U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

PUBLIC MEETING REGARDING FITNESS-FOR-DUTY PROGRAM EFFECTIVENESS, REQUIREMENTS, GUIDANCE, AND OPTIONS TO MINIMIZE FUTURE POLICY CHANGES

10 CFR Part 26, Fitness for Duty Programs

A Direct Contribution to Safety and Security

April 19, 2016

Agenda

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

12:50 – 1:00 pm	Introductions and Administration
1:00 – 4:45 pm	Technical Topic Discussions
4:45 pm	Wrap Up
5:00 pm	Adjourn

Disclaimer

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

The information in this presentation and the discussions during the public meeting are provided as a public service and solely for informational purposes and is not, nor should be deemed as, an official NRC position, opinion or guidance, or "a written interpretation by the General Counsel" under 10 CFR 26.7, on any matter to which the information may relate. The opinions, representations, positions, interpretations, guidance or recommendations which may be expressed by the staff in this presentation or during the public meeting are solely the staff's and do not necessarily represent the same for the NRC. Accordingly, the fact that the information was obtained through the staff will not have a precedential effect in any legal or regulatory proceeding.

Meeting Purpose

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

The purpose of this Category 3 meeting is to discuss fitness-for-duty (FFD) program effectiveness, requirements, guidance, and options to minimize future FFD-related policy changes.

The NRC staff will present FFD performance data and trend information, discuss the requirements detailed in Title 10 of the Code of Federal Regulations, Part 26, "Fitness for Duty Programs," review program guidance, and seek collaboration on areas where policy rule and guidance can be improved.

The agenda will include a discussion regarding the U.S. Department of Health and Human Services' "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (HHS Guidelines).

Technical Topics

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

1. Prescriptions, medically-disqualifying drugs, and marijuana
2. Expansion of the drug testing panel
3. Pre-access, random, for-cause, post-event, and multiple population testing
4. Subversion of the drug testing process
5. Hair, oral fluid, and point-of-collection testing
6. Abstinence, sanctions, and determinations of fitness (DOF)
7. Access authorization (AA) program and behavioral observation program (BOP)
8. Performance-based requirements (e.g., audits and inspection)
9. Reactors under construction, independent spent fuel storage installations, and decommissioning reactors
10. U.S. Department of Health and Human Services' "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (HHS Guidelines) and future updates

Technical Topics (continued)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

If time permits, questions and comments outside the scope of these technical topics will be discussed at the end of the meeting.

All technical topics may not be covered during the meeting.

Need for Rulemaking

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Petition for Rulemakings

1. PRM-26-4, NRC-2010-0269, from the California Association of Marriage and Family Therapists (CAMFT)

2. PRM-26-7 from the American Academy of Health Care Providers in the Addictive Disorders (i.e., the Academy)

3. PRM-26-8, NRC-2012-0290, from Mr. Thomas L. King, Regarding Synthetic Drugs et al.

FFD Performance Objectives

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

(a) Provide reasonable assurance that individuals are trustworthy and reliable as demonstrated by the avoidance of substance abuse;

(b) Provide reasonable assurance that individuals are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties;

(c) Provide reasonable measures for the early detection of individuals who are not fit to perform the duties that require them to be subject to the FFD program;

(d) Provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs and alcohol; and

(e) Provide reasonable assurance that the effects of fatigue and degraded alertness on individuals' abilities to safely and competently perform their duties are managed commensurate with maintaining public health and safety.

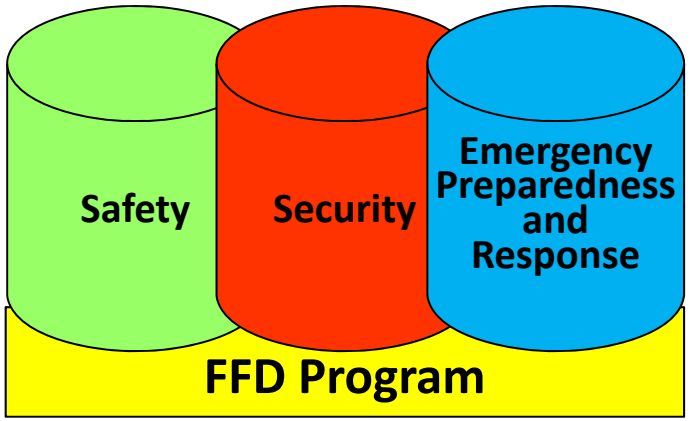
Part 26 and the Physical Protection of Plants and Materials

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Part 26 provides a substantial increase in the overall level of protection of public health and safety and the common defense and security by enhancing a licensee's ability to identify individuals who:

1. use illegal drugs or misuse of legal drugs and
2. are not trustworthy and reliable as demonstrated by their illicit use of controlled substances or attempt to subvert the drug testing process.

NRC considers the 10 CFR Part 26, "Fitness for Duty Program," provisions as security-related requirements (with a strong safety nexus) and inspects the testing requirements under the NRC's Inspection Manual Chapters 2200 (construction reactors), 2201 (power reactors), and 2681 (special nuclear material).



General Observations

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

The NRC staff has observed that:

1. FFD performance data indicates that NRC-licensed facilities are not workplaces free from the presence and/or effects of illegal drugs and alcohol

2. Subversion of the drug testing program is a continuing challenge

3. Flexibilities afforded in Part 26 are not being voluntarily implemented by the industry to address societal changes in substance abuse

4. Periodic rulemaking may not be effective or timely to address adverse trends and rulemaking requires money and effort (i.e., burden)

Industry Feedback on the Staff-proposed HHS Guidelines Rulemaking

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Nuclear Energy Institute letter[1] to NRC on the U.S. Department of Health and Human Services' "Mandatory Guidelines for Federal Workplace Drug Testing" (HHS Guidelines) regarding alignment of the Part 26 drug testing panel with that in the HHS Guidelines.

