

Presentation to the Nuclear Energy Institute's Access Authorization and Fitness for Duty Workshop

Fitness for Duty Program Performance and Trends and Regulatory Updates

July 14, 2022

Discussion Topics



- ☐ FFD Program Performance in 2021 and Trends
- ☐ Regulatory Updates:
 - ➤ Part 26/HHS Guidelines Final Rule
 - > Part 73 Access Authorization





FFD Program Performance and Trends

Note: 2021 FFD Program Performance results are DRAFT. NRC finalizing the standard quality assurance and quality control process to validate the information received.

FFD Program Performance Results by Test and Employment Categories, 2021



Test Category	Tested	Tested Positive	
Pre-Access	63,044	733	1.16%
Random	45,528	274	0.60%
For Cause	260	39	15.00%
Post-Event	360	3	0.83%
Followup	5,016	51	1.02%
Total	114,208	1,100	0.96%

	Licen	Licensee Employees			actor/Ven	idors	Total			% of Total
Test Category	Tested	Positive	Percent Positive	Tested	Positive	Percent Positive	Tested	Positive	Percent Positive	Positives
Pre-Access	7,825	46	0.59%	55,219	687	1.24%	63,044	733	1.16%	66.6%
Random	28,575	79	0.28%	16,953	195	1.15%	45,528	274	0.60%	24.9%
For Cause	69	7	10.14%	191	32	16.75%	260	39	15.00%	3.5%
Post-Event	75	-	0.00%	285	3	1.05%	360	3	0.83%	0.3%
Followup	2,284	17	0.74%	2,732	34	1.24%	5,016	51	1.02%	4.6%
Total	38,828	149	0.38%	75,380	951	1.26%	114,208	1,100	0.96%	100.0%

FFD Program Performance Results, 2017-2021

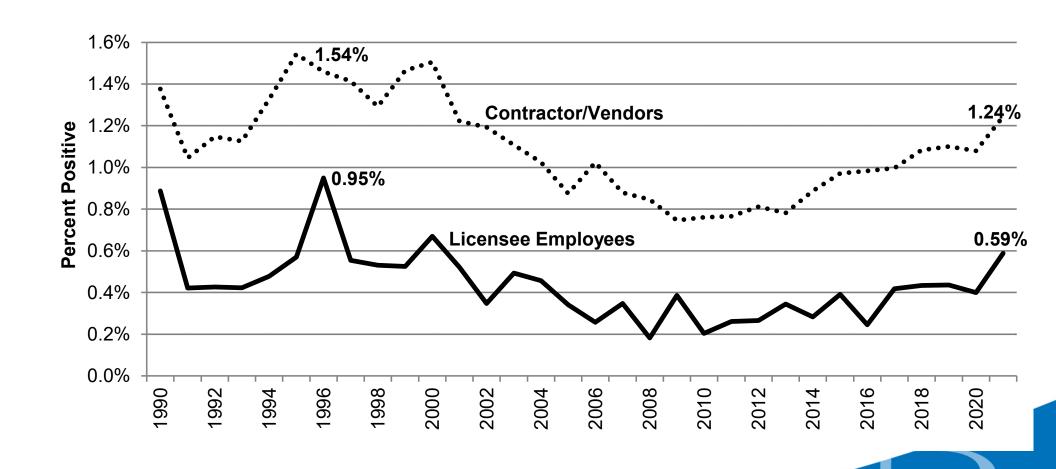


	2017	2018	2019	2020	2021
Number of Facilities Reporting	72	71	70	70	69
Individuals Tested	148,741	145,797	131,417	124,678	114,208
Individuals Testing Positive*	1,176	1,187	1,085	1,047	1,100
Identified at Pre-access Testing	64.4%	69.6%	67.3%	67.4%	66.6%
Identified at Random Testing	22.5%	17.8%	21.8%	22.7%	24.9%
Pre-Access Testing Positive Rates	0.93%	1.02%	1.03%	1.01%	1.16%
Licensee Employee	0.42%	0.43%	0.44%	0.40%	0.59%
Contractors/Vendors	0.93%	1.08%	1.10%	1.08%	1.24%
Random Testing Positive Rates	0.45%	0.37%	0.45%	0.49%	0.60%
Licensee Employees	0.14%	0.17%	0.19%	0.23%	0.28%
Contractors/Vendors	0.90%	0.68%	0.86%	0.92%	1.15%

