

Presentation for Nuclear Energy Institute

Fitness for Duty Programs

Drug and Alcohol Testing

at

Commercial Nuclear Power Plants and Fuel Facilities

“A Direct Contribution to Safety and Security”

Paul Harris, US NRC
Chicago, IL
July 18-20, 2011

Enclosure 1

1

Presentation for Nuclear Energy Institute

**Proposed Rulemaking
HHS Guidelines
and other Technical Issues**

Paul Harris, US NRC
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July 18-20, 2011

Discussion Topics

HHS Guidelines

- Background
- Items proposed for Direct Final Rulemaking – Handout #1
- Items proposed for Normal Rulemaking – Handout #2
- Items not proposed for rulemaking – Handout #3
- Questions and Answers

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Background

HHS Guidelines

10 CFR Part 26

1989 previous rule published

1995 proposed rule published for comment

2000 public meeting – the “new” was not so “new” any more

2008 published current rule, over 600 pages long with 100,000 pages of supporting documentation

HHS Guidelines

1986 Executive Order 12564 (51 FR 32889)

1988 Public Law 100-71, Section 503; U.S.C. 7301

2008 Most recent HHS Guidelines published

Previous revisions were: 1988, 1994, 1997, 1998, & 2004

40 CFR Subparts F & G et.al.

2010 current rule published

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Background (cont.)

HHS Guidelines

HHS Guidelines Change Categories

1. Drug testing panel and cutoffs
2. Processes, training, editorials, and clarifications
3. Establishment of the initial instrumented test facility (IITF)
4. Collectors – roles, responsibilities, & certification
5. Medical Review Officers – roles, responsibilities, & certification
6. Point of collection, hair, oral fluid, and sweat patch testing were deferred

Note: Regarding Bullet 6, proposed guidelines were published on April 13, 2004 (69 FR 19673).

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Handout #1

HHS Guidelines

Changes Being Considered for Direct Final Rulemaking (summary)

1. Drug testing panel and cutoffs
2. Definitions: Cancelled test Federal COC form Rejected for Testing
Carryover Chain of Custody (CoC) Certifying Scientist
3. Require LOD testing for low creatinine dilutes (2-5 mg/ml)
4. 9.x pH issue regarding time & temperature (9.0 – 9.5 pH)
5. Require LOQ (rather than LOD) testing for adulterant testing
6. Updating of Collector, MRO, and Certifying Scientist responsibilities
7. MRO documentation of donor's request to split a specimen
8. Notification on spilt samples (immediate recollection and no notice)
9. Blind performance test lots – expiration date set by manufacturer
10. Discard any collected specimen if the person then refuses to test

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Handout #2

(Tables 2A and 2B)

Part 26 Changes

Changes Being Considered for Normal Rulemaking (summary)

1. Synthetic opiates, address legitimate medical use
2. Drug cocktailing & prescription shopping
3. Synthetic urine considerations
4. Reportability of Certified Fuel Handlers
5. Alcohol testing – Blanking the Blow (26.95)
6. QV/QC req's for initial drug & validity tests
7. > 5-day shy bladder – removal of authorization
8. Split specimen testing with a 26.719 notification
9. Clarify “controlled substance” & “illegal drug”
10. Strengthen the Policy Statement, syn-marijuana
11. Allow limited DOT collections
12. Use of another's prescription
13. Clarify test notification procedure
14. Require LOD testing if dilute
15. Annual reporting descriptions
16. Protection of Information (litigation)
17. Specify Refusal-to-Test actions
18. Part 55 conforming changes
19. 0.30 BAC and < 1 hour issue
20. Apply FFD SF handling (ISFSI, et al)

Handout #2 (cont.)

Part 26 Changes

Changes Being Considered for Normal Rulemaking (summary)

21. Recordkeeping of negative BAC breath strips
22. Nitrite and opiate assays & published precisions – ensure accuracy
23. Clarify pre-work 5-hour abstinence requirements
24. Enhance self-discloser statements and actions (e.g., those in 26.77)
25. Require mandatory removal of authorization for LTF positive initial drug results
26. Clarify 26.111(d) to test an OOS temp specimen & why the LTF exclusion?
27. Conforming change for cyber protection (disaster recovery), 26.153(f)(3) & 26.711(b)
28. Require an escort for a for-cause and post-accident testing to prevent subversion
29. Describe that an MRO-directed alternative test (e.g., blood testing) is a Federal test
30. Clarify subversion procedures if the 1st specimen is OOS temperature and 2nd is positive

Handout #3

HHS Guidelines

Changes in the guidelines we intended not to pursue (summary)

1. Revision of names and/or definitions

alternate responsible person/technician	failed to confirm	negative result
initial validity test	QC sample	confirmatory validity test
dilute specimen	PT sample	cutoff
LOD & LOQ		

2. Removal of the terms: follow-up, non-negative, post-accident, random, reasonable suspicion, and return-to-duty tests

3. Donor option to request to use alternate HHS lab for testing Bottle B

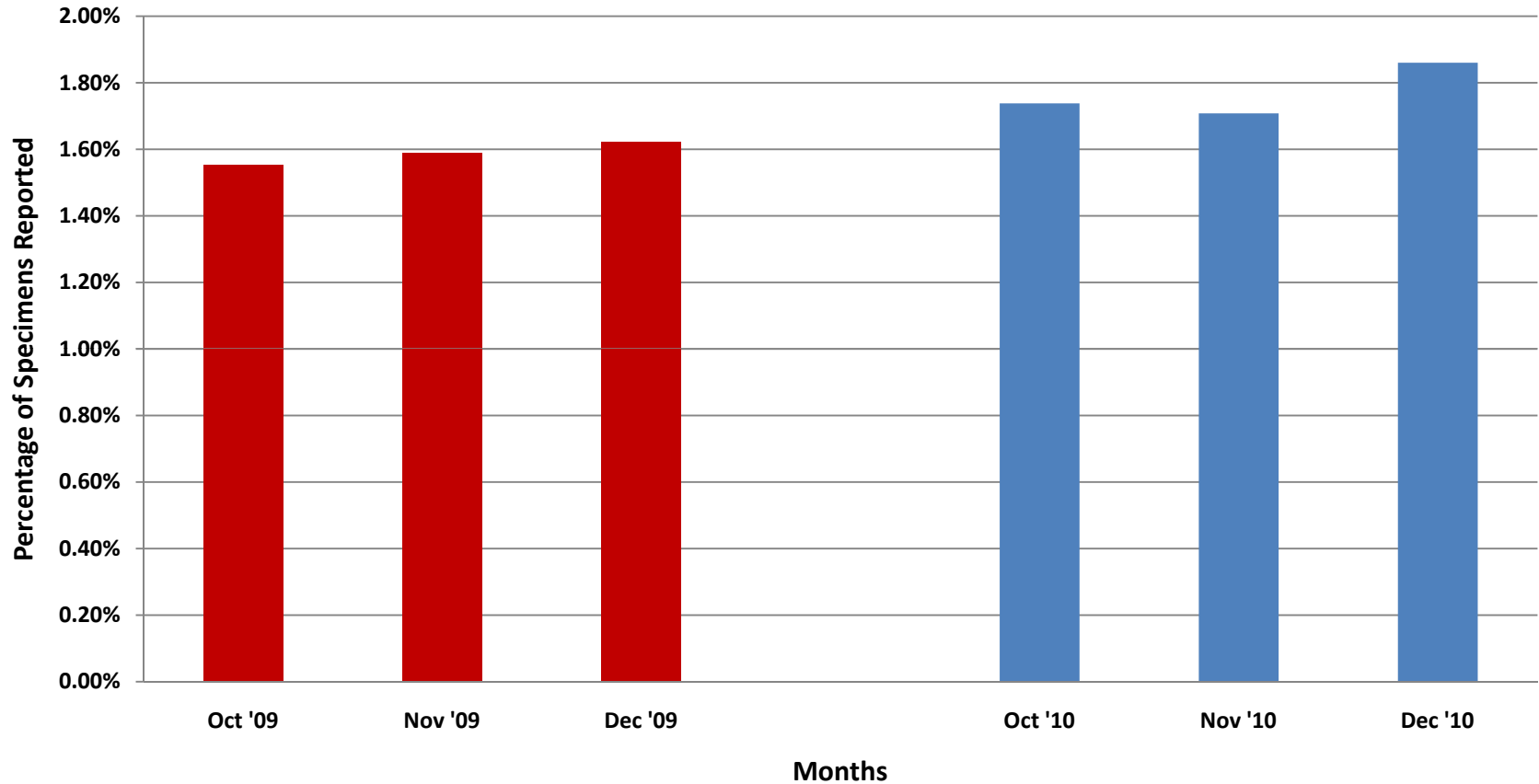
4. Train the collector trainer requirements

5. Supervisor must concur on Direct Observation collection of specimens their employees

HHS/SAMHSA Drug Data

(Positive, adulterate, invalid, or substituted)

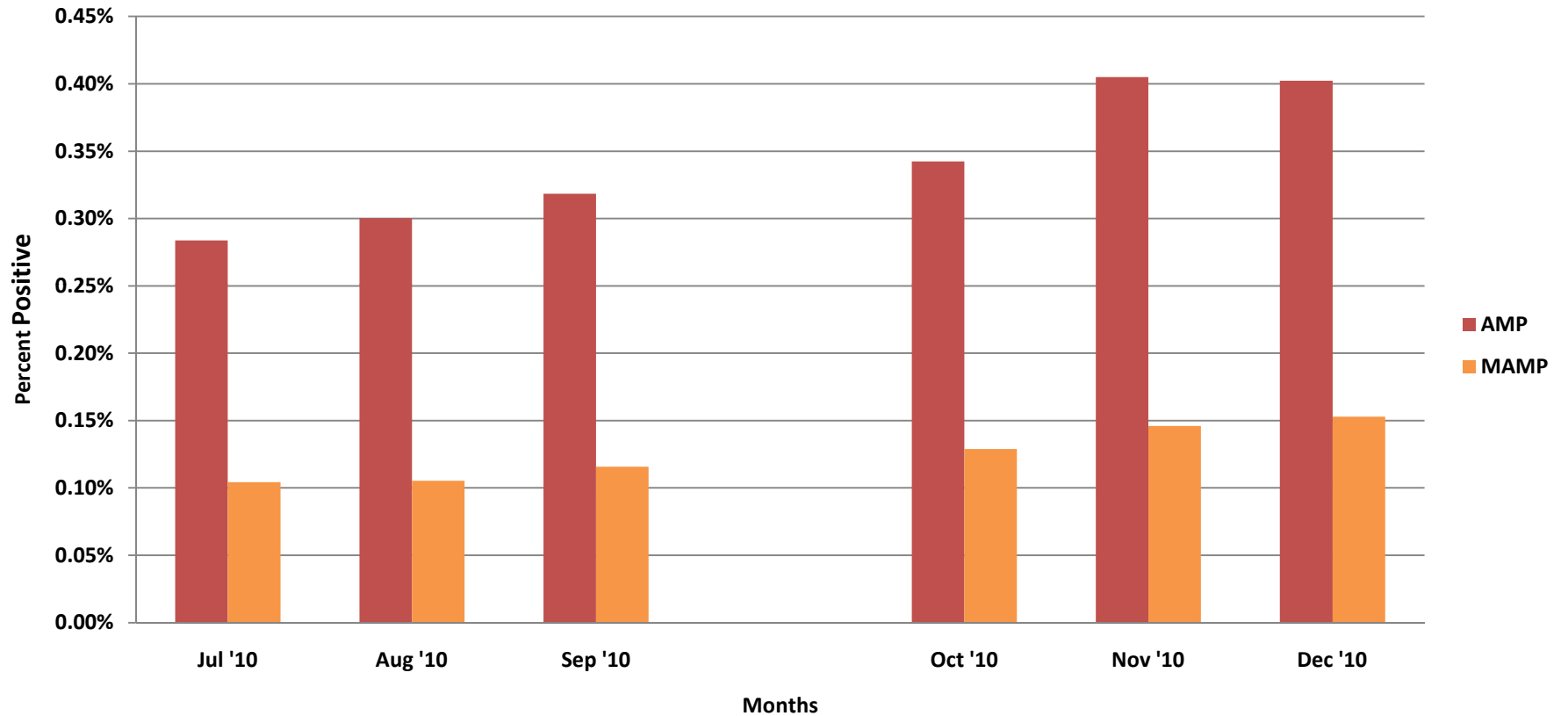
Before & After



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HHS/SAMHSA Drug Data (Methamphetamine & Amphetamine)