"all companies responding to the survey responded that they would change their panel only if the NRC mandated the expansion of the panel to the 7 drugs specified in the HHS Guidelines. The reason is that many of the companies have had to negotiate with bargaining units on the drug testing process and expansion of the panel by the company without a mandate within the rule would subject the drug panel to the negotiation process and not guarantee its adoption."

Notes

1. Letter received on received on May 31, 2009
2. Underline provided as a visual aid

NRC Staff Long-Term Goal

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Establish a risk-informed (RI), performance-based (PB), and pro-active Part 26 regulation that:

1. Enhances worker Trustworthiness, Accountability, and Reliability, and maintains appropriate worker Protections (TARP)

2. Improves efficiency and effectiveness with or without regulatory action

3. More effectively evaluates and addresses changes in substance use, abuse, and subversion technologies

4. Reduces future burden on licensees and NRC staff by minimizing future policy and guidance changes

Disclosure of Prescription Medication

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

With the exception of drug testing and disclosure of legal actions, the Part 26 framework may not identify individuals who may be impaired because of medication use.

A pro-active regulatory framework would identify and evaluate potential FFD performance issues prior to the individual conducting a 10 CFR 26.4 duty or responsibility.

One option under consideration is the disclosure of prescription medications to the licensee medical staff. Some power reactor licensees already have this provision in their corporate medical program.

NRC-licensed operators and NRC-required security officers already undergo medical examinations that assess medications being used by these individuals.

Disclosure of Prescription Medication

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

P1 Should all new individuals be required to disclose their prescriptions to the site medical staff prior to being granted unescorted access authorization (UAA)?

- Current employees could be grandfathered (see P2)
- Consent form, disclosure form, and medical information release form

P2 Should a periodic review of prescription use be required by regulation?

- All employees must disclose when issued or changed
- MRO enabled to review long-term use of potentially impairing prescriptions

P3 Evaluation of prescriptions could represent a significant burden on the site medical staff. What strategies could be employed to reduce burden?

Medically Disqualifying Drugs (MDD)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

An MDD is a prescription medication that could cause impairment and thereby prevent the safe and competent accomplishment of assigned duties and responsibilities.

A pro-active, risk-informed regulatory framework that incorporates the MDD concept could look like this:

1. An individual discloses their use of a prescription medication at pre-access and when a prescription changes or is issued

2. The medication is assessed by the site medical staff to evaluate whether its prescribed use could cause impairment of job functions

3. Clear guidance or requirements will detail if use is prohibited when conducting 10 CFR 26.4 activities or whether a waiver is needed

Medically Disqualifying Drugs

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

The staff believes that use of the following drugs could be medically disqualifying:

Schedule I	Heroin, PCP, methamphetamine, MDMA/MDEA/MDA
Cocaine	Intense euphoria then depression, edginess, increased heart rate, muscle spasms, dilated pupils, convulsions, paranoia, anger, hostility
Cannabis	All cannabis, including prescription medications; causes: euphoria, increased heart rate, panic attacks, slowed thinking and reaction times, and confusion; and, impaired balance, coordination, memory, and learning
Opiates/narcotics	Morphine, codeine, semi- and fully-synthetic opiates; causes: drowsiness, irritability, confusion, euphoria, anxiety, dizziness, and fatigue
Opiate Maintenance Drugs – buprenorphine, methadone, etc.	
Amphetamine	CNS stimulants, high doses cause depression, lethargy, mental confusion, and paranoia
Benzodiazepines	Causes depression, drowsiness, clumsiness, dizziness, slurred speech
Barbiturates	Benzodiazepine-like effects, plus unusual excitement, irritability, poor judgement, impaired ability to communicate, and psychomotor impairment
Muscle Relaxants	Causes heart rhythm disorders and congestive heart failure
Anti-psychotics	Treats schizophrenia and mania; causes malaise, anxiety, heart issues, strokes, convulsions, and seizures
Anti-depressants	Tricyclics, SSRIs; causes nausea, blurred vision, fatigue, drowsiness

Medically Disqualifying Drugs

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

MDD1 Should a list of medically disqualifying be developed?

- Pro-active regulatory framework
- Individual is impaired by substance use alone – waiver not allowed

MDD2 Should MDDs be based on FDA "Black Box" warnings or FAA "Do Not Issue Do Not Fly" list of pharmaceuticals?

- Leverages FAA work – works for the airline pilots
- Very clear requirements – perhaps too prescriptive

MDD3 Some MDDs could be allowed with a waiver. Should these MDDs be evaluated based on an individual's roles and responsibilities?

- Individual cannot work until evaluated and a waiver is issued

Medically Disqualifying Drugs

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

MDD4 Instead of developing a list of MDDs, should the process defer to medical staff determination?

MDD5 If MDDs are listed, should there be "exempt" prescriptions?

- e.g., birth control, etc.

Marijuana

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

There has been much press information regarding the possible medicinal benefits and potential re-Scheduling of marijuana.

Even if marijuana is re-Scheduled, the current staff position is that marijuana use be medically disqualifying because low levels of marijuana causes impairment and there are no conclusive studies that correlate marijuana titration to impairment.

M1 If marijuana is re-scheduled, should marijuana be medically disqualifying?

M2 Should medicinal marijuana be allowed with a waiver?