^{*} Positive = Positive drug and alcohol tests, adulterated and substituted validity test results, and refusals to test All results in presentation are MRO verified

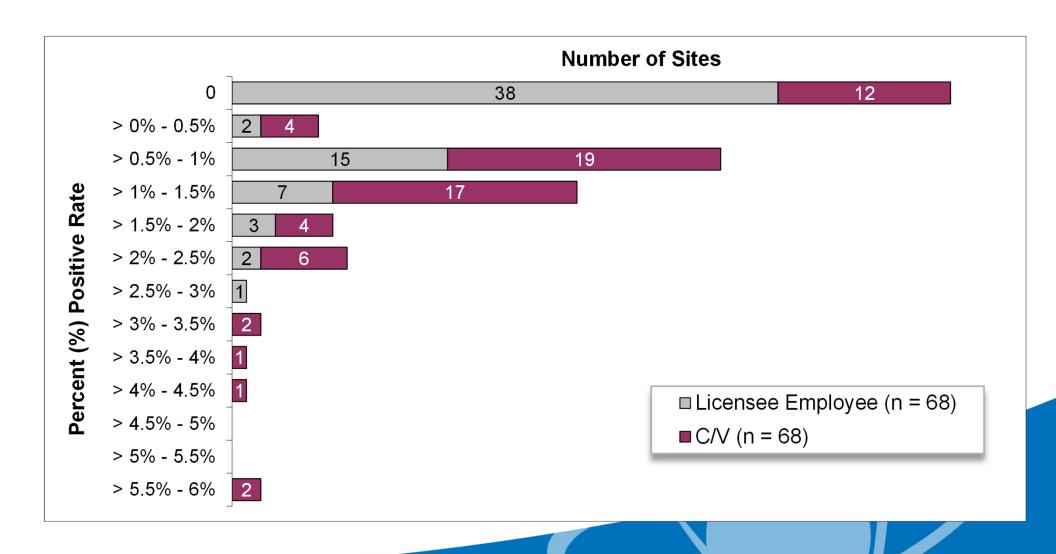
Pre-Access Testing (1990-2021) Positive Rates by Employment Category





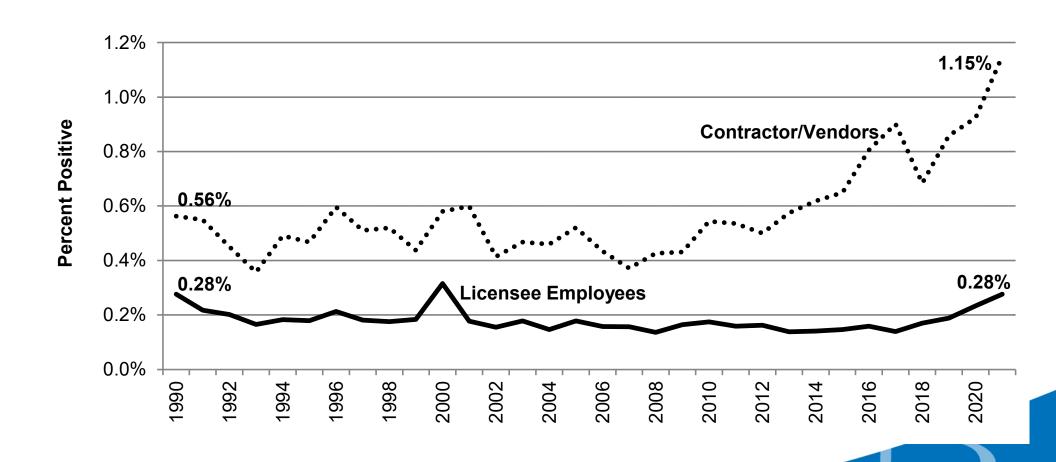
Pre-Access Testing, 2021 Distribution of Site-Specific Positive Rates by Employment Category





Random Testing (1990-2021) Positive Rates by Employment Category





Random Testing (2017-2021) Distribution of Site-Specific Positive Rates by Employment Category