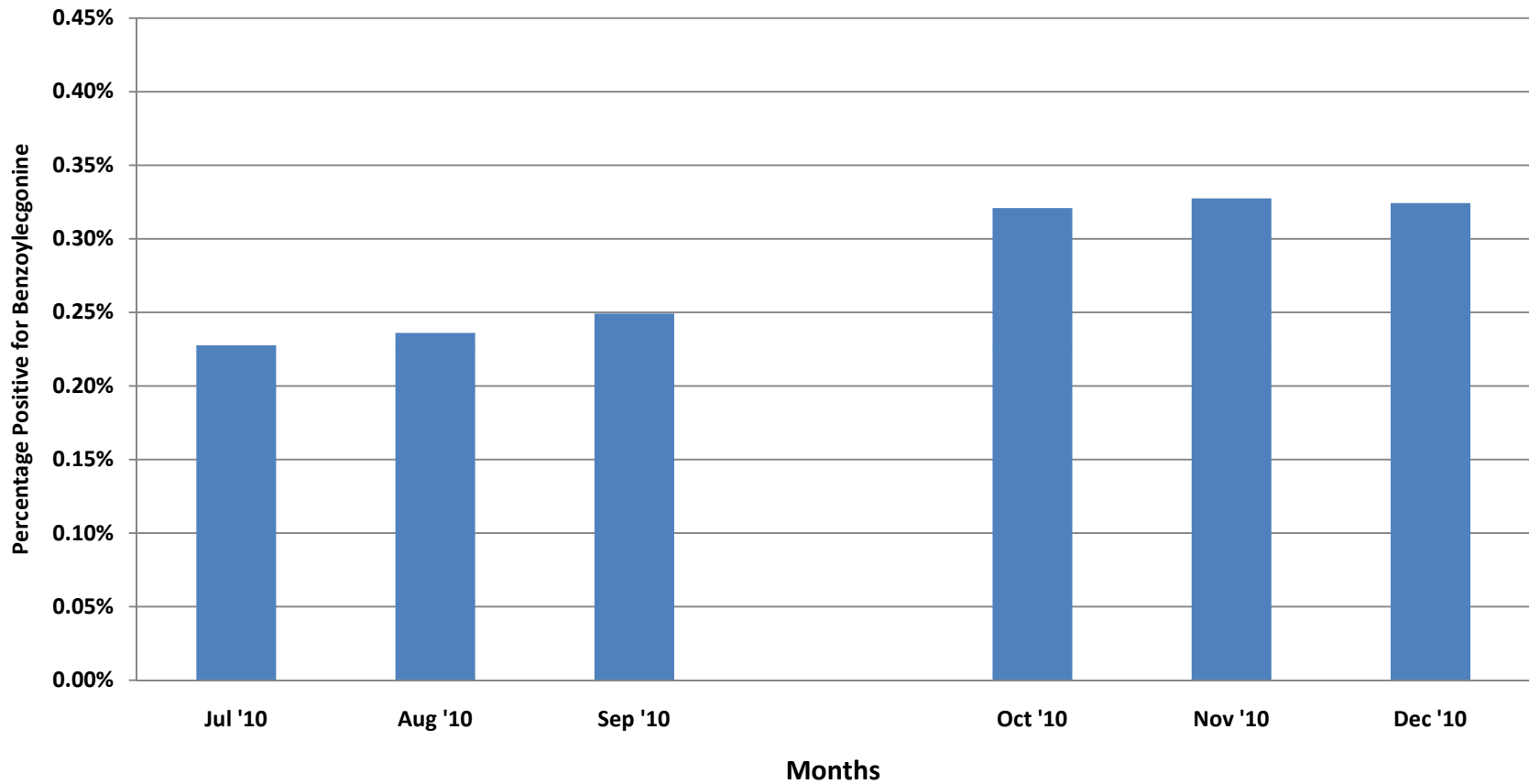
Before & After



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HHS/SAMHSA Drug Data (Benzoylcegonine)

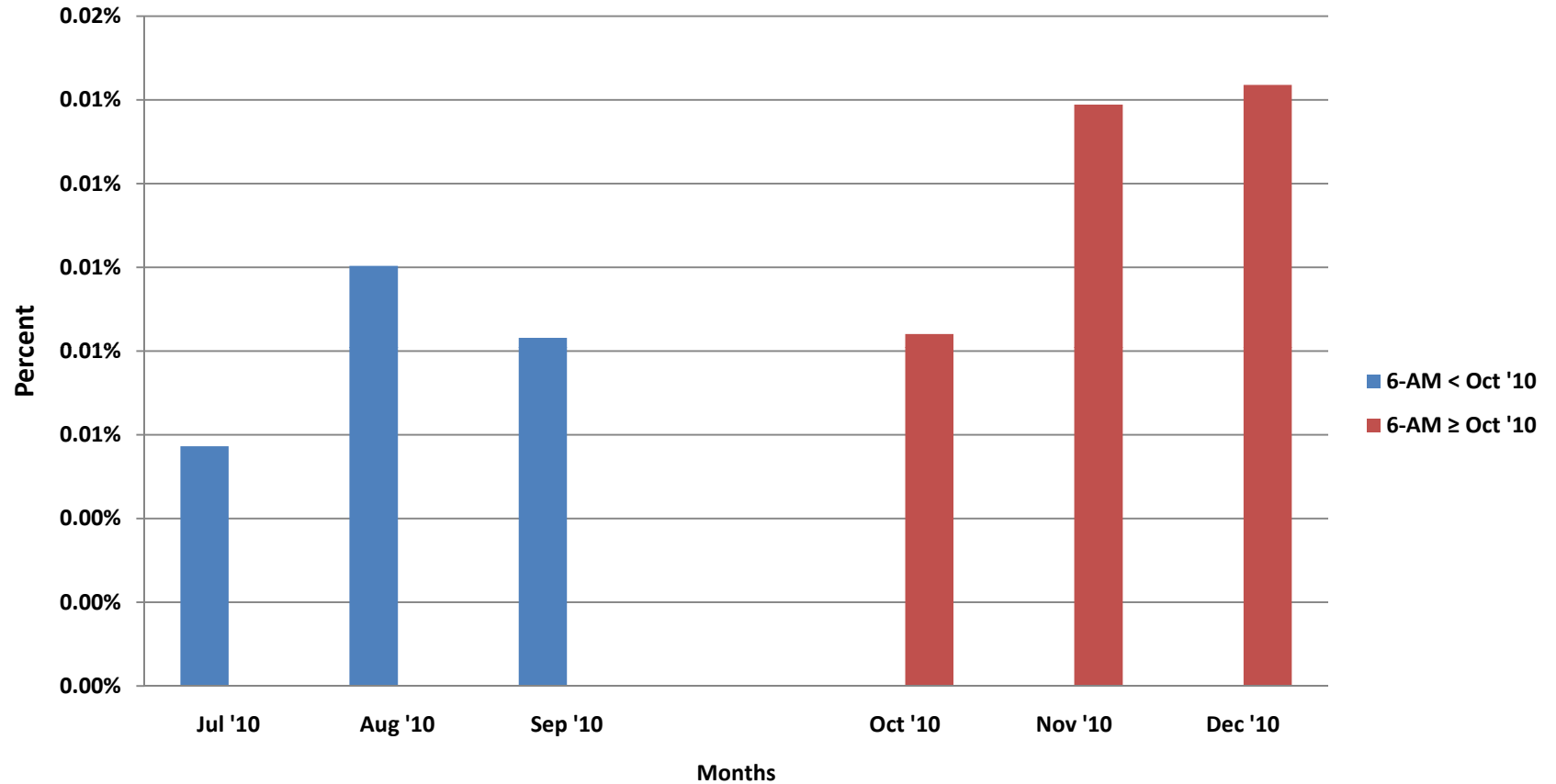
Before & After



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HHS/SAMHSA Drug Data (6-acetyl morphine)

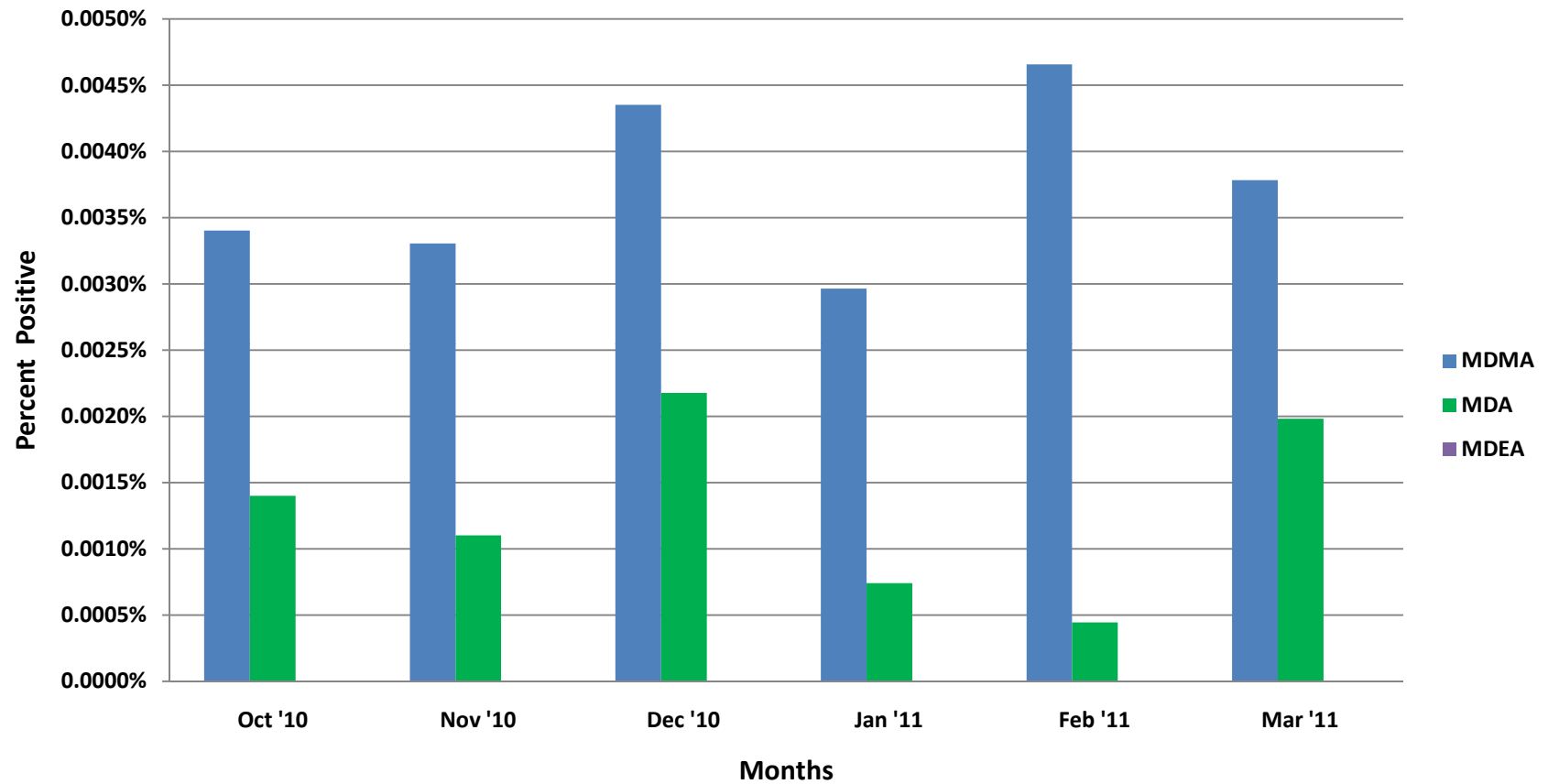
Before & After



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HHS/SAMHSA Drug Data (Ecstasy)

Before & After



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HHS/SAMHSA Drug Data

(summary)

Before & After

- ❑ After the implementation of the revised Guidelines on October 1, 2010, there were:
 - Reduction in the number of specimens tested (5.4%)
 - Increase in the percent of specimens reported as positive
- ❑ The major drugs responsible for the increase in the percent of specimens reported positive were those whose cutoffs were lowered:
 - Cocaine
 - Amphetamine
 - Methamphetamine
- ❑ Smaller increases were observed in 6-AM and codeine

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Fitness for Duty
Status of Regulatory Issues

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Discussion Topics

Regulatory Issues

- NEI 06-06, rev. 5
- Chapter 13.7 for NUREG 0800
- CYs 2009 and 2010 FFD Performance Data
- Behavioral Observation Assessment
- Performance Indicators
- Drug Testing Advisory Board, May 3, 2011
- Rulemaking
 - HHS Guidelines
 - Technical Issues Rulemaking
- e-Reporting

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Status of Regulatory Issues

- NEI 06-06, rev. 5
 - NRC Office of Regulatory Research technical review of rev. 5 s completed
 - Additional guidance identified for inclusion; industry efforts to propose rev. 6
 - Upon receipt of rev. 6, NRC will hold a public meeting to discuss changes
- Chapter 13.7, Fitness for Duty Programs
 - Technical write up completed
 - Chapter 13.7 is written for operating reactors and reactors under construction
 - NUREG-800, the standard review plan for reactor construction will be updated
- Behavioral Observation Programs (BOP)
 - Focuses on reactor construction
 - Oak Ridge National Laboratory review of best practices, publication as NUREG/CR
 - E.g., BOP for construction biased towards safety- and security-significant activities
- Performance Indicators (PI)
 - Originally 3 Pis – two removed
 - Consistent with the Reactor Oversight Process to risk-inform the inspection process

Status of Regulatory Issues

■ Drug Testing Advisory Board

- U.S. Department of Health and Human Services' federal advisory board
- Reviewing e-Fed COC forms & oral fluids (OF); OF reviews will delay hair testing
- Discussed synthetic opiates, electronic Federal Control and Custody forms

Some other discussion items

Is OF collection a privacy issue?