M2 Should all marijuana be prohibited at an NRC-licensed facility similar to how alcohol is controlled?

Expansion of the Drug Panel (ExPD)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

ExDP1 Should the testing panel be expanded for pre-access, random, for-cause, and post-event testing?

- May prevent future policy changes
- Burden as the panel is not consistent with HHS Guidelines

Current Panel

Marijuana metabolite

Cocaine metabolite

Opiates
- Codeine
- Morphine
- 6-acetylmorphine

Amphetamines
- Amphetamine
- Methamphetamine

Phencyclidine

Potential Expanded Panel

MDMA/MDEA/MDA

Semi-Synthetic Opiates**
- Hydromorphone
- Hydrocodone
- Oxymorphone
- Oxycodone

Barbiturates

Benzodiazepines

Buprenorphine

Methadone

Pre-Access Testing (PAT)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

PAT1 Should the use of oral fluids and urine specimen testing be randomized during PAT?

- Helps address urine minimum volume issues
- Helps prevent subversions

PAT2 Should a hair test be required prior to granting UAA?

- Improves access authorization assurances (10 CFR Part 73)
- Possibly reduces post-employment costs
- If head hair is not available, the test will not be conducted and the finding would be equivalent to no criminal history
- If recently shaved to subvert the test, consider as PDI
- Testing focused on Schedule I drugs

PDI – potentially disqualifying information, 10 CFR 26.5

Random Testing (RT)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

RT1 Should the random testing rate be site-specific (instead of FFD program specific) to incorporate a risk-informed and performance-based FFD strategy?

RT2 If an individual demonstrates adequate performance in following FFD policy and procedures, could that individual be placed in a population with a lower random testing rate?

- Other assurance will be needed (e.g., prescription disclosure, hair testing, alcohol monitors, etc.)

RT3 Would stakeholders support hair testing to augment (i.e., enable but not require) oral fluids and urine testing?

- Should all three matrices be randomized?
- Could the random rate be lowered because of the hair testing?
- Would deterrence improve?
- Would burden exceed costs?

For-Cause Testing (FCT)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

FCT1 Should individuals identified for for-cause testing be escorted to the collection site?

- Worker protection
- Reduces subversion potential
- Burden increase

FCT2 Since there is little to no correlation between metabolite concentration levels and impairment, should FCT be conducted to the Limit of Quantitation?

Post-Event Testing (PET)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

PET1 Should the phrase “human error” be defined?

PET2 Would stakeholders support removal of the highly-specific OSHA-related post-event testing requirement contained in 10 CFR 26.31(c)(3)?

PET3 Since there is little to no correlation between metabolite concentration levels and impairment, should PET be conducted to the Limit of Quantitation?

Follow-Up Testing (FT)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

FT1 Should the FT requirement (10 CFR 26.69(b)(6)) be revised to reflect current clinical practice?

FT2 Should the FT program by revised to better account for: (1) individual's specific case; (2) severity of the violation; (3) number of FFD policy violations; and (4) substance(s) involved?

FT3 Should the FT program test to the Limit of Quantitation?

FT4 Should the FT program enable the use of hair testing?

Multiple Population Testing (MPT)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

MPT is the use of multiple testing populations within an FFD program to enable FFD testing in a risk-informed and performance-based manner.

By identifying individual populations and monitoring performance, trends might be identified and focused corrective actions could be implemented to restore or ensure performance. For example:

- If a population consists of individuals with "demonstrated FFD performance," could these individuals be subject to a lower random testing rate?
- If a population consists of individuals that do not have "demonstrated FFD performance," corrective actions could be focused on that population

Use of multiple populations for testing is not explicitly precluded by regulation.

Many FFD programs are already implementing MPT; however, this testing is not performance-based or risk-informed.

Multiple Population Testing (MPT)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Guidance could be developed to help licensees:

1. Populate their multiple populations
2. Ensure a minimum number of individuals in a population
3. Change and manage the MPT program to maintain program effectiveness and worker protections

Multiple Population Testing (MPT)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

MPT1 If the overall random testing rate is maintained at 50 percent, would stakeholders support MPT or pilot MPT program?

- a measured regulatory approach

MPT2 Would stakeholders support performance-based population testing?

- FFD performance is monitored by populations
- Corrective actions are focused on the populations with identified FFD performance issues

MPT3 Would stakeholders support credible information-based population testing?

- Credible information exists to warrant the testing of multiple individuals who are determined to be associated with an unresolved FFD policy violation or security infraction involving FFD-related contraband
- Similar to a security search for contraband

Prevalence Testing

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Prevalence testing is a pro-active and risk-informed NRC regulatory strategy that would determine whether a particular drug or drug metabolite is prevalent in the commercial nuclear industry prior to the conduct of rulemaking.

PT would be laboratory-based and would be conducted on valid specimens that screen negative by immunoassay testing that are normally discarded by the laboratory.

If specimens are not “pooled,” test results could possibly be linked to an individual (consideration of sanctions for Schedule I drugs).

The number of PT specimens (pooled or unpooled) would need to be statistically representative.

PT could possibly be modeled off the U.S. Department of Defense program.

Prevalence Testing (PT)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

PT1 Would stakeholders conduct prevalence testing to ascertain whether they need to implement any HHS-proposed changes to its "Mandatory Guidelines for Federal Workplace Drug Testing"?

- HHS Guideline changes for semi-synthetic opiates

PT2 Would stakeholders have a basis for significant concern if the NRC-conducts an independent ongoing PT program that is designed to inform staff assessments on the need for future rulemaking?