Positive Rate	Licensee Employee						Contra	actor/Ve	ndor	
Range (%)	2017	2018	2019	2020	2021	2017	2018	2019	2020	2021
0	37	29	34	30	25	32	28	35	26	26
> 0% - 0.25%	20	22	17	17	11	1	4			1
> 0.25% - 0.5%	12	16	15	10	18	10	14	6	6	5
> 0.5% - 0.75%	2	4	3	8	12	13	6	6	8	7
> 0.75% - 1%			1	4	1	6	10	6	5	7
> 1% - 1.25%				1		4	5	5	10	5
> 1.25% - 1.5%						1	1	7	3	3
> 1.5% - 1.75%					1	2	1	3	4	5
> 1.75% - 2%						1		1	4	2
> 2% - 2.25%									1	
> 2.25% - 2.5%							1		1	3
> 2.5% - 2.75%									1	1
> 2.75% - 3%										
> 3% - 3.25%										
> 3.25% - 3.5%						1				l
> 3.5% - 3.75%							1			2
> 3.75% - 4%								1		
> 4%						1			1	1

Results by Employment Category, 2021

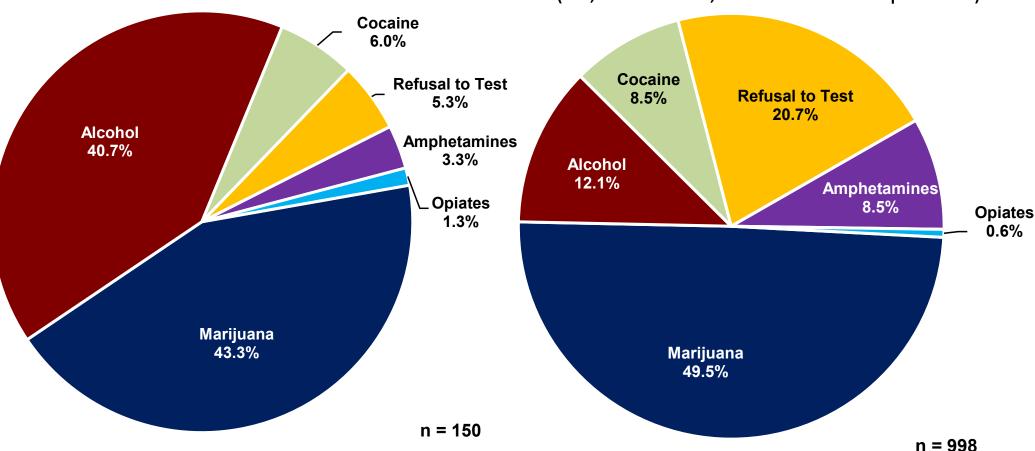




(38,828 tested, 149 individuals positive)

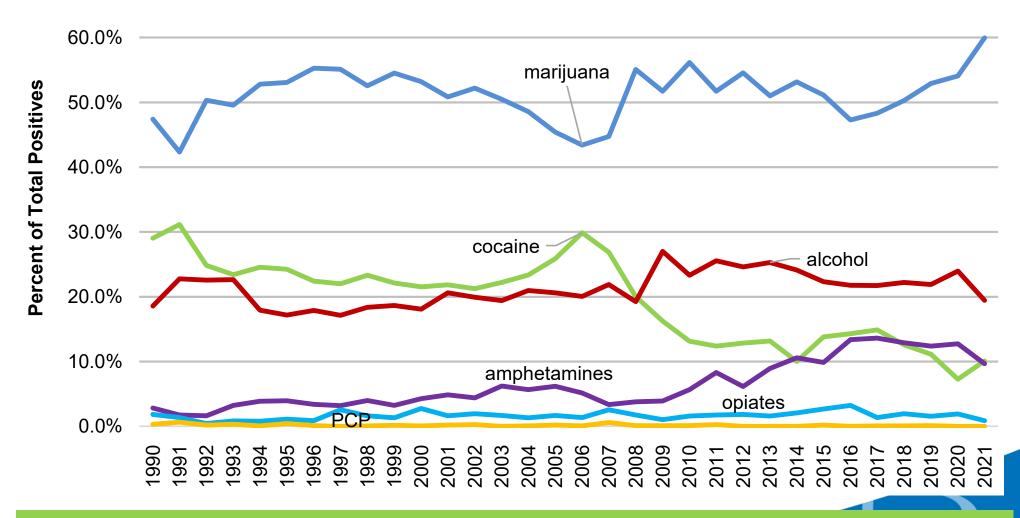
Contractor/Vendors

(75,380 tested, 951 individuals positive)