Are there scientific markers of OF validity on the market?

Are adulterate, cutoff, invalid substituted, dilute, etc. appropriate descriptions?

If stimulated to obtain sufficient OF, then is it “dilute”?

Should drinking or mouth rinsing be allowed?

Should the oral cavity be inspected? If so, is this an observed collection?

For split sampling: is is serial or simultaneous collection?

OSHA considers OF a bio-hazard. (alcohol saliva devises are not bio-hazards)

Should OF fluid devices be FDA cleared?

Device needs to collect >95% but not more than 120% of the drug/metabolite

Device needs to deliver/release 80% into the test

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Status of Regulatory Issues (cont.)

■ Rulemaking

HHS Guidelines

- High Priority rulemaking
- Proposing to go to Direct Final Rulemaking
- Proposed Public Meeting – mid-September, 2011

Part 26 Technical Issues

- High Priority rulemaking
- Proposing to go normal rulemaking route
- Incorporates HHS Guideline, FAQ, and other technical issues
- Budgeted for 2012 - 2014

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Fitness for Duty
Electronic Reporting (e-Reporting)
of
FFD Performance Data

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e-Reporting

Regulatory Issues

- Voluntary e-reporting system, consistent with §26.11
- Developed with industry input
- Beta-test years: 2009 and 2010
- Current results represent 63% of facilities & entities
- Current data have not been thoroughly validated for accuracy
- Hard copy report data not in presentation at this time
- We will disable the “FFD Portal” submission method
 - Licensees will need to use the “General Portal”

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e-Reporting

Regulatory Issues

- Staff Review of e-Submissions
 - Routine staff acceptance review (10 CFR 26.11)
 - Not part of an inspection or a licensing review
 - Staff positions based on its QA/QC review
- No “requirement” for licensees to implement or respond
- All Submissions are Official records
 - Subject to inspection
 - Must not contain personally identifiable information
 - Publicly available

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e-Reporting

Regulatory Issues

Personally Identifiable Information

- Unique Identifier

■ 2011- NRC – pwh001	Initials w/occurrence #	PII
■ 011 – NRC – ph1234	Initials w/last 4 SSNs	Questionable
■ 2011 – NRC – HQ5456	Site Badge Number	PII

- Please use only your company email address

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e-Reporting Pros & Cons

■ Pros

- Ability to perform detailed drug & alcohol analysis
- Consistency
 - Clear & unambiguous reporting requirements
- Effectiveness
 - Performance-based regulation – inform the inspection process
 - Timely trend analysis (e.g., monthly updates with quarterly postings)
- Efficiency
 - “fill-in-the-blank” forms – simplicity
 - 26.717 & 26.719 integration

■ Cons

- Start-up burden (e.g., procedures, computers, etc)
- Periodic reporting
- Un-informed Statements or Conclusions (USCs)

E-reporting Analysis

Unique occurrence designator
Collection date
Employment type (employee or C/V)
Test type (pre-access, for-cause, etc)
Labor category (ops, maintenance, etc)
Substance(s) detected
Validity and temperature results
Descriptive (subversion, FTFP, adulteration, etc.)
Refusal action description (if any)
Administrative actions taken (if any)

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Successes

- e-Reporting
 - More than doubled participation
 - We have informed the inspection process (planned updating of the Insp. Proc.)
 - Strong steps towards performance-based regulatory oversight
- Budgets and Staffing
 - Staff augmentation
 - Contracted expertise (ICF International, Inc.)
- Communication
 - Thank you for all the calls and emails
 - Thank you for the professionalism

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Fitness for Duty

Frequently Asked Questions

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Discussion Topics

- Background
- FAQ Performance
- Process Improvements
- Next Steps

FAQ Process

Frequently Asked Questions

■ Background

- FAQ initiative was to answer questions from the new rule
- Answers have transcended to be *defacto* inspection or policy guidance
- Original intent was to “turn-off” FAQ portal after two years (December 2010)

■ FAQ Performance

- Internal metrics have not been met

■ Process Improvements

- Procedure developed
- Administrative help assigned
- Contracted expertise (ICF International)

■ Next Steps

- Develop regulatory guidance to formalize the answers to FAQs (endorse NEI guidance?)
- Integrate FAQs into rulemaking as needed.

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Fitness for Duty
Calendar Years 2009 and 2010
Performance Data

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E-Reporting Summary

(CYs 2009 & 2010)

	CY 2009	CY 2010 *	Change
Reporting Facilities	19	47	+ 28
Industry Participation	25%	63%	+ 38%
Tests Conducted by EIE reporting licensees	46,162	106,443	60,281
Positive Results Reported	290	648	+ 358

* CY 2010 results draft (as of 4/29/11)

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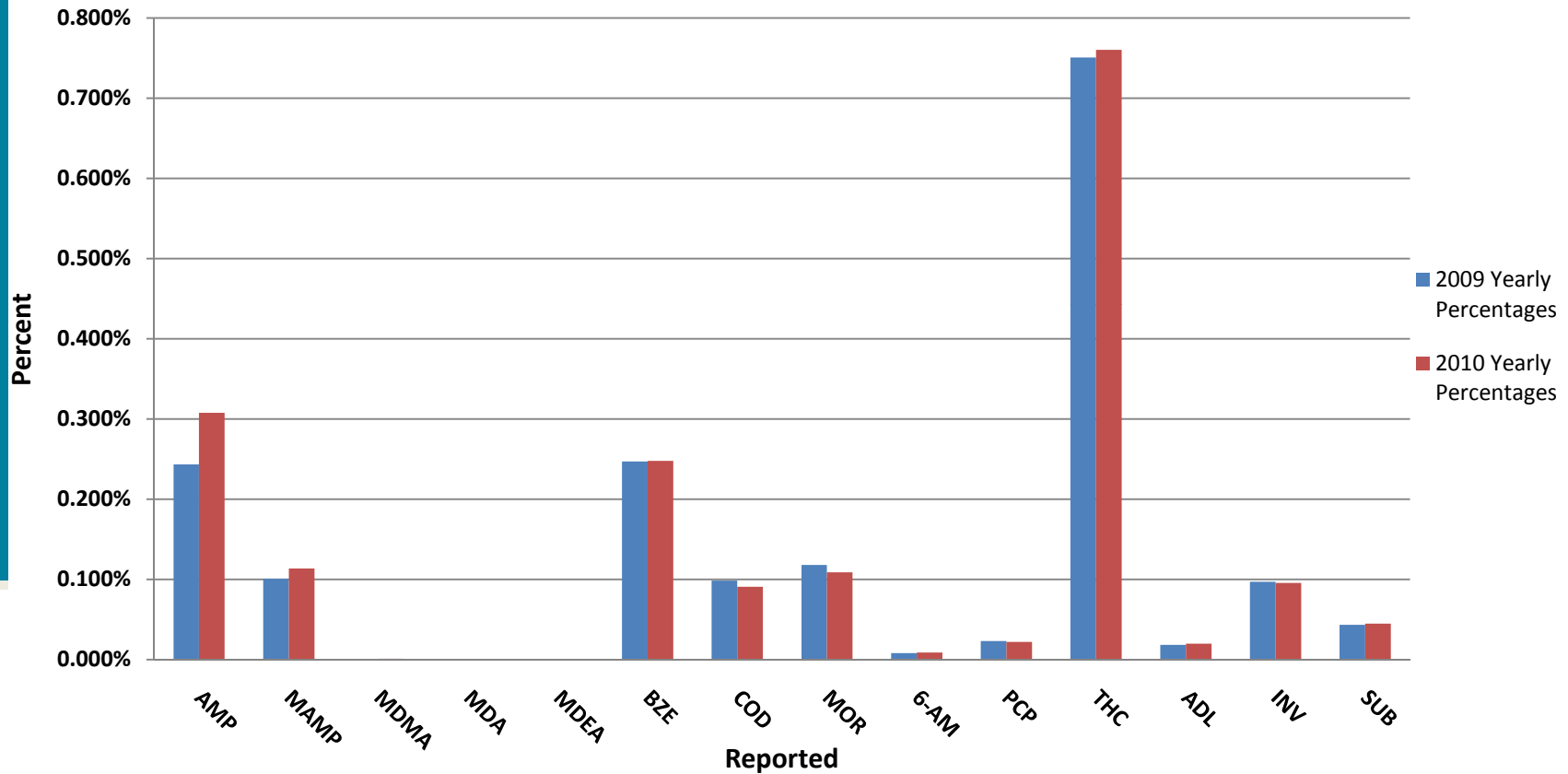
NRC Drug and Alcohol Testing Results (2005-2009)

Type of Test	2005	2006	2007	2008	2009
Pre-Access					
Number Tested	79,005	79,980	81,932	87,468	95,878
Number Positive	648	747	668	664	677
Percent Positive	0.82%	0.93%	0.82%	0.76%	0.71%
Random					
Number Tested	50,286	52,557	51,665	54,759	60,877
Number Positive	147	132	117	127	154
Percent Positive	0.29%	0.25%	0.23%	0.23%	0.25%
For Cause					
Number Tested	671	716	720	797	547
Number Positive	105	104	81	94	108
Percent Positive	15.65%	14.53%	11.25%	11.79%	19.74%
Post-Event					
Number Tested	490	905	895	986	893
Number Positive	1	5	10	7	1
Percent Positive	0.20%	0.55%	1.12%	0.71%	0.11%
Followup					
Number Tested	4,057	4,766	4,991	5,756	6,252
Number Positive	31	37	31	44	53
Percent Positive	0.76%	0.78%	0.62%	0.76%	0.85%
TOTAL*					
Number Tested	134,509	138,924	140,203	149,766	164,447
Number Positive	932	1,025	907	936	993
Percent Positive	0.69%	0.74%	0.65%	0.62%	0.60%

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HHS/SAMHSA Drug Data (2009-2010)

Overall



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DOT Drugs & Test Conditions

Laboratory Drug Testing Data 2005 - 2010

I. Positive Drug Testing:

	2005 Full Year	2006 Full Year	2007 Full Year	2008* July-Dec	2009* Full Year	2010* Full Year
Total Results	7,145,907	7,542,360	6,568,447	2,850,106	5,163,165	5,463,833
Positives	143,993	136,724	136,908	46,858	77,865	84,211
% Positives	2.02%	1.81%	2.08%	1.64%	1.51%	1.54%
Drug Types as Percentage of all Positives						
Amphetamine	14.66%	12.82%	17.54%	16.09%	18.23%	21.67%
Cocaine	26.84%	28.48%	23.32%	19.19%	16.59%	16.17%
Opiates	7.81%	8.23%	10.05%	11.52%	12.83%	10.94%
PCP	0.91%	1.18%	1.21%	1.76%	1.70%	1.52%
THC	49.77%	49.30%	47.87%	51.45%	50.66%	49.70%