Prevalence Testing

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

For an HHS-proposed change to its HHS Guidelines, an industry-led PT pilot could look like:

1. 3-year testing program that implements the HHS-proposed change (e.g., test panel, cutoffs, specimen validity testing, etc.) at a representative number of sites for a statistically-significant number of specimens

2. During the 4th year, NRC and industry will evaluate PT results and discuss positions and possible actions (Category 1 public meeting)

3. A risk-informed and performance-based metric may need to established to quantitatively inform decision making

Subversion/Adulteration (SA)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

SA1 Should a non-invasive pat down be conducted prior to a drug test or should the clothing provisions be strengthened?

- Boots, pant legs, etc.
- Enhanced identification of subversive paraphernalia
- Conducted pursuant to 10 CFR Part 73 requirements (contraband)

SA2 Should drugs and drug-related paraphernalia be explicitly defined as contraband?

SA3 Would stakeholders have a significant basis for concern if select site-performance data or program requirements are controlled as security-related information to help prevent subversion?

- May help prevent subversion of the drug testing program

Hair Testing (HT)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

HT1 Should hair testing be required for pre-access testing?

- Pro-active regulatory framework to identify substance abusers prior to being granted UAA to protected areas, strategic special nuclear material, or sensitive information
- Conducted pursuant to Part 73 requirements for UAA
- Only focused on Schedule I drugs

HT2 Should hair testing be enabled for random and follow-up testing?

- Significantly increased window of detection – improved detection and deterrence
- Possible reduction in testing frequency

HT3 If hair testing is used in random drug testing and the testing rate is decreased, would stakeholders agree to install automated alcohol monitors?

- Helps maintain workplaces free from the presence or effects of alcohol

Oral Fluids Testing (OFT)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

OFT1 Should oral fluids testing be permitted or required?

- Used in conjunction with urine testing – randomize method used
- Helps resolve urine minimum volume issues
- Helps prevent subversion attempts

Point of Collection Testing (POCT)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

The staff is principally reviewing POCT for oral fluids (OF) because it, in part, is relatively easy to perform, minimizes privacy issues, and test results are more representative of the drugs or metabolites in an individual's blood stream.

- POCT could be used as a screening device for alcohol and drugs
- POCT screening test results typically indicate in less than 10 minutes
  - POCT also enables field testing to keep workers on-the-job longer
- POCT could screen individuals prior to conducting duties and responsibilities – e.g., at the protected area boundary (random testing)
- POCT would enable immediate evaluation of an individual identified for for-cause or post-event testing

POCT for Oral Fluids

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

<u>If POCT-OF technologies improve</u> …

POCT1 Could POCT-OF be used at the PA boundary to screen individuals prior to entry into the work place?

- This is a pro-active strategy to identify potentially impaired individuals prior to conducting 10 CFR 26.4 duties and responsibilities
- Testing would contribute to the site random testing rate
- Testing could improve deterrence

POCT2 Could POCT-OF be used to:

- Screen individuals in the field for random, for-cause, post-event, and follow-up testing

POCT3 Would the industry support a protected area POCT-OF pilot program?

POCT for Oral Fluids

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

If the POCT-OF technologies improve …

POCT4 Could POCT-OF testing be used to provide assurance that individuals are fit for duty prior to the start of a short-duration highly safety- or security-sensitive activity?

- This is a pre-evolution testing proposal to enable timely contractor/vendor access to the site while providing at-that-time reasonable assurance that he or she is fit for duty
- Could this type of testing be used in lieu of placing the individual in the random testing program?
- Would this type of performance-based testing be of benefit to the industry and contractor/vendors?

Abstinence (A)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

A1 Would stakeholders support a definition for abstinence?

- Clarifies use associated with the 5-hour abstinence period, follow-up testing program, and Substance Abuse Expert treatment plans

A2 Based on the continuing prevalence of alcohol in the workplace, would stakeholders support an increased abstinence period?

Sanctions (SANC)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Sanctions help improve deterrence and the period of denial of UAA helps in the timely completion of treatment.

SANC1 Should sanctions be based on the safety- or security-significance of the occurrence and/or roles and responsibilities of the individual?

SANC2 Should a first-time drug-related (except Schedule I drugs, see SANC4) FFD policy violation result in a longer period of denial for individuals?

SANC3 If an individual screens positive for a Schedule I drug for any test type, should the confirmatory testing be conducted at the Limit of Quantitation?

SANC4 Should a permanent denial of authorization be issued for a Schedule I drug FFD policy violation?

Sanctions (SANC)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

SANC5 Should a first-time alcohol-related FFD policy violation result in a longer period of denial?

SANC6 Should 10 CFR 26.75 be enhanced to make clear that the denial of authorization at one site is applicable to all NRC facilities?

- Conforming changes needed to Part 73

SANC7 If disclosure of prescription medication to site medical staff is required, should the sanctions be developed to address this FFD policy change?

Sanctions (SANC)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

SANC8 Should a user who tests positive for multiple substances be administered with more strict sanctions?

- Multi-substance use significantly enhances the chance of being impaired, increases recidivism, and whether the individual can be trusted and relied upon; therefore the individual represents a higher risk and a longer treatment plan may be necessary

SANC9 Should the Part 26 regulatory framework be enhanced to make clear that all individuals who desire or maintain UAA will be held accountable by rule for their deliberate disregard or willful violation of Part 26 requirements?

Sanctions (SANC)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

SANC10 Should the Part 26 regulatory framework be enhanced to require licensees apply sanctions to individuals who violate certain Part 26 provisions that are not explicitly listed in 10 CFR 26.75?