Detection Trends – NRC Testing Panel Percentage of Total Positives by Substance Tested

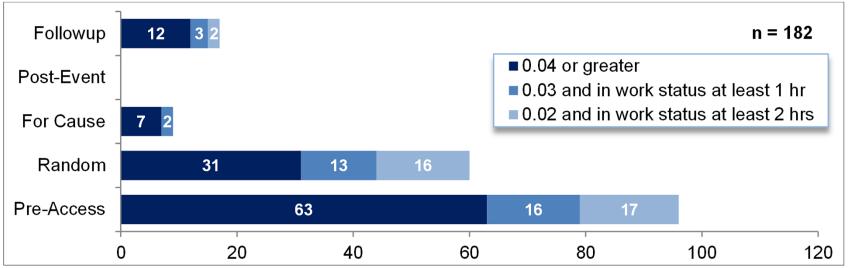


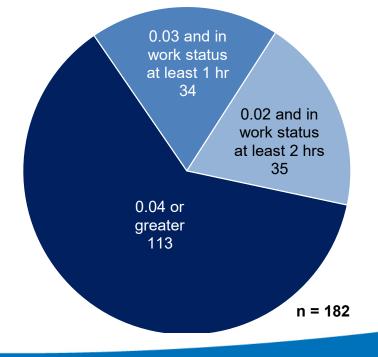


Since at least 2014, this chart under reports the substances used by individuals with a drug testing violation. This is because of the high number of subversion attempts where no specimen is tested (at least 60% of subversion attempts each year)

Alcohol Positive Results, 2021 Effectiveness of Lower Cutoff Levels



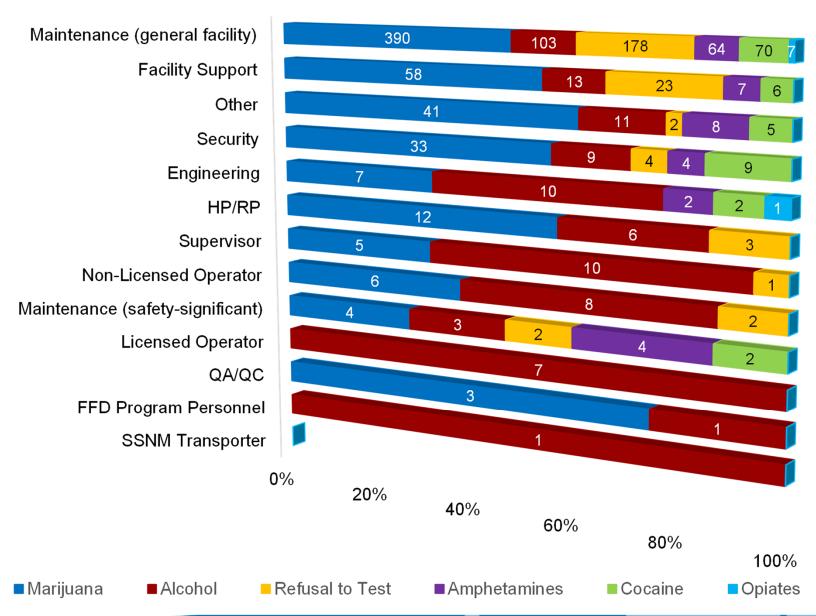




- 38% of alcohol positives due to time-dependent cutoff levels (BAC < 0.04)
- Must abstain from alcohol use at least 5 hours prior to arrival for work

