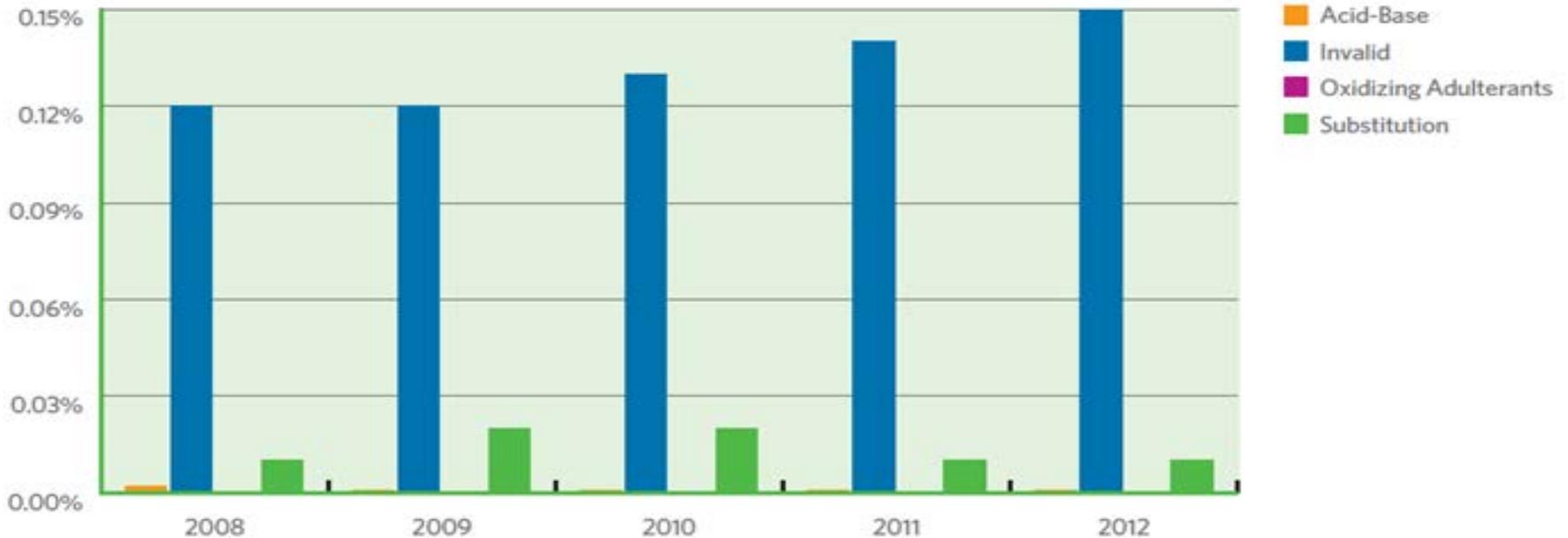
| SVT Category | 2008 | 2009 | 2010 | 2011 | 2012 |
|-----------------------|--------|--------|--------|--------|--------|
| Acid-Base | 0.002% | 0.001% | 0.001% | 0.001% | 0.001% |
| Invalid | 0.12% | 0.12% | 0.13% | 0.14% | 0.15% |
| Oxidizing Adulterants | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |
| Substitution | 0.01% | 0.02% | 0.02% | 0.01% | 0.01% |

