UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

April 17, 2000

MEMORANDUM TO: File

FROM: Richard P. Rosano, Chief (R Skelton for)
Reactor Safeguards Section
Operator Licensing, Human Performance
and Plant Support Branch
Division of Inspection, Program Management
Office of Nuclear Reactor Regulation

SUBJECT: MINUTES OF THE MARCH 23, 2000, PUBLIC MEETING WITH THE NUCLEAR ENERGY INSTITUTE (NEI) ON RISK INFORMING 10 CFR PART 73

On March 23, 2000, NRC staff held a public meeting with representatives from NEI, industry, and the public. The purpose of the meeting was to discuss the overall format and structure to be used in risk-informing 10 CFR Part 73 and for NRC to provide comments on a working draft outline proposed by NEI.

NRC staff presented an analytical view of the expected rule which capsulated the overarching criteria in a rough draft table of contents outlining Performance Objectives, Critical Safety Functions, Protection of Target Sets, Protective Strategies, and Program Evaluation. The criteria would be captured through additional security program elements similar to those currently in 10 CFR 73.55, and the evaluation of the force-on-force area would be piloted in conjunction with the licensees' Self Assessment Program (SAP). NEI reviewed the contents and commented on the salient points.

NEI representatives presented a Working Draft paper on the new rule (Attachment 1). NEI proposed that performance objectives would be achieved and logical order and public health and safety would be preserved through a performance-based approach in risk-informing the rule. NRC staff discussed the paper and provided overall positive remarks. NRC staff presented an example of an alternative rulemaking format currently proposed for a federal regulations (Attachment 2).

CONTACTS: Jesse Arildsen, NRR
301-415-1026

Brad Baxter, NRR
301-415-1088

The information above and the information in Attachments 1 and 2 were not intended as a verbatim record. Attachment 3 lists the attendees of the March 23, 2000, public meeting.

Attachments: As stated.

cc. R. Beedle, NEI
R. Enkeboll, NEI
J. Brons, NEI
J. Davis, NEI
E. Lyman, NCI

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D. Thompson, Region II	T. Reis, OE		J. Birmingham, DRIP	
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NAME	BBaxter	JArildsen	RRosano RS for
DATE	04/13/00	04/14/00	04/17/00

OFFICIAL RECORD COPY

Discussion Paper
Working Draft
March 23, 2000

Rulemaking guiding principles:

Provide a single source for security requirements for nuclear power plants.

A looking forward rule that support the reactor oversight process four key elements (Maintain safety, enhance public confidence, improve effectiveness and efficiency, reduce unnecessary regulatory burden.)

The structure of the proposed rule is a performance based approach using risk insights, resulting in a new logical order. Each performance objective supports the previous objective.

Consideration should be given to reducing any confusion of older and overlapping or contradictory guidance. Since this proposal is intended to lead to a revised regulation, only post-issuance guidance or interpretations should be valid, since earlier material pertains to the old version of the rule.

Throughout this proposal, we are focusing resources to support the key processes necessary to protect public health and safety, including new requirements (i.e. target set identification) and the elimination of some unnecessary regulatory burden.

Proposed Rule Structure and Objectives

Purpose and Scope (Objective)

The objective of nuclear power plant security is to provide adequate protection of public health and safety from a radiological release caused by attempted radiological sabotage (malevolent acts) by design basis threats. This is accomplished through the key process of positive access controls to counter the design basis threats as described in 73.1 (a) (1). As part of this objective the security program design will incorporate supporting processes (defense in depth principles) so that no single event can disable the security response capability and maintain a visible hard target image. Operator action will be credited during attempted radiological sabotage as part of the integrated plant response process.

1) Access Authorization Program
   a) The objective of the access authorization program is to ensure that those granted unescorted access are trustworthy and reliable and that they remain so through continuing programs.
      i) Background and criminal history checks. {73.56/73.57}
      ii) Psychological evaluations. {73.56}
      iii) Fitness-for-duty. {part 26-pending rule change}
      iv) Behavioral Observation. {73.56/ part 26}