II. Specimens Tampered-With:

	2005 Full Year	2006 Full Year	2007 Full Year	2008* July-Dec	2009* Full Year	2010* Full Year
Total Results	7,145,907	7,542,360	6,568,447	2,850,106	5,163,165	5,463,833
Tampered	12,349	14,199	31,554	5,106	8,421	8,901
% Tampered	.172%	.188%	.480%	.179%	.163%	.163%
As Percentage of all Tampered-with Specimens						
Adulterated	4.7%	5.3%	4.8%	9.3%	10.50%	11.27%
Substituted	22.4%	23.1%	33.5%	25.0%	27.81%	29.14%
Invalid	72.9%	71.6%	61.7%	65.7%	61.69%	59.59%

III. Other:

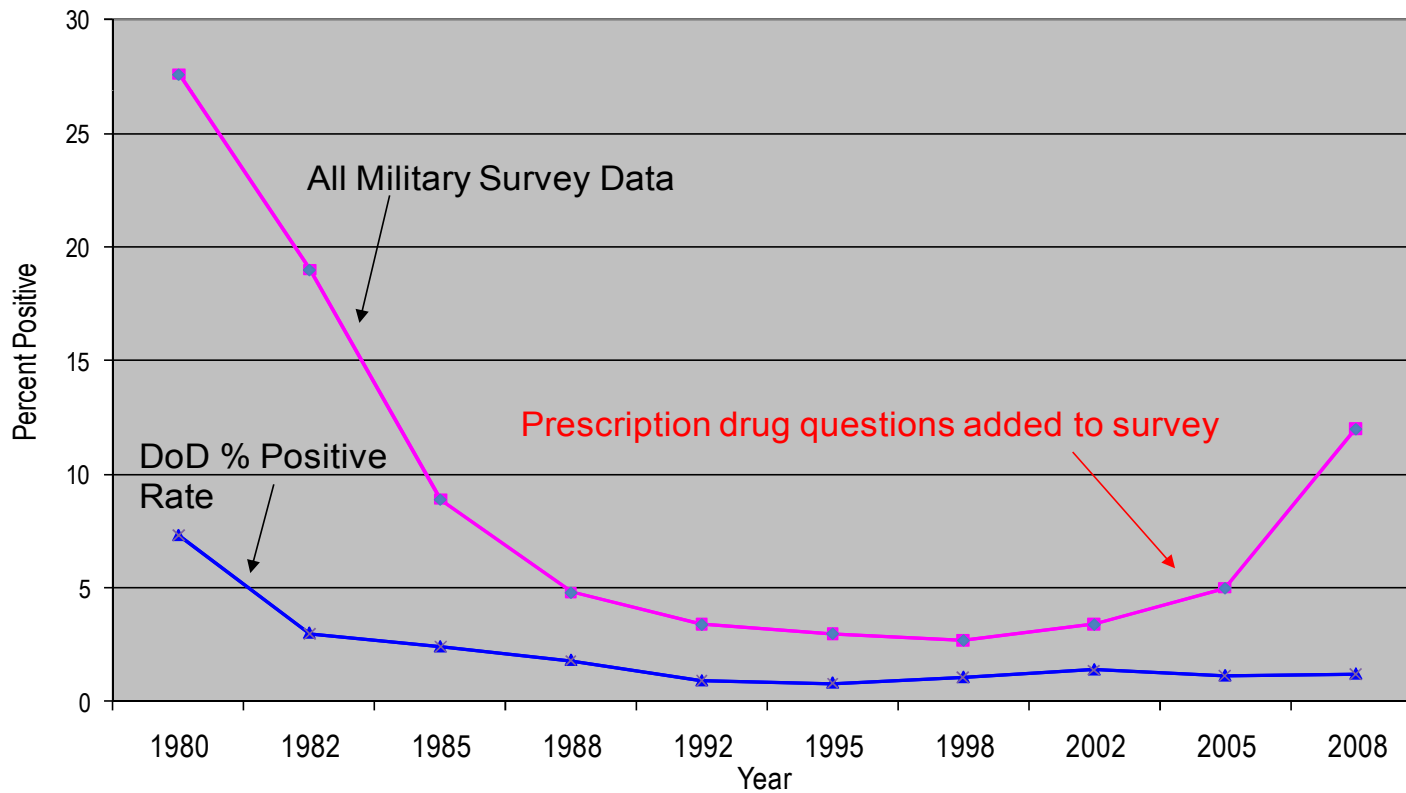
	2005 Full Year	2006 Full Year	2007 Full Year	2008* July-Dec	2009* Full Year	2010* Full Year
Total Results	7,145,907	7,542,360	6,568,447	2,850,106	5,163,165	5,463,833
Rejected	13,770	13,499	13,012	4,636	7,106	7,532
% Rejected	0.19%	0.18%	0.20%	0.16%	0.13%	0.14%

* DOT-Only Data (and 2008 only represents a 6-month period)

Dod Drugs & Opiates

DoD Fiscal Year	2006	2007	2008	2009	2010
Illicit Drug Positive Rate	1.25%	1.21%	1.20%	1.18%	1.13%
Mean Testing Ratio	1.62	1.61	1.73	1.72	1.65

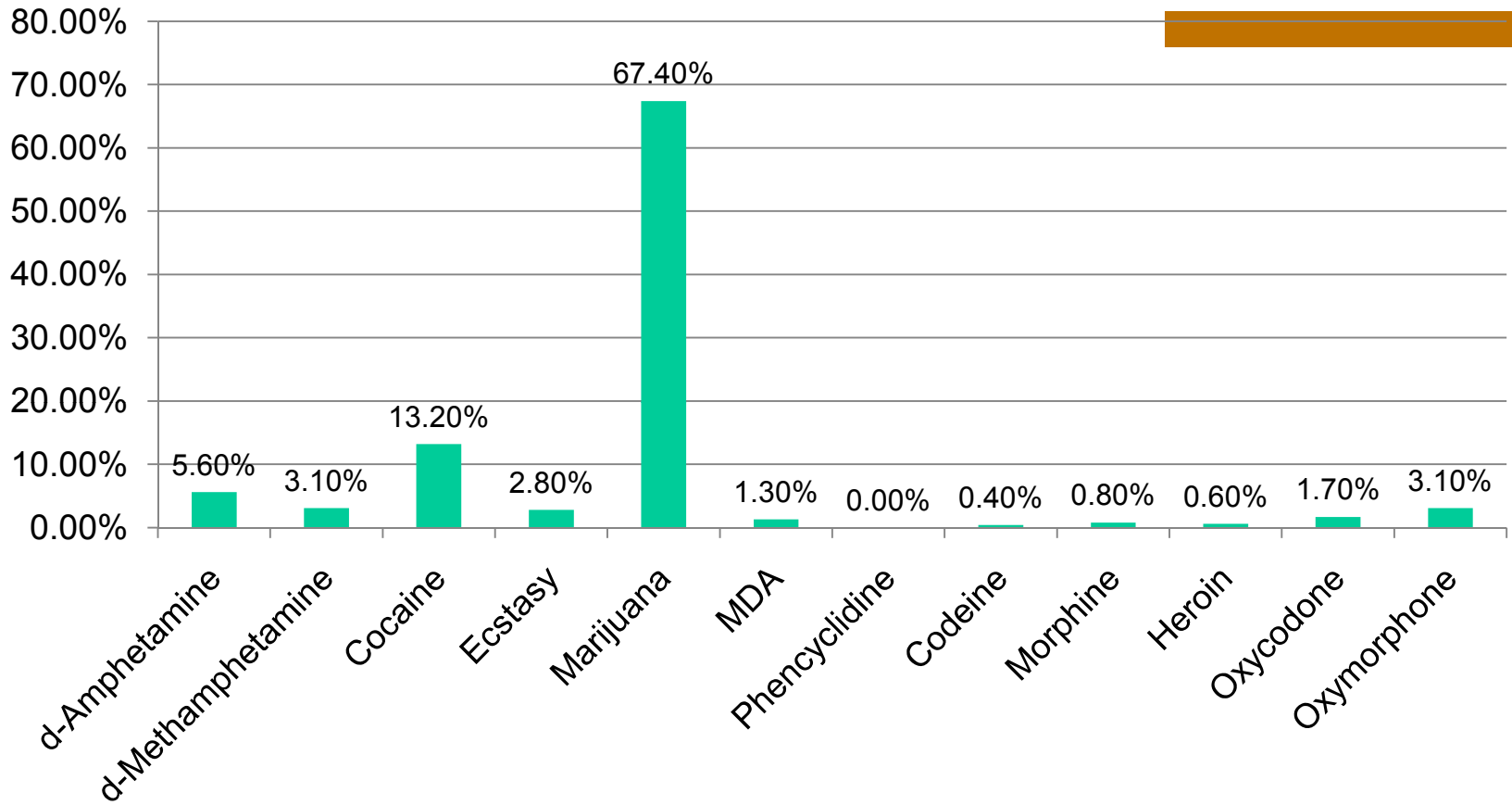
Drug Positive Rate vs Survey Data 1980 - 2008



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Kevin Klette
May'11 DTAB

Dod Drugs & Opiates



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*phencyclidine, codeine, morphine, oxycodone, oxymorphone are tested at a pulse rate of 20%.

NRC Opiate Positive Rates compared to Quest Diagnostic Data (CYs 2009 & 2010)

	2006	2007	2008	2009	Jan-Jun 2010
Federal Tests – urine	0.17	0.18	0.20	0.21	0.18
USG – urine	0.32	0.35	0.38	0.45	0.38
USGP – oral fluid	0.45	0.67	0.76	0.86	0.91
USGP – hair	0.14	0.17	0.14	0.15	0.07

		2000	2009
NRC Industry wide	Max High	0.026	- -
	Max Low		0.006

- Notes:
1. CY 2010 results draft
 2. All data presented as a percent (e.g., 17%)
 3. USGP = U.S. General Population (workforce)

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Hospital Alcohol & Opiate Data Data

(Patients with unintended injuries & positive results)

	1985 ¹	1990 ¹	1995 ¹	2000 ¹	2005 ²
Alcohol	31.1	32.5	23.3	17.7	alcohol = 15
Cocaine	2.2	4.7	11.4	8.5	1 drug = 26
Opiates	2.2	5.2	14.2	16.9	1 drug + alcohol = 12
					>1 drug = 9
					>1 drug + alcohol = 4

- Notes:
1. Gordon Smith, M.D., M.P.H, May 2011, DTAB
 2. Phase II AAP 2005
 3. All numbers in percent, %

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2009 Confirmed Positive Test Results by Substance and Work Category (All Test Types, Including Testing Refusals)

Positive Test Result	Licensee Employees		Contractors		Total	
	Number	Percent	Number	Percent	Number	Percent
Marijuana	50	31.06%	450	50.62%	500	47.62%
Alcohol	86	53.42%	175	19.69%	261	24.86%
Cocaine	14	8.70%	143	16.09%	157	14.95%
Refusal to Test*	5	3.11%	78	8.77%	83	7.90%
Amphetamines	4	2.48%	34	3.82%	38	3.62%
Opiates	2	1.24%	8	0.90%	10	0.95%
Phencyclidine	0	0.00%	1	0.11%	1	0.10%
TOTAL**	161	100.00%	889	100.00%	1,050	100.00%

* Includes adulterated and substituted validity test results and refusal to test actions.