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



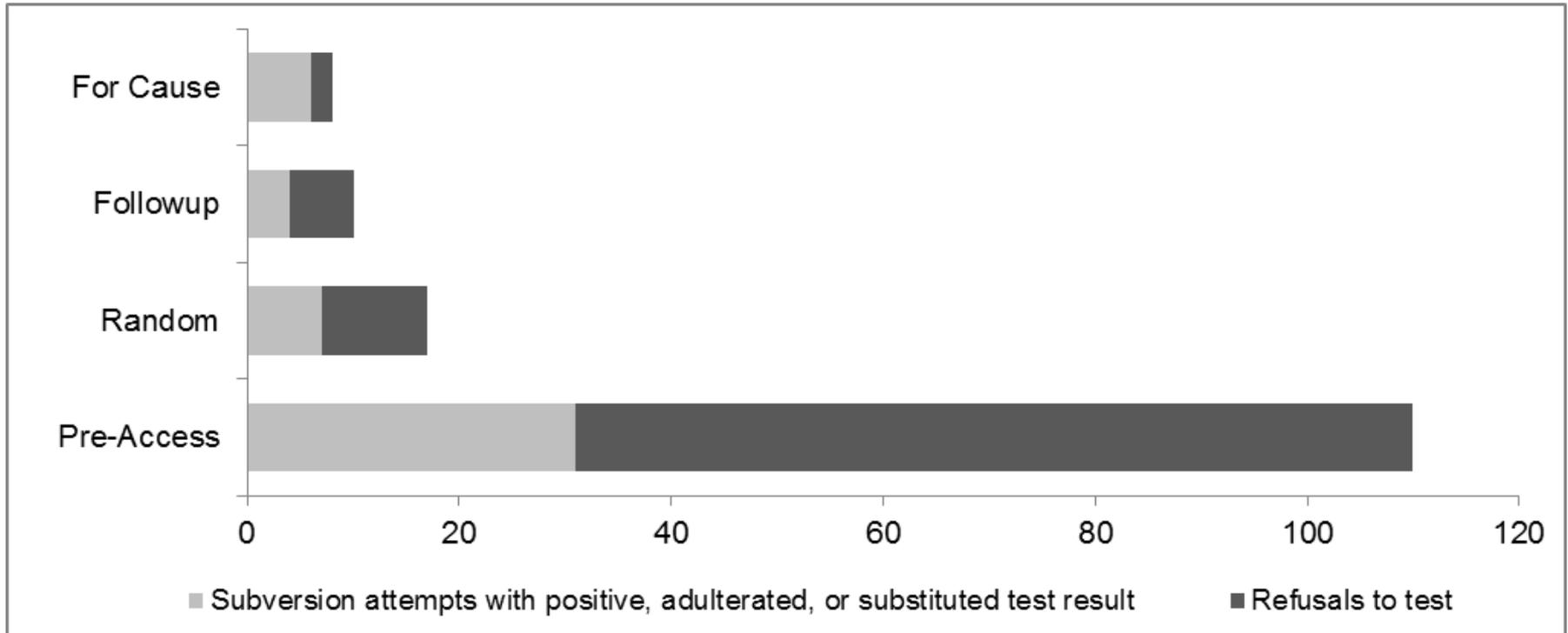
More than 5 million test results from January to December 2012