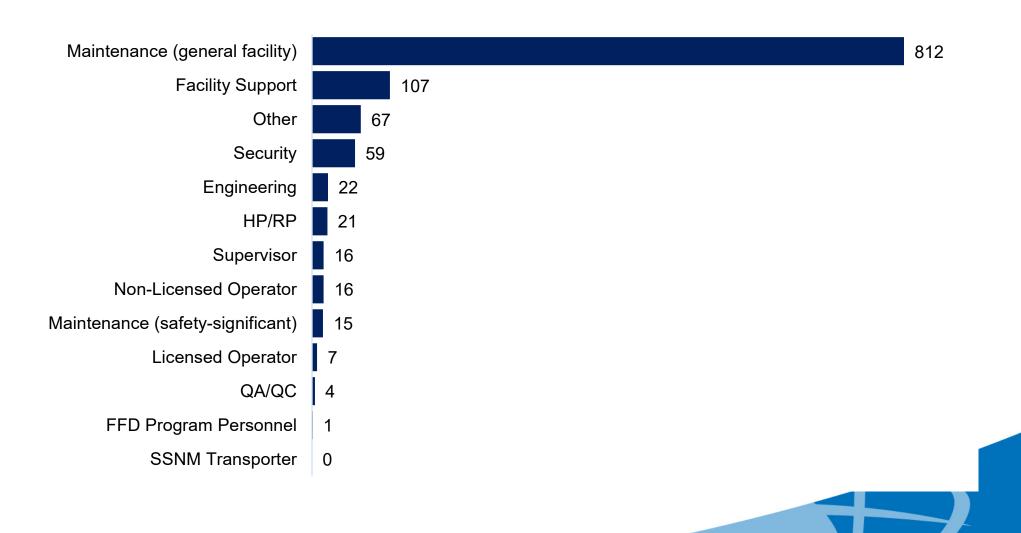
Results by Labor Category, 2021





Total Substances by Labor Category, 2021





Subversion Attempt Trends (2016-2021)



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)

	2016	2017	2018	2019	2020	2021
Number of Subversion Attempts	305	305	298	307	288	273
Percentage of Drug Testing Violations	32.4%	31.9%	31.0%	34.5%	34.4%	29.6%
Identified at Pre-access Testing	72.1%	67.5%	77.5%	73.3%	74.7%	71.3%
Committed by Contractor/Vendors	98.0%	97.7%	95.6%	97.4%	96.2%	94.5
Percentage of Sites Reporting At Least One Subversion	53%	64%	70%	61%	72%	71%

Subversion attempt sanction:

Permanent denial unescorted access, 10 CFR 26.75(b)

Subversion Attempt Road Map, 2021



United States Nuclear Regulatory Commission

First Collection

No Specimen Collected

Subversion Suspected*

Specimen temperature (201)

Specimen characteristics (26)

Paraphernalia discovered (43) Donor refused directions (18)

Specimen Appears Normal

Specimen Appears Normal, Invalid Test Result

Second Collection

No Specimen Collected

Directly Observed Specimen Collection

No Specimen Collected

Directly Observed Specimen Collection

Subversions (273)

Donor did not appear (12)

Donor refused 1st collection (16)

Shy-bladder no medical explanation (7)

Alcohol positive, refused drug test (1)

- 1 First specimen positive
- Donor refused 2nd collection or collection process stopped
 - 54 Drug Test Results
 (1st specimen neg./2nd specimen pos.)

Validity Test Results

- O Adulterated (0); Substituted (0); Dilute & positive at LOD (0)
- 3 Donor refused 2nd collection or collection process stopped
- 2 Drug Test Results
 (1st specimen invalid/2nd specimen pos.)

Subversion Attempt Trends by Labor Category (2016-2021)



Labor Category	2016	2017	2018	2019	2020	2021	Total
Maintenance (general facility)	158	193	226	255	245	219	1,296
Other	124	77	16	7	6	6	236
Facility Support	10	17	25	18	17	26	113
Maintenance (safety-significant)	10	9	14	10	10	2	55
Security	-	4	4	6	4	9	27
Supervisor	2	1	7	4	1	2	17
HP/RP	-	2	2	2	1	6	13
Engineering	-	1	2	3	4	-	10
Non-Licensed Operator	-	1	2	-	-	3	6
QA/QC	-	-	-	2	-	-	2
Maintenance (craft)	1	-	-	-	-	-	1
FFD Program Personnel	-	-	-	-	-	-	-
Licensed Operator	-	-	-	-	-	-	-
SSNM Transporter	-	-	-	-	-	-	-
Total	305	305	298	307	288	273	1,776

Special Analyses Limit of Detection Testing of Dilute Specimens, 10 CFR 26.163(a)(2)