Chart 1

2009 Positive Test Results by Substance - Licensee Employees

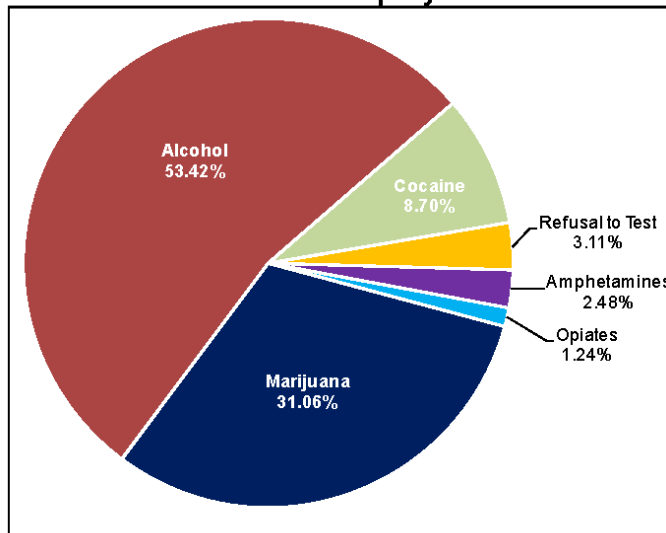
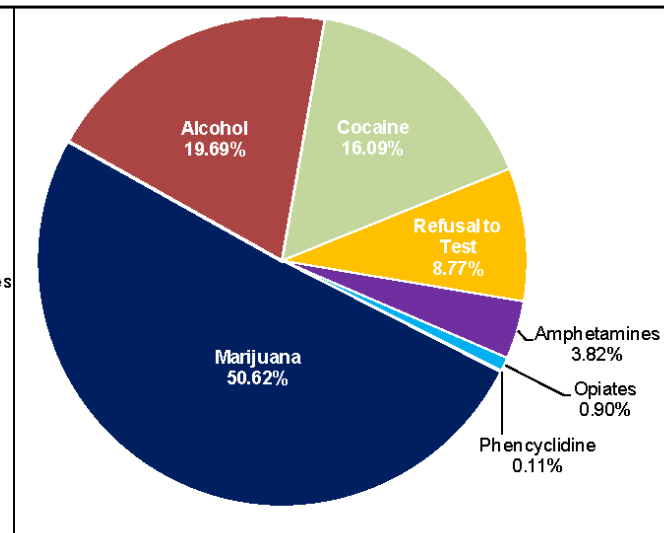


Chart 2

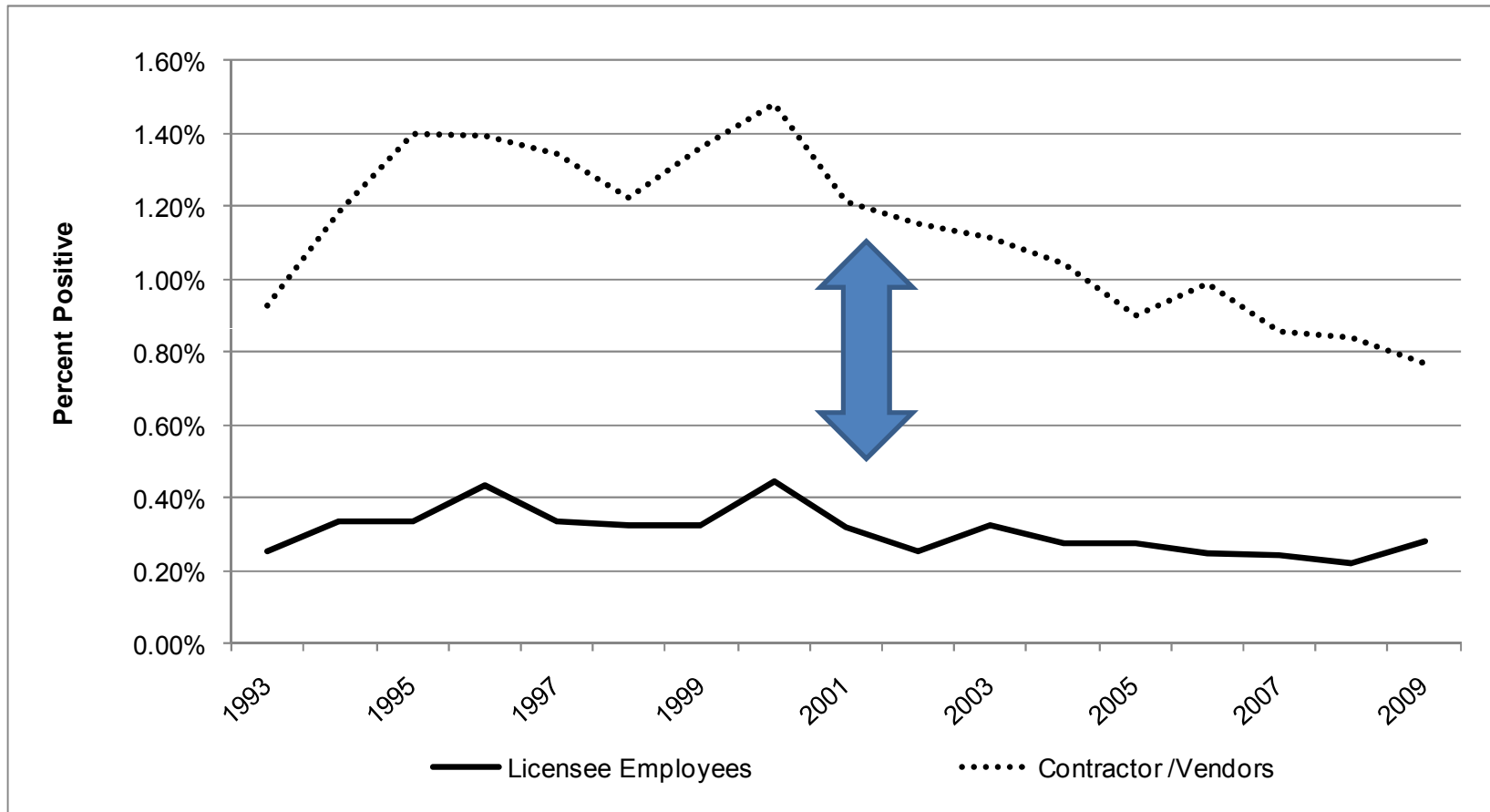
2009 Positive Test Results by Substance - Contractors



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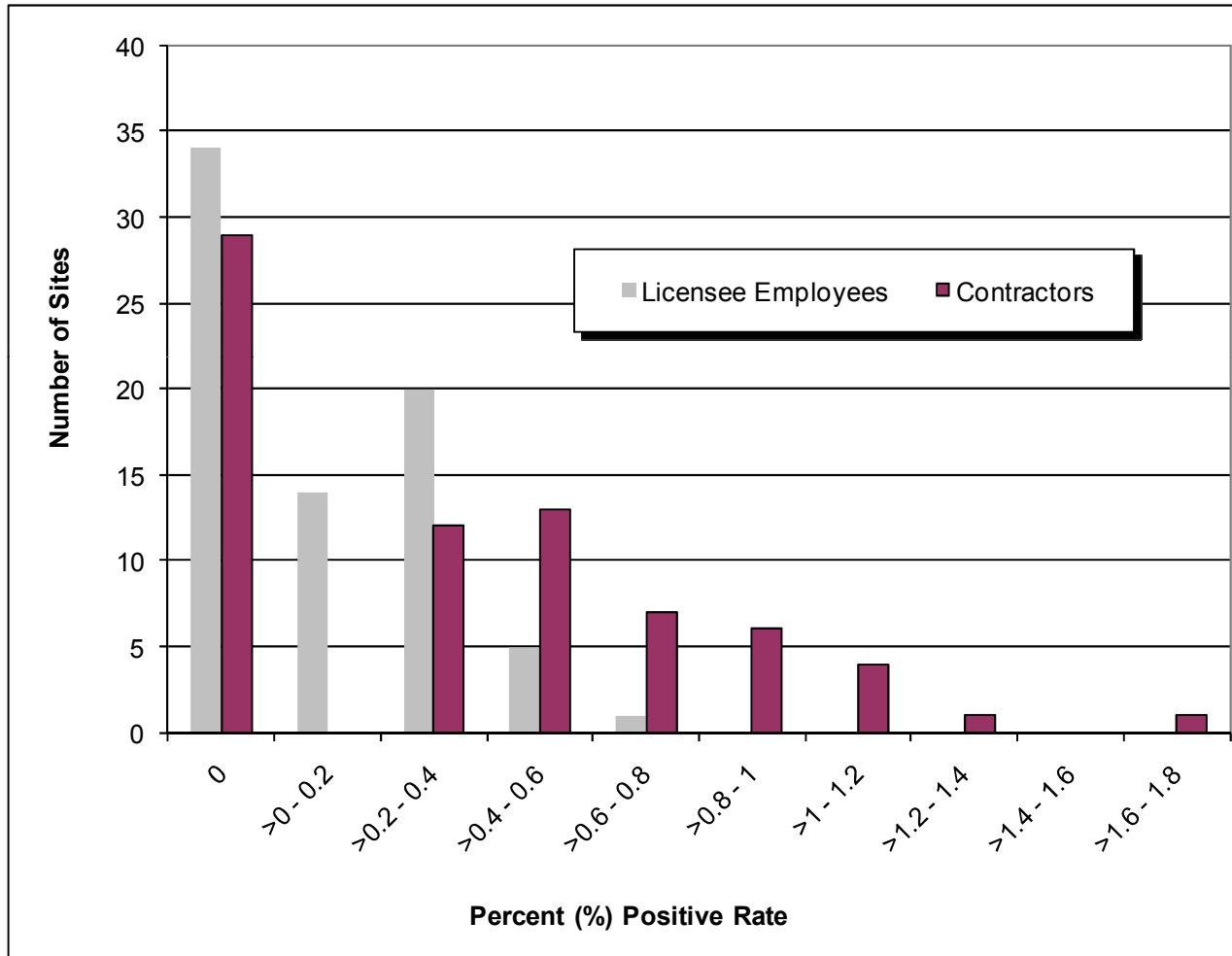
Distinct Testing Populations

Positive Testing Rates (All Test Types) by Work Category (1993 – 2009)



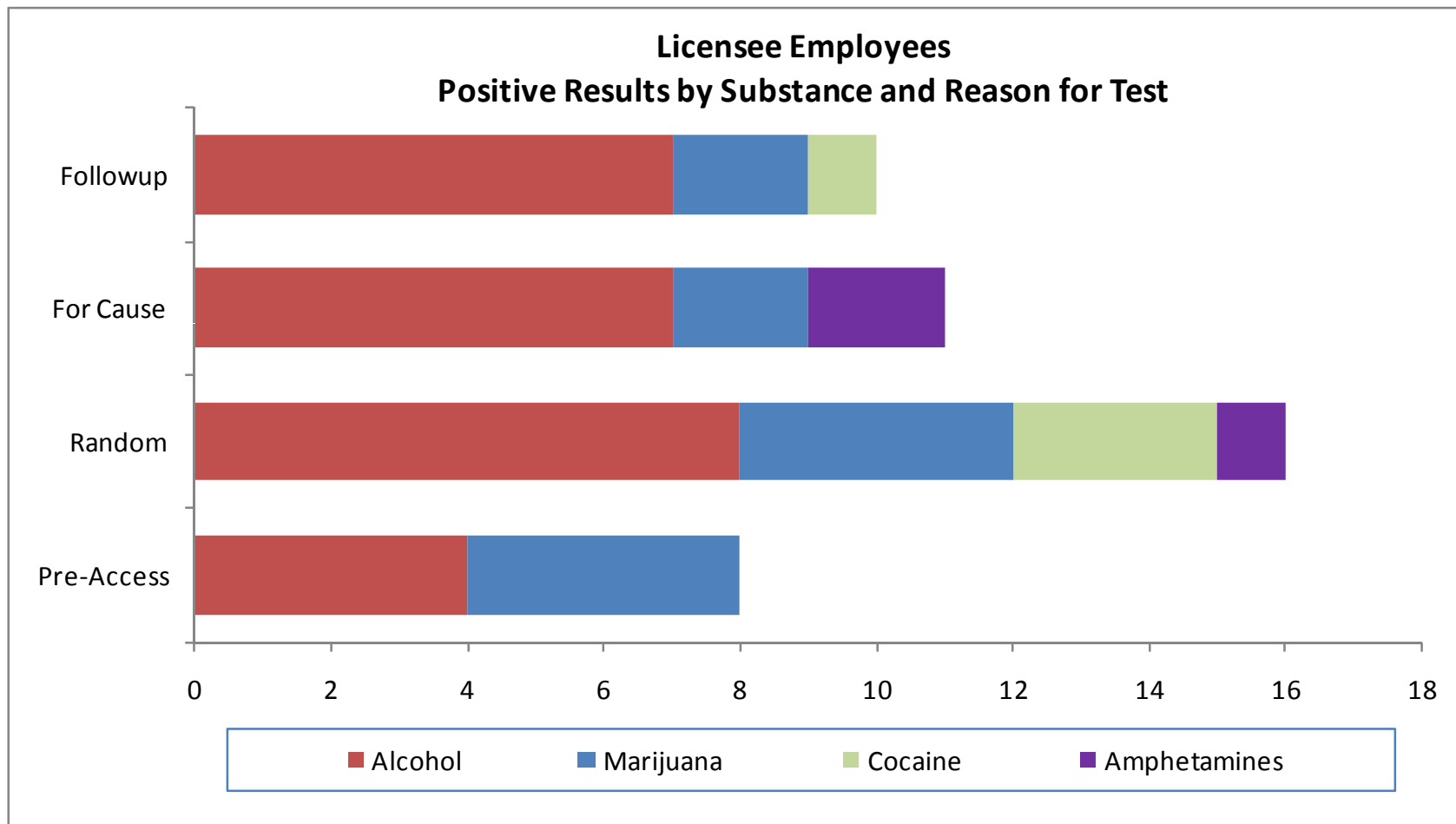
Evaluate Positive Rates by Work Category by Licensee Site