These provisions for example could include, but are not limited to:

- failure to timely or accurately report FFD concerns or legal actions;
- failure to adhere to a follow-up program or treatment plan;
- failure to implement consent and medical information provisions;
- failure to provide a full and accurate self-disclosure;
- failure to report legal actions or disclose medications (if required); and,
- cheating on an any NRC-required training test

The failure of an individual to meet Part 26 obligations is conclusive evidence that the individual cannot be trusted and relied upon to perform the types of duties and responsibilities that make him or her subject to Part 26.

Determination of Fitness (DOF)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

DOF1 Is additional information in Part 26 or guidance on administrating Substance Abuse Expert treatment plans?

Access Authorization Program (AAP)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

AAP1 Should the authorization provisions in 10 CFR Part 26, Subpart C, be moved to 10 CFR Part 73? (see AAP3 below)

- Enhanced security framework under the high assurance objective
- Industry has already consolidated authorization provisions

AAP2 Part 26 requires licensees and other entities to maintain an Employee Assistance Program (EAP) and make this program available to individuals. Section 26.35(c)(2), requires EAP personnel to report "to FFD program management if the individual, in part, poses or has posed an immediate hazard to himself or herself or others."

Should the regulatory framework provide examples in which licensees shall administer a denial of authorization where the individual is "likely to commit self-harm or harm to others"?

For example, should an immediate denial of FFD authorization be required mental or psychological conditions associated with: (1) Federally-recognized felony offenses; (2) extremist or terrorist groups; and (3) a desire to violently overthrow the government of the United States?

Behavioral Observation Program (BOP)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

BOP1 Should the BOP provisions in 10 CFR Part 26.33 be enhanced or combined with the BOP required by 10 CFR Part 73?

- Enhanced security framework – high assurance
- Regulatory clarity
- Industry implements one BOP

BOP2 Should additional clarity be provided on how the BOP shall be implemented? For example, "the BOP applies onsite and offsite and the following actions, at a minimum, shall be reported …"

Performance-Based Requirements (PBR)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

PBR1 Could a performance-based model for auditing laboratories and blind performance specimen providers be implemented?

PBR2 If PBR1 is implemented, would stakeholders support forwarding laboratory test information to the NRC or place a provision in your laboratory contracts for the laboratory to provide this information to the NRC?

PBR3 Are there any other Part 26 provisions that the industry believes could possibly be amended as a performance-based regulation?

Reactors under Construction (RUC), Independent Spent Fuel Storage Installations (ISFSI), and Decommissioning Reactors (DR)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

RUC — Based on the discussions already conducted, would specific provisions need to be considered for reactors under construction? For example: random testing rates, sanctions, prevalence testing, hair testing, multiple population testing, etc.

ISFSI — Would stakeholders support the application of Part 26 to all ISFSIs only during safety-significant activities, such as fuel moves or pressure boundary maintenance?

- This could be an example of pre-evolution testing (e.g., POCT prior to transport, see POCT4, slide 37)

DR — (blank)

"Mandatory Guidelines for Federal Workplace Drug Testing Programs"

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

- Developed by the U.S. Department of Health and Human Services (HHS)
- The national standard for drug testing of Federal employees and civilians in safety-sensitive positions subject to Federal testing (e.g., U.S. DOT)
- Licensees and other entities subject to Part 26 are required to use HHS-certified laboratories for confirmatory testing
- Updated periodically to address drug use trends and to utilize scientific improvements in testing capabilities
- Current HHS Guidelines have been in effect since October 2010
- 10 CFR Part 26 requires licensees to use HHS-certified laboratories
- HHS Guidelines will change again to account for semi-synthetic opiate testing, oral fluid testing, and hair testing

HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

HHS1 Would stakeholders support adherence to the HHS Guidelines into their Security Plans as a license commitment?

HHS2 Would stakeholders commit to updating their testing panel in the Security Plan if prevalence testing identified prevalent drug use or the HHS Guidelines change?

HHS3 Would stakeholders support removal of select provisions from Part 26 because the Part 26 requirements are verbatim with those in the HHS Guidelines?

Summary

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

A significant number of technical topics were discussed in an effort to collaborate on a possible initiative to establish a risk-informed, performance-based, and pro-active Part 26 framework designed to:

1. Enhance worker trustworthiness, accountability, and reliability, and maintains appropriate worker protections

2. Improve efficiency and effectiveness with or without regulatory action

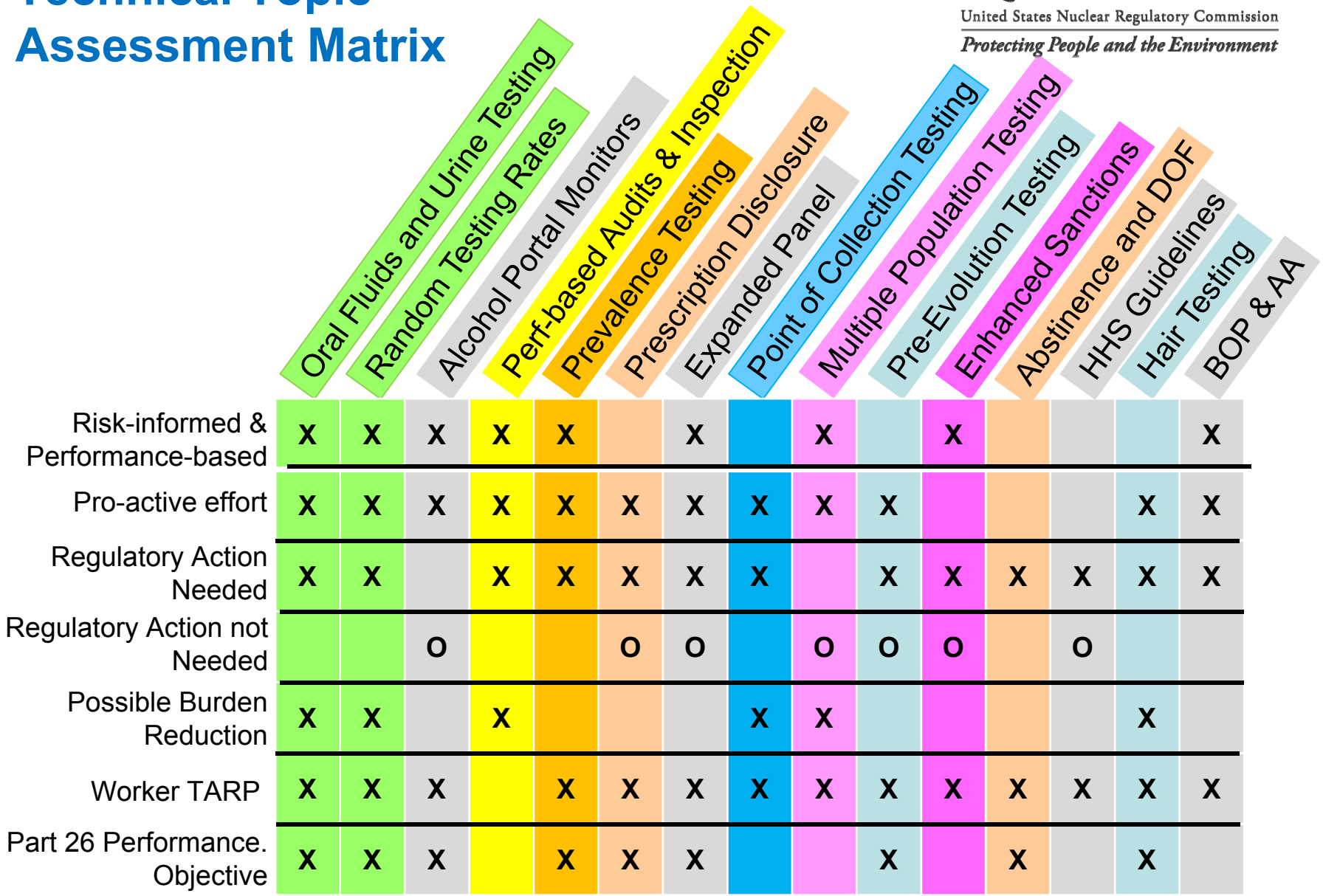
3. More effectively evaluate and address changes in substance use, abuse, and subversion technologies and

4. Reduce future burden on licensees and NRC staff by minimizing future policy and guidance changes.

And how would all of this all fit together?