Total	10	3	10	6	17	8	7	13	74
Amphetamine								1	1
Marijuana						1		2	3
Followup									
Marijuana	1								1
For Cause									
Methamphetamine					1				1
Cocaine	1	1			1		1	1	5
Marijuana				1	3	1	2	2	9
Random									
Cocaine; Marijuana			1						1
Amphetamine; Marijuana	1								1
Alcohol; Marijuana								1	1
Amphetamine; Methamphetamine	1		1		1				3
Cocaine			2	2		1	1	1	7
Marijuana	6	2	6	3	11	5	3	5	41
Pre-Access									
	2014	2015	2016	2017	2018	2019	2020	2021	Total

HHS-Certified Laboratory Performance, 2021



- Specimen shipments impacted by a severe weather event (snowstorm) that shut down a major express mail service shipping hub
- Shipments of specimens lost in transit to laboratory
- Specimen testing delays (not meeting 5-business day test result reporting requirement under 10 CFR 26.169)
- One laboratory (Quest Diagnostics Tucker, GA) ceased operations, which impacted a number of licensee FFD programs



Part 26/HHS Guidelines Draft Final Rule

Part 26 Rulemaking

(RIN 3150-AI67; Docket NRC-2009-0225)

Aligning Part 26 drug testing requirements more closely with the U.S. Department of Health and Human Services' 2008 and 2017 Mandatory Guidelines for Federal Workplace Drug Testing of urine specimens. Also incorporating lessons learned from implementing Part 26.

United States Nuclear Regulatory Commission

Protecting People and the Environment

- Final Rule approved by Commission March 2022
- Expect Final Rule to be published in October 2022
- Substantive changes:
 - ☐ Add testing for MDMA, MDA, hydrocodone, hydromorphone, oxycodone, oxymorphone
 - ☐ Lower drug testing cutoff levels for amphetamine, methamphetamine, cocaine
 - ☐ Improve testing method to identify heroin
 - ☐ Improve methods to detect donor subversion attempts
 - Include option to collect and drug test oral fluid for observed collection conditions

Part 26, Draft Final Rule: Drug Testing Panel Changes



Drugg or drug motabalitas	Testing Cutoff	Levels (ng/mL)
Drugs or drug metabolites	Initial	Confirmatory
Cocaine metabolites	<mark>300</mark> 150	<mark>150</mark> 100
Opioids Opiate metabolites:		
6-acetylmorphine (6-AM)	10	10 <mark>1</mark>
Hydrocodone	300	100
Hydromorphone	300	100
Oxycodone	100	100
Oxymorphone	100	100
Amphetamines		
Amphetamine	1000 = 00	<mark>500</mark> 2 50
Methamphetamine	1000 500	<mark>500</mark> 250 ²
Methylenedioxymethamphetamine (MDMA)	F00	250
Methylenedioxyamphetamine (MDA)	500	250

¹ Confirmatory testing for 6-AM performed only when morphine concentration exceeds 2,000 ng/mL

Only substances with changes displayed

² To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than ²⁰⁰100 ng/mL

Part 26, Draft Final Rule: Subversion Detection Enhancements



Special analyses testing under 26.163(a)(2):

- Required for dilute specimens (before optional)
- Required for specimens collected under direct observation conditions:
 26.115(a)(1)-(a)(3), and (a)(5) [new]
- Change drug concentration on initial test that triggers special analyses testing (from 50% of cutoff to 40% of cutoff)
- Change confirmatory testing cutoff to Limit of Quantitation (LOQ) from the Limit of Detection (LOD)

Validity testing cutoff levels under 26.161(h):

 Permit use of more stringent cutoffs for validity tests than specified in Part 26 only if testing is performed at an HHS-certified laboratory (before, use of more stringent cutoffs levels prohibited)

Part 26, Draft Final Rule: Additional Changes

U.S.NRC

United States Nuclear Regulatory Commission

Protecting People and the Environment

- Donor protections:
 - Verbal request for retest (MRO document request)
 - MRO review of invalid specimens pH 9.0 to 9.5 (handling conditions)
- Hydration monitor: permit an individual other than the original specimen collector to monitor a donor with a shy-bladder
- Issuing a new Regulatory Guide 5.89 that covers three topics specific to the final rule (observed collections, donor hydration during shy-bladder events, MRO review of invalid specimens – pH 9.0 to 9.5)
- Revising "NRC Form 890, Single Positive Test Form," and "NRC Form 891, Annual Reporting Form for Drug and Alcohol Tests"