(CY 2009 Random Testing Results)

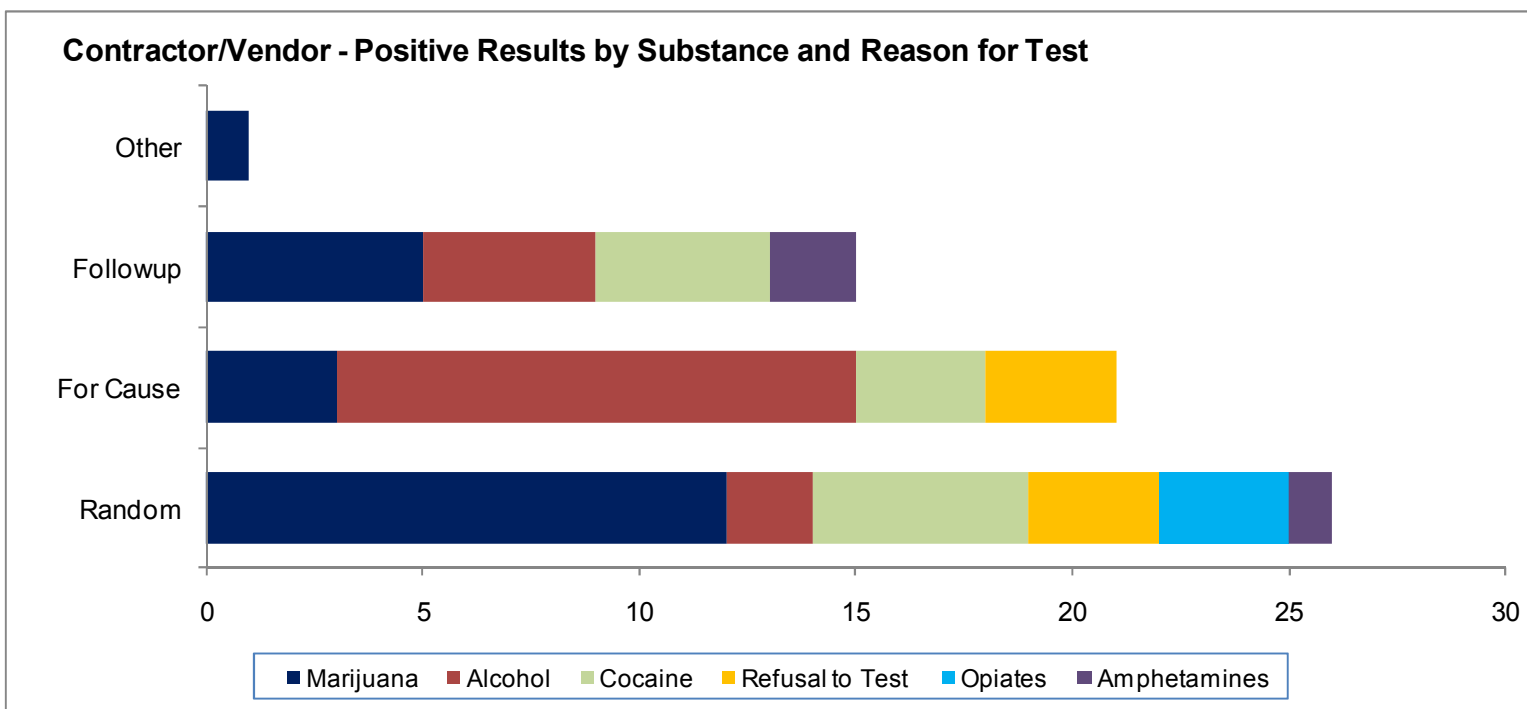
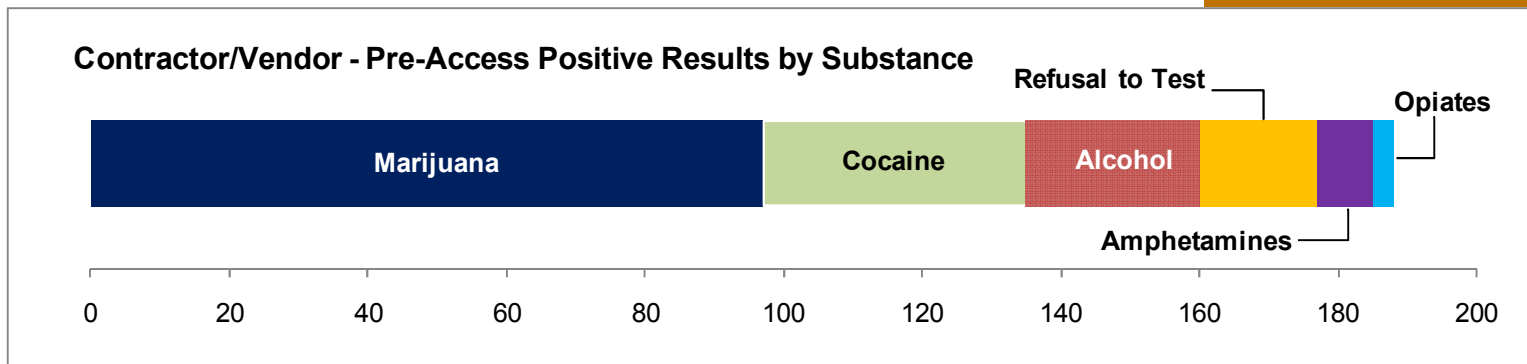


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CY 2009 Licensee Employee Substances by Reason for Test

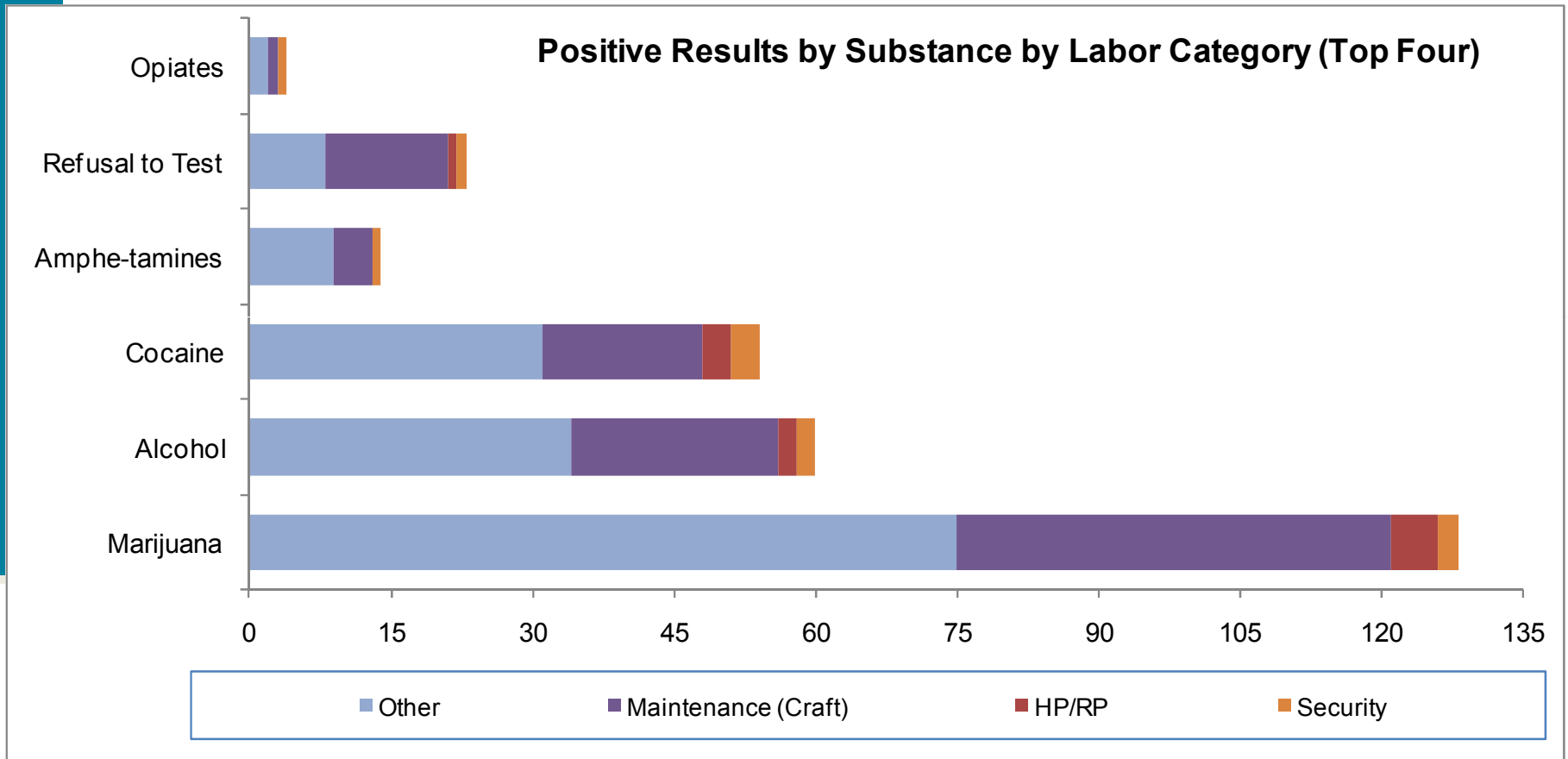


CY 2009 Contractor/Vendors Substances by Reason for Test



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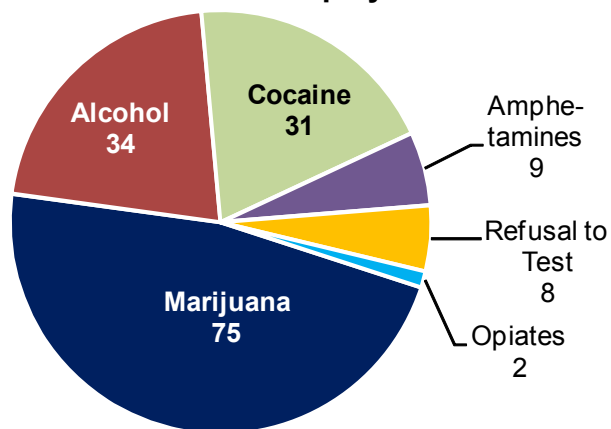
CY 2009 Positive Results by Substance by Top 4 Labor Categories



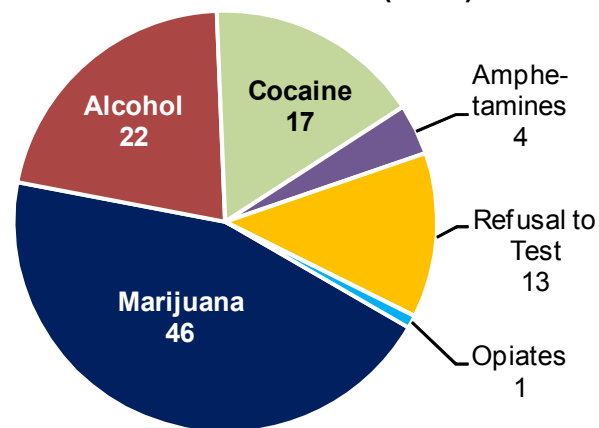
CY 2009 Positive Results by Labor

(Top 4 Labor Categories)

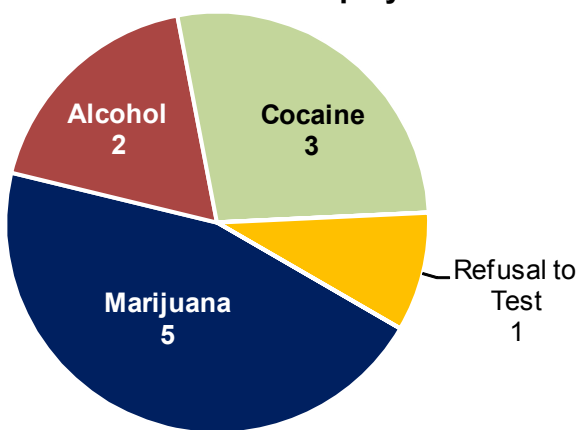
Results - Other Employees



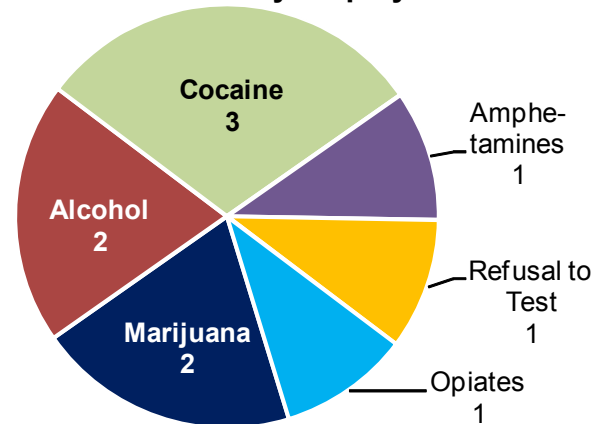
Results - Maintenance (Craft)