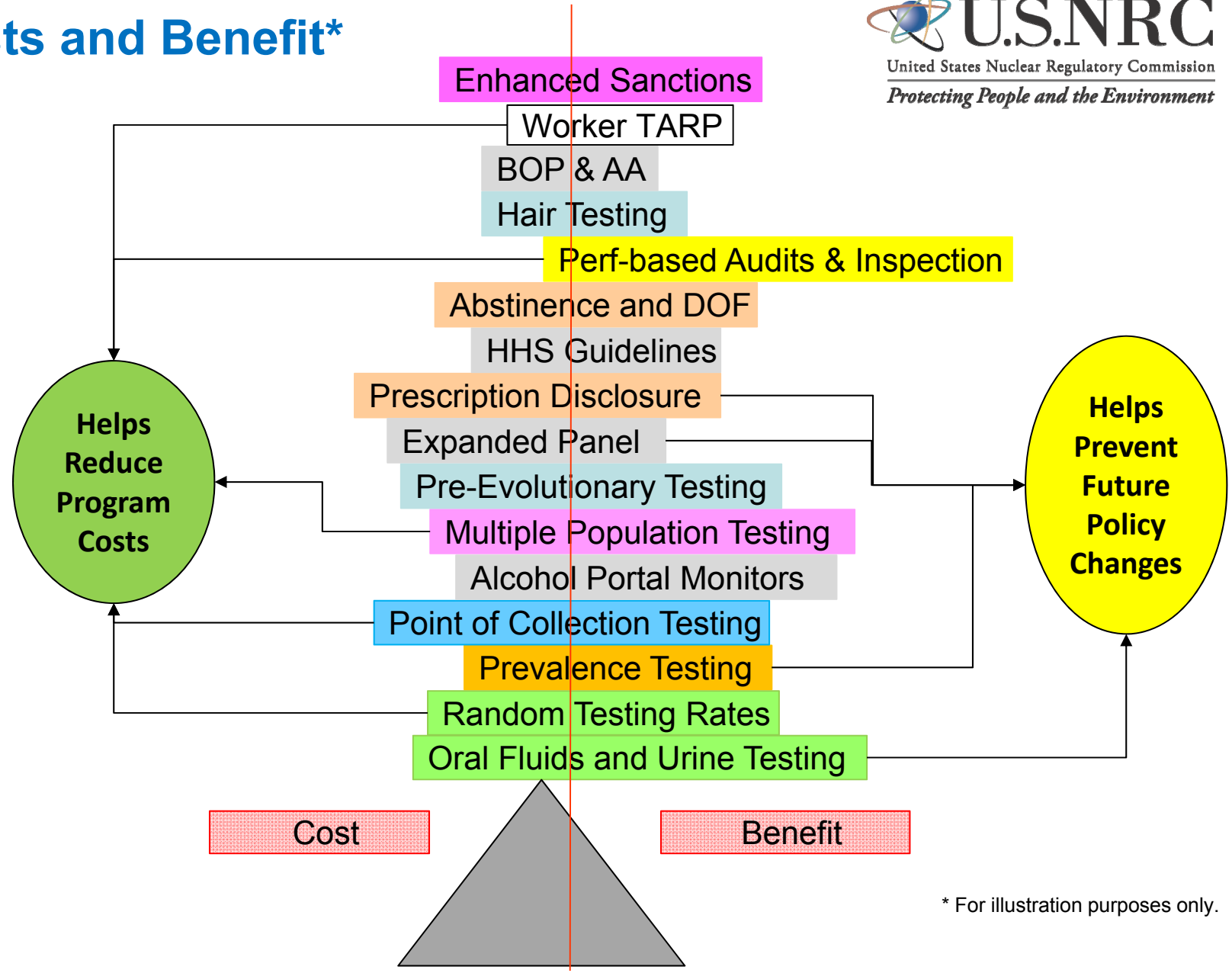
Technical Topic Assessment Matrix

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment



	Oral Fluids and Urine Testing	Random Testing Rates	Alcohol Portal Monitors	Perf-based Audits & Inspection	Prevalence Testing	Prescription Disclosure	Expanded Panel	Point of Collection Testing	Multiple Population Testing	Pre-Evolution Testing	Enhanced Sanctions	Abstinence and DOF	HHS Guidelines	Hair Testing	BOP & AA
Risk-informed & Performance-based	X	X	X	X	X		X		X		X				X
Pro-active effort	X	X	X	X	X	X	X	X	X	X				X	X
Regulatory Action Needed	X	X		X	X	X	X	X		X	X	X	X	X	X
Regulatory Action not Needed			O			O	O		O	O	O		O		
Possible Burden Reduction	X	X		X				X	X					X	
Worker TARP	X	X	X		X	X	X	X	X	X	X	X	X	X	X
Part 26 Performance. Objective	X	X	X		X	X	X			X		X		X	

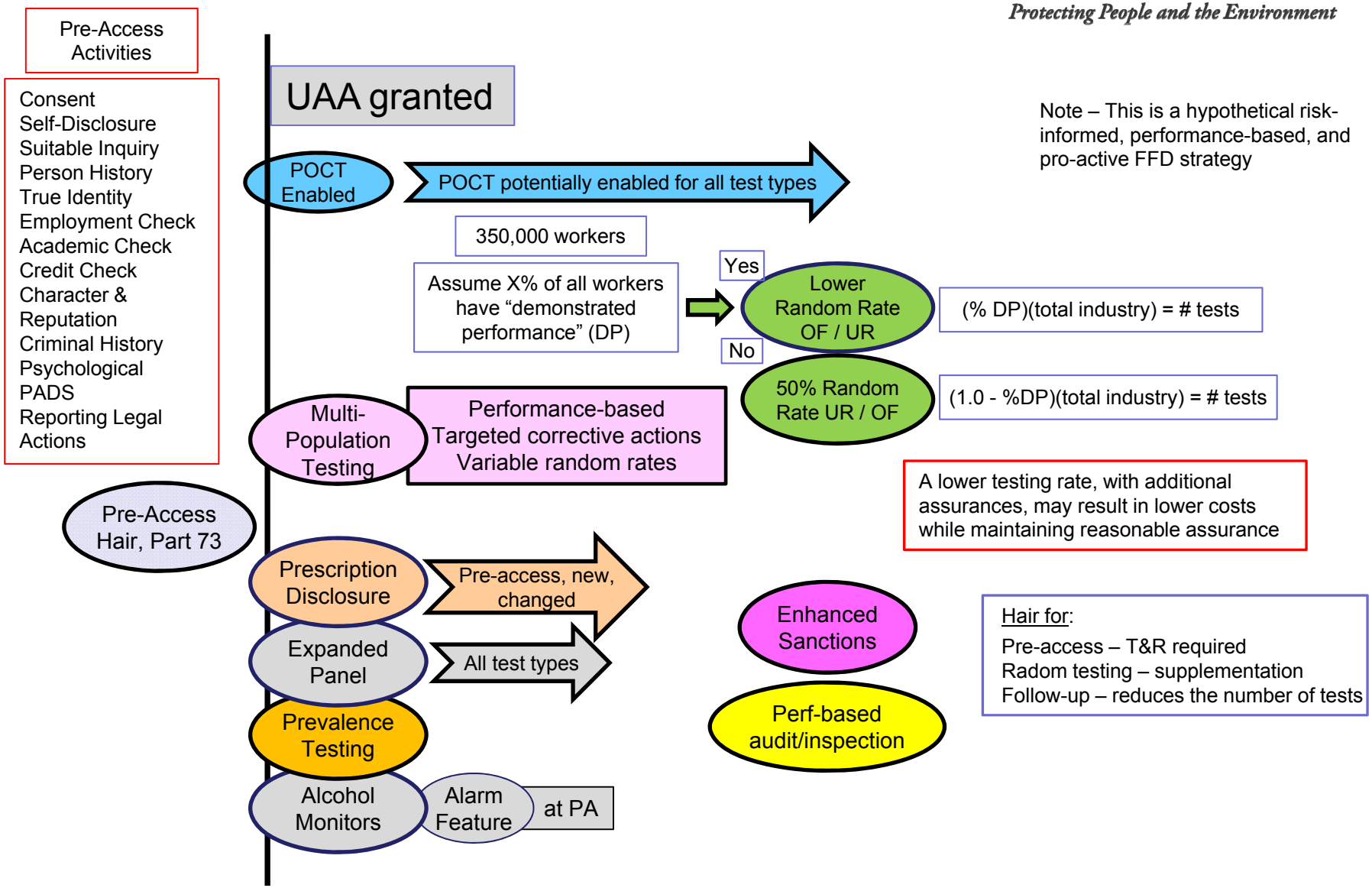
Costs and Benefit*



* For illustration purposes only.