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

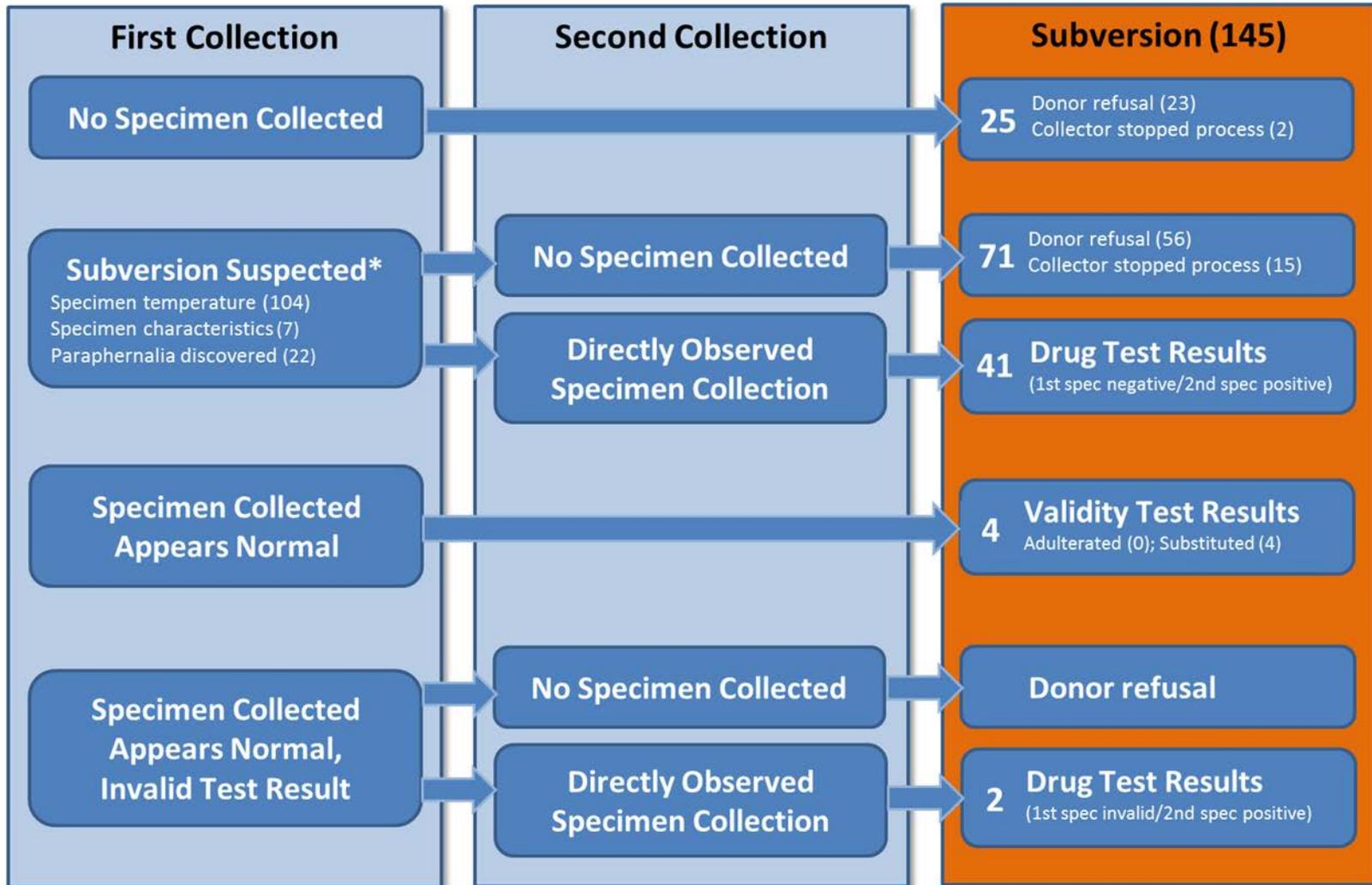
Things We Need

- 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



The Subversion Matrix (CY2013) - DRAFT



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

Temperature Profile



United States Nuclear Regulatory Commission

Protecting People and the Environment

| | | | | | | |
|-----------------------------------------------------------|---------------|----------|---------------------------------|-----------------------------|-----------------------------------------------------------|----------------------------|
| Room Temp | 68 F | 20 C | Sample Bottle Properties | | Room Temp | 20 C |
| | | | Material | HD Polyethylene | | |
| Body Temp | 98.8 F | 37.111 C | Size | 100 ml | Body Temp | 37.11111111 C |
| | | | Thickness | 1.3 mm | | |
| Sample Fill Line | 30 ml | | Height | 75 mm | | |
| | | | Width | 53 mm | Total Contact Area of sample | 0.004375989 m ² |
| Min Sample Temp | 90 F | 32.222 C | Density | 0.93 g/cm ³ | Min Sample Temp | 32.22222222 C |
| | | | Specific Heat Cap | 1.55 J/(gK) | Contact Area of Wall of Cup | 0.002380952 m ² |
| | | | k | 0.465 W/(mK) | Contact Area of Top and Bottom of Cup (rt angle cylinder) | 0.001995037 m ² |
| Urine Temp after Sample Supplied into Cup | 98.80462035 F | 37.114 C | Thermal Diffusivity | 3.23E-03 cm ² /s | | |
| | | | k Table | 0.25 W/(mK) | | |
| LID Added (1=yes, 0=NO) | 1 | | h Urine | 500 W/(m ² K) | Inner Radius Cup | 0.0252 m |
| NOTE: Assume Lid is same material and thickness as bottle | | | h Air | 60 W/(m ² K) | Volume of Fluid | 0.00003 m ³ |
| Resting Surface Table (1=Metal, 0=Other) | 0 | | k Urine | 0.6 W/(mK) | Height of Fluid | 0.015037315 m |
| | | | k Air | 0.025 W/(mK) | Outer Cup Radius | 0.0265 m |
| | | | Specific Heat Cap Urine | 4.18 J/(gK) | | |
| | | | Density Urine | 0.985 g/cm ³ | Shape Factor (Disk) | 0.106 m |
| Time before Sample is no longer good For Testing | 3.022607923 | Mins | Thermal Resistance Wall | 8.984909712 K/W | | |
| | | | Thermal Resistance Top | 10.75787848 K/W | Lump Capacitance Determination | |
| | | | Thermal Resistance Bottom | 40.13966359 K/W | Bi(Wall) | 0.103131898 |
| | | | Total Thermal Resistance | 0.229165869 W/K | Bi(Bottom) | 0.049458545 |
| | | | | | Bi(top) | 0.12 |
| | | | Energy Losses | 11.6541046 W | | |

Questions?