Results - HP/RP Employees



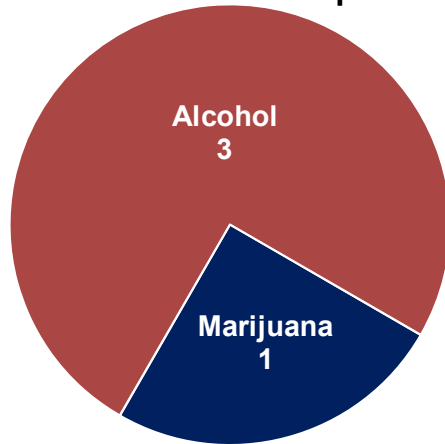
Results - Security Employees



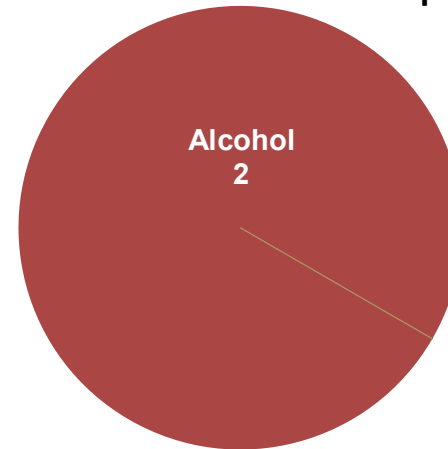
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CY 2009 Positive Results by Substance (Reactor Operators)

Results - Licensed Operators



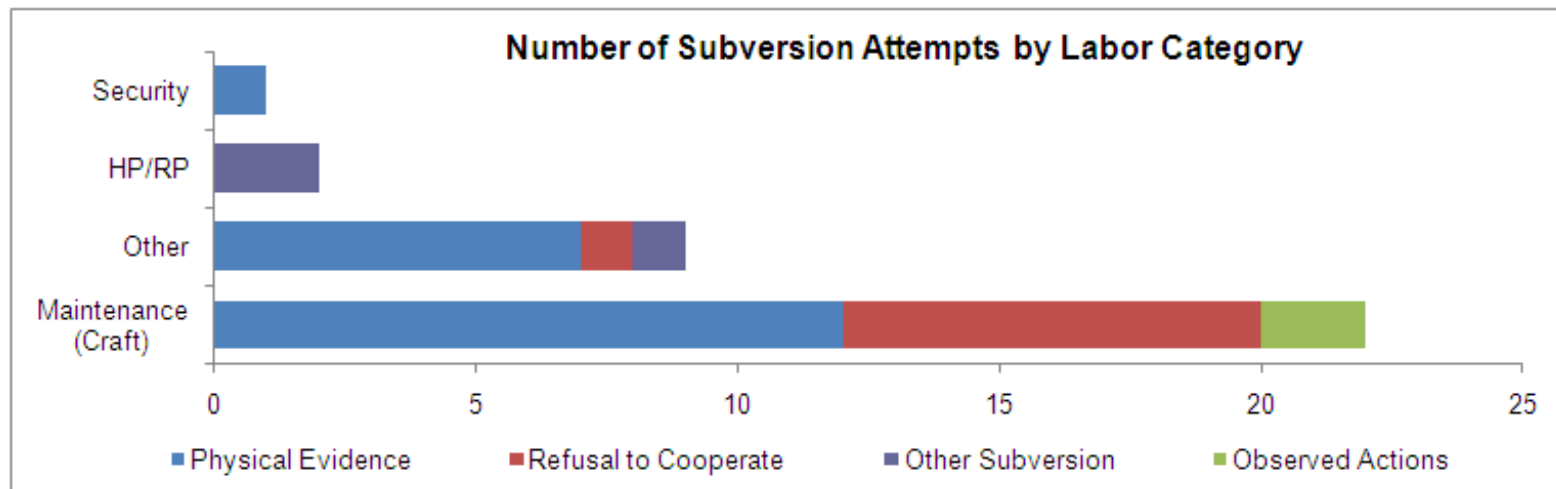
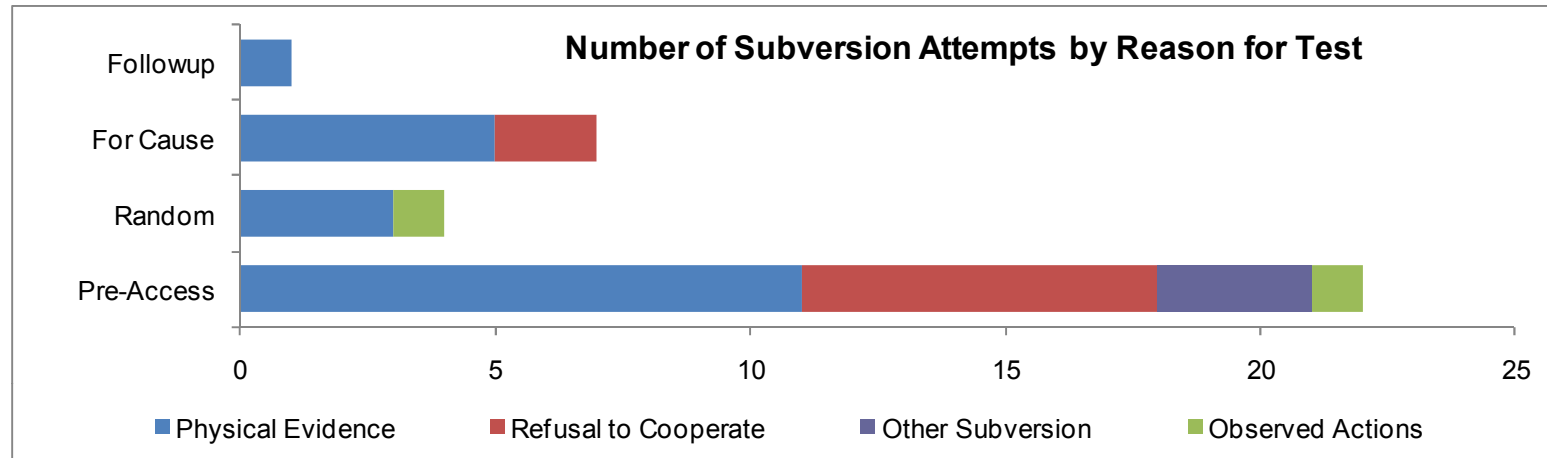
Results - Non-Licensed Operators



Labor Category	Substances	Pre-Access	Random	For Cause	Total
Licensed Operator	Alcohol		1	1	2
	Alcohol, Marijuana			1	1
Non-Licensed Operator	Alcohol	1	1		2
	Total	1	2	2	5

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CY 2009 Subversion Attempts by Reason for Test and Labor Category



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Tests Results for Each Test Category

(CY 2010 – e-Reporting)

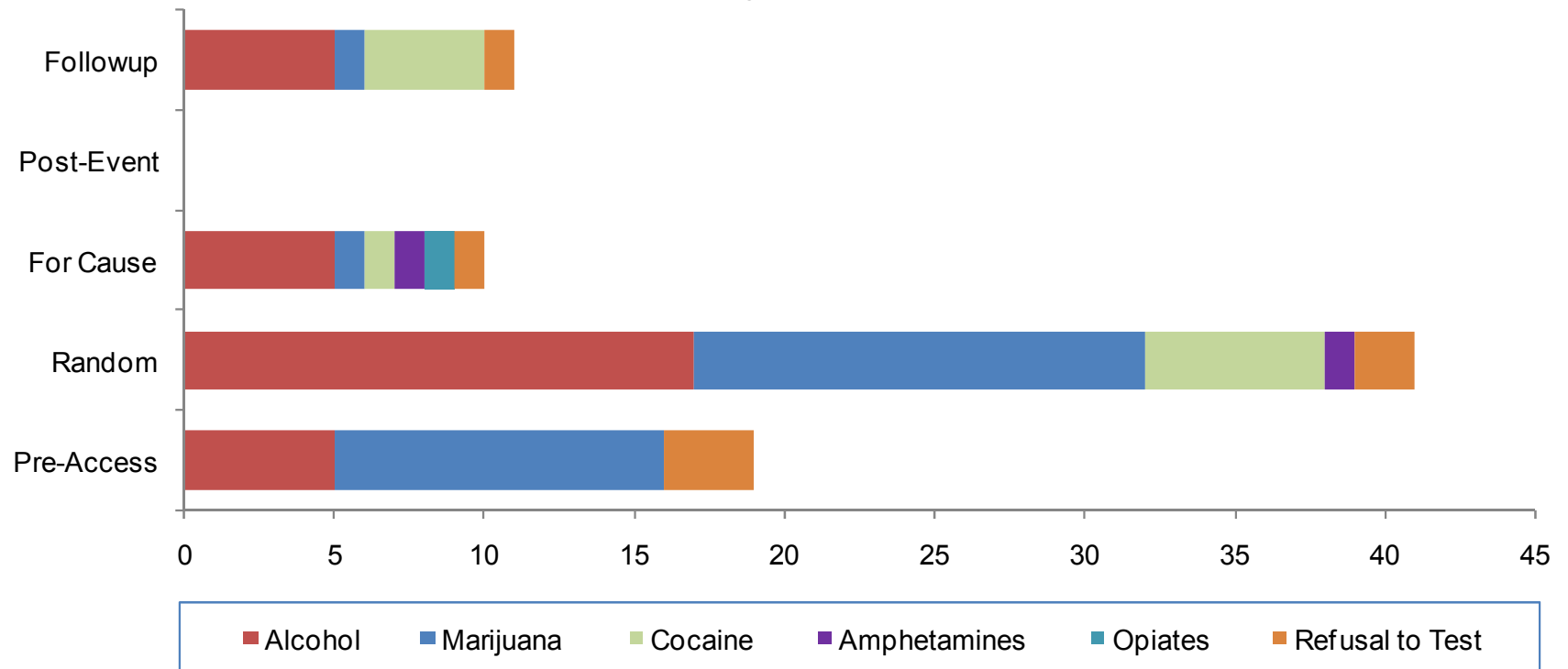
Test Category	Number of Tests	Positive Tests	Percent Positive
Pre-Access	62,331	457	0.73%
Random	38,549	110	0.29%
For Cause	382	61	15.97%
Post-Event	530	2	0.38%
Followup	4,295	38	0.88%
Other	356	10	2.81%
Total	106,443	678	

Draft results (as of 4/29/11)

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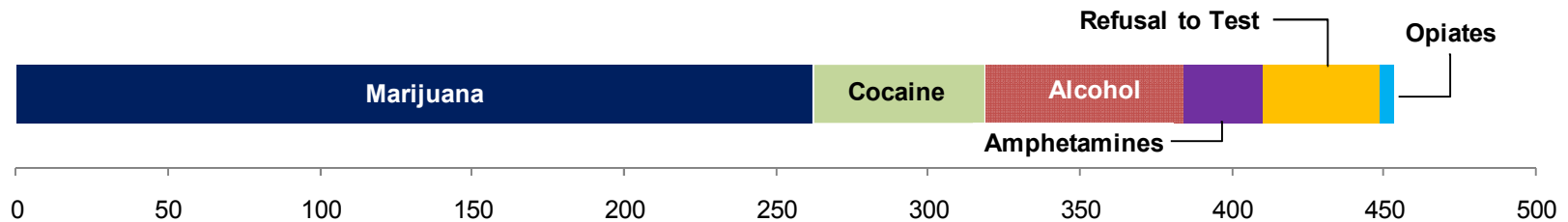
CY 2010 Licensee Employee Substances by Reason for Test [Draft]