A Risk-Informed Performance-Based Framework

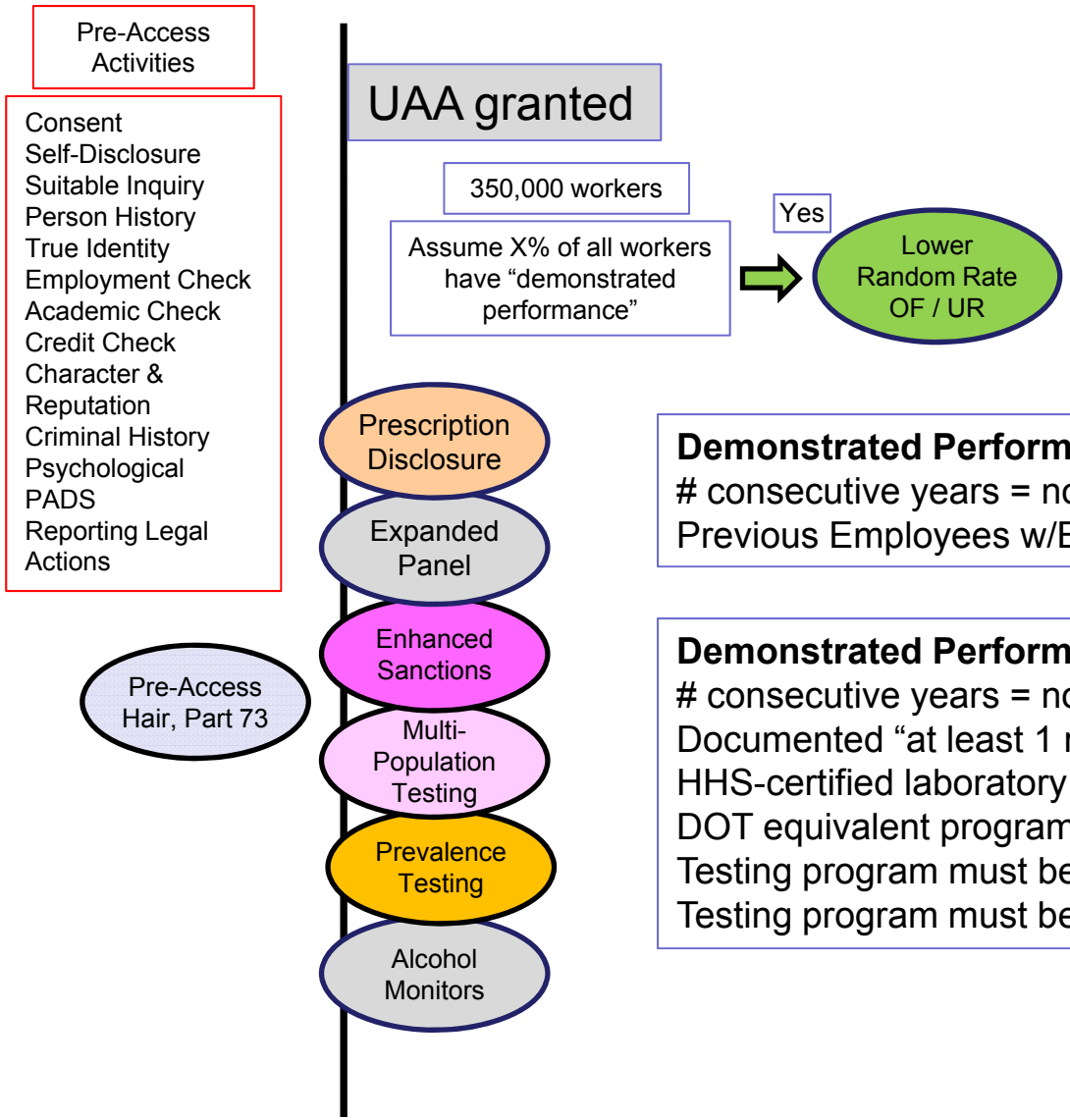
U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment



Note – This is a hypothetical risk-informed, performance-based, and pro-active FFD strategy

Staff presentation material. Please see "Disclaimer" Slide 3.

Demonstrated Performance



Note – This is a hypothetical risk-informed, performance-based, and pro-active FFD strategy

Demonstrated Performance – License Employees*
consecutive years = no positive tests results and no PDI
Previous Employees w/Broken Service > # days = hair test

Demonstrated Performance – Contractor/Vendors*
consecutive years = no positive tests results and no PDI
Documented "at least 1 random hair test/year" program
HHS-certified laboratory use required – MRO reviewed
DOT equivalent program – Results reportable to NRC
Testing program must be certified – DOT medical examiner
Testing program must be subject to licensee/NRC inspection

* Provided for discussion purposes only

Conclusion

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

- Review of parking lot items
- Review of any commitments
- Review of questions/topics outside the pre-identified technical topics
- Publication of an NRC public meeting summary
- Thank you

Contact Information

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

Brian Zaleski
301-287-0638
Brian Zaleski@nrc.gov

Will Smith
301-287-3541
Will.Smith@nrc.gov