All Draft Final Rulemaking documents available at: https://www.nrc.gov/docs/ML2111/ML21111A017.html

Part 26 Final Rule – Implementation Considerations



- Revise FFD policies and procedures
- Revise contracts with HHS-certified laboratory(ies)
- Update blind performance test samples consistent with revised drug testing panel (cutoff level changes for existing substances, addition of new substances)
- Provide training to covered personnel on rule changes
- If utilizing a Licensee Testing Facility, obtain and validate drug testing assays consistent with testing panel and cutoff level changes, train laboratory technicians.



Access Authorization – 10 CFR Part 73 Regulatory Updates

Access Authorization: Discussion Topics



- Draft Regulatory Issue Summary (RIS), "Personnel Access Authorization Requirements for Non-Immigrant Foreign Nationals Working at Nuclear Power Plants"
- Regulatory Guide (RG) 5.77 "Insider Mitigation Program" (Status)
- NRC/FBI RAP Back Initiative
- Controlled Unclassified Information (CUI)

DRAFT RIS: "Personnel Access Authorization Requirements for Non-Immigrant Foreign Nationals Working at Nuclear Power Plants



- Published for public comment on June 13, 2022 (87 FR 35798)
 [Comment period closes August 12, 2022]
- The NRC, in collaboration with the Department of Homeland Security, identified several instances where a licensee failed to appropriately verify the claimed non-immigration status of a foreign national seeking unescorted access (UA) and/or unescorted access authorization (UAA), which resulted in individuals being granted UA/UAA at U.S. nuclear power plants [did not have visa category that permitted work in the U.S]
- Verification of foreign national employment eligibility (correct nonimmigration status) is a required aspect of true-identity verification under 10 CFR 73.56(d)(3) (visual inspection of a document/credential is not sufficient, independent verification is necessary using an authoritative resource)
- NRC Technical Lead: Mark Resner

RG 5.77 "Insider Mitigation Program" (Revision 1) - Status



The Commission approved issuance of Revision 1 to RG 5.77 on July 14, 2021 (Staff Requirements Memorandum—SECY-17-0095) (ML21195A356)

- Before issuing Revision 1, the Commission directed the staff to:
 - ☐ Edit the document for consistency, accuracy, formatting, and a determination regarding which content should be marked "Unclassified" and "Official Use Only Security Related Information"
 - ☐ Provide the revised guidance to the Commission in a Commissioners Assistant's (CA) note, including notifying the Commission of any recommended substantive changes based on information and experience gained since this paper was submitted to the Commission
- The revised guidance is in the concurrence process
- NRC Technical Lead: Brad Baxter

NRC/FBI RAP Back Initiative



- The Records of Arrest and Prosecution (RAP) Back Service is a feature of the FBI Next Generation Identification System (NGI). It provides continual monitoring of arrests/criminal activity of enrollees with fingerprints on file.
- The NRC signed an MOU with FBI/DOJ on January 16, 2020
- Cooper Nuclear Station is the first licensee site to participate:
 - Signed MOU with the NRC: March 3, 2020
 - Licensee enrollment rollout began: May 6, 2021
 (Public meeting was held as part of this rollout ML21125A037)
- RAP Back is provided by the FBI at no cost
- NRC Technical Lead: Mark Resner

Controlled Unclassified Information (CUI) **Program**



 On November 12, 2021, the NRC issued a final policy statement in the Federal Register to describe how the agency will comply with regulations issued by the National Archives and Records Administration to implement a CUI program (https://www.federalregister.gov/documents/2021/11/12/2021-

- On June 2, 2022, the NRC held a public meeting with stakeholders to discuss topics such as information-sharing agreements related to NRC's plans to transition from Sensitive Unclassified Non-Safeguards Information (SUNSI) to CUI.
- The NRC has reached out to the FBI to discuss the implications of CUI on Criminal History Information.

24543/controlled-unclassified-information-program).

NRC Program Staff FFD and Access Authorization



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