Licensee Employees
Positive Results by Substance and Reason for Test [DRAFT]

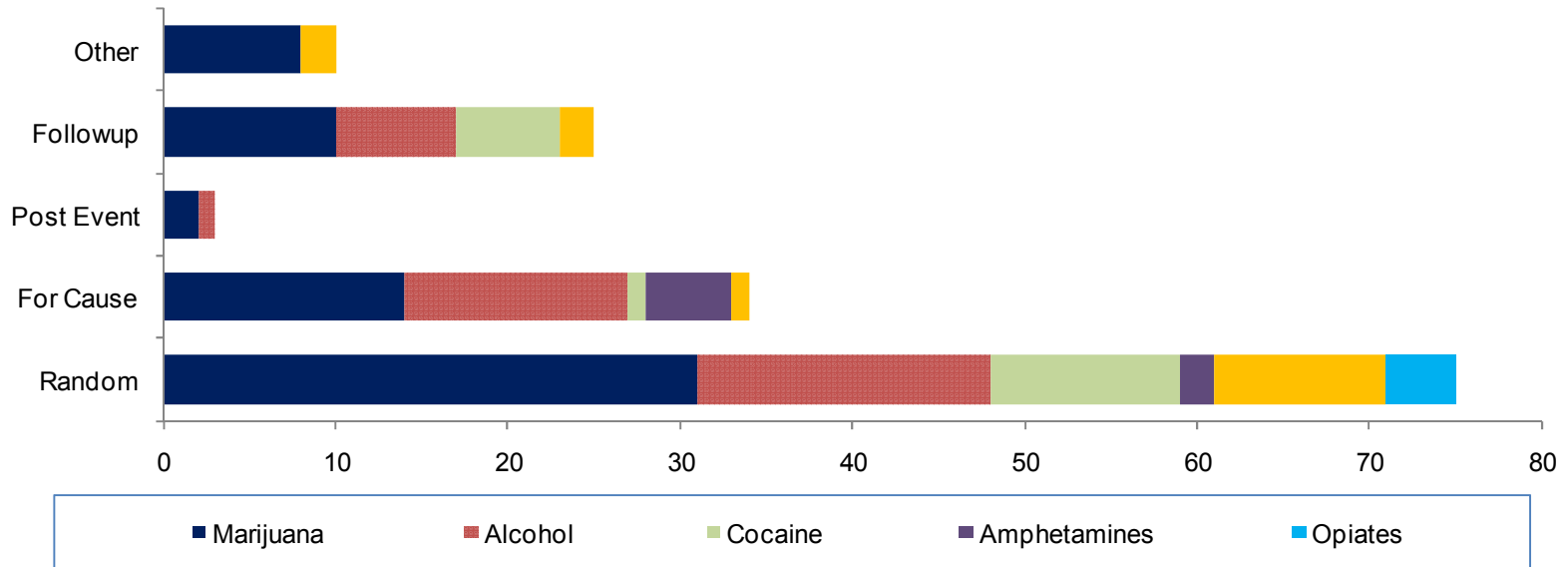


CY 2010 Contractor/Vendors Substances by Reason for Test [Draft]

Contractor/Vendor - Pre-Access Positive Results by Substance [DRAFT]

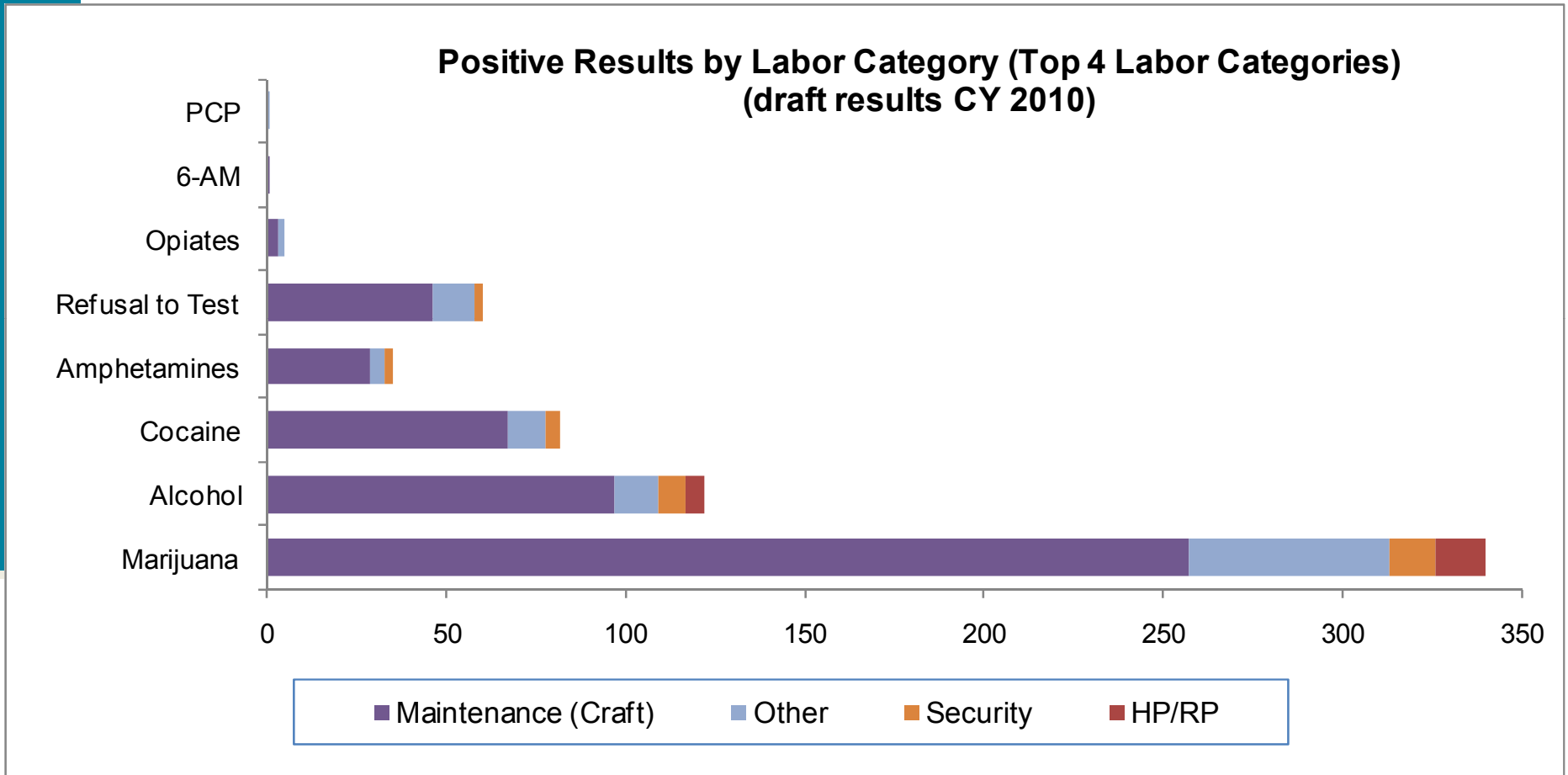


Contractor/Vendor - Positive Results by Substance and Reason for Test [DRAFT]

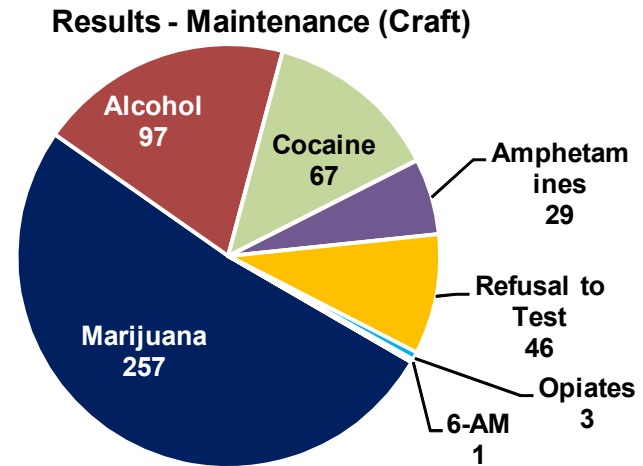
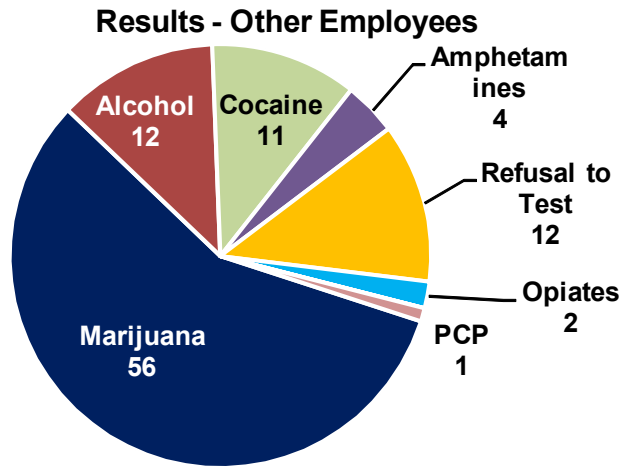


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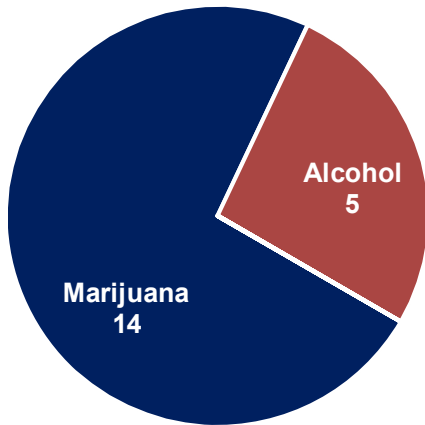
CY 2010 Positive Results by Substance for Top 4 Labor Categories



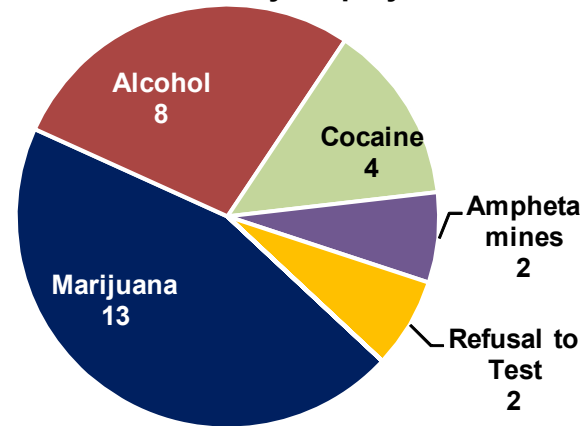
CY 2010 Positive Results by Substance for Top 4 Labor Categories



Results - HP/RP Employees



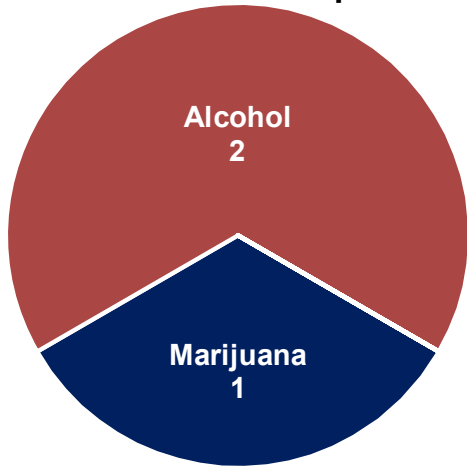
Results - Security Employees



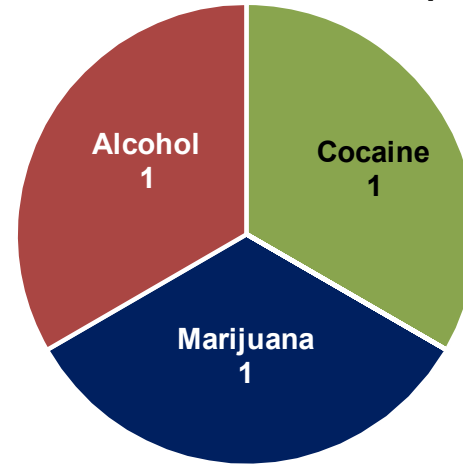
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CY 2010 Positive Results by Substance and Test Category (Reactor Operators)

Results - Licensed Operators



Results - Non-Licensed Operators



Labor Category	Substances	Random	Followup	Total
Licensed Operator	Alcohol	2		2
	Marijuana	1		1
Non-Licensed Operator	Alcohol	1		1
	Cocaine		1	1
	Marijuana	1		1
Total		5	1	6

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