2) Physical Protection Program
   a) The objective of the physical protection programs is to ensure that unauthorized personnel or materials [firearms, explosives or incendiary devices] are prevented unimpeded access to protected areas. These programs also provide for a system of responses in the event of an attempt to introduce unauthorized personnel or materials into the facility.
      i) Systems and People
         (1) Vehicle barriers - The objective of vehicle barriers is to prevent penetration of the design basis vehicle, as defined. {use first half of 73.55 (c)(7) }
         (2) Personnel Barriers - The objective of personnel barriers is to delineate areas where access is controlled, to impede personnel attempting to gain unauthorized access and to provide an opportunity for assessment of the threat. Personnel barriers shall be configured so as not to obstruct safe plant operation (rapid ingress and egress) {use 73.55 (d)(7)(ii)}
         (3) Detection - The objectives of the detection systems are to provide indications to the security organization of an attempt at unauthorized entry or activity. {73.55 (h)(4)}
         (4) Assessment - The objective of assessment is to determine the validity and extent of the threat, if any. {73.55 (h)(4)(ii)}
      ii) Contingency Response - The objective of contingency response is to take immediate concurrent measures to neutralize the threat of unauthorized access or activity. {73.55 (h)(4)(iii)}
         (1) CAS/SAS – The objective of the CAS/SAS is to provide monitoring, assessment and notification. {73.55 (h)(4)(iii)}
         (2) Communications – The objective of communications is to provide a reliable method to transfer information needed for a coordinated response.
         (3) Armed Responders – The objective of an armed response force is to ensure properly trained and equipped personnel execute response strategies.
         (4) Response strategies – The objective of the response strategies is to ensure that a site specific plan provides adequate personnel,

appropriately equipped, responding in a timely manner to predetermined protected positions to neutralize the threat.
(a) Timelines(See SAP)
(b) Target sets (See SAP)
(c) Command and Control (See SAP)

iii) Training and qualification – The objective of the training and qualification program is to ensure those individuals responsible for implementing the physical protection program have been trained, equipped and qualified to perform each assigned security duty.{73.55 (b)(4)(i)}

iv) Maintenance, testing and calibration - The objective of the maintenance, testing and calibration program is to ensure security equipment is capable of performing its intended function. {73.55 (g)(1)}

v) Search Programs – The objective of the search program is to examine all personnel, vehicles and materials entering the protected area to provide reasonable assurance that certain unauthorized materials are not surreptitiously introduced. {73.55 (d)(1)}

vi) Positive ID – The objective of the positive ID program is to assure that the person granted access is the person with proper authorization. {73.55 (d)(5)(i)}

vii)Administrative Infrastructure – The objective of the administrative infrastructure is to support physical protection with a management system for the development, revision, implementation, and enforcement of security plans, programs and procedures.{73.55 (b)(3)}

3) Self Assessment Program
   a) The objective of the self assessment program is to assess the effectiveness of programs outlined in '1' and '2' to ensure they remain adequate for the protection of the public health and safety.
      i) The self assessment program is based on performance criteria that assess the effectiveness of the implementation of key program elements.
      ii) The standardized self assessment approach uses drills and exercises to assess the effectiveness of the contingency response plans.

EXAMPLE OF ALTERNATIVE FORMAT FOR RULEMAKING

Excerpts of Department of Transportation's Proposed Rule 49 CFR Part 40

Note section, "**Organization of Draft**."

The following document, "Notice of Proposed Rulemaking, 49 CFR Part 40, Procedures for Transportation Workplace Drug and Alcohol Testing Programs," is basically the same as that appearing in the Federal Register on December 9, 1999. We have taken the liberty to further assist readers understand the origin of provisions of the proposed rule text by frequently inserting notes, in brackets and bold type, at the end of most rule text paragraphs. For example, if you see **[40.33(b)]** at the end of a rule text paragraph, this means that the material in the proposed rule comes from §40.33(b) of the current 49 CFR Part 40. We trust you will find these bracket notations helpful.

4910-62U

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket OST-99-6578]

RIN 2105-AC49

Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, DOT

ACTION: Notice of proposed rulemaking

SUMMARY: The Department of Transportation proposes to revise its drug and alcohol testing procedures regulation. The purposes of the revision are to make the organization and language of the regulation clearer, to incorporate guidance and interpretations of the rule into its text, and to update the rule to include new provisions responding to changes in technology, the testing industry, and the Department's program.

DATES: Comments should be received by [120 days from date of publication in the *Federal Register*]. Late-filed comments will be considered to the extent practicable.

ADDRESSES: Comments should be sent to Docket Clerk, Attn: Docket No. OST-99-6578, Department of Transportation, 400 7th Street, SW., Room PL401, Washington DC, 20590. For the convenience of persons wishing to review the docket, it is requested that comments be sent in triplicate. Persons wishing their comments to be acknowledged should enclose a stamped, self-addressed postcard with their comments. The docket clerk will date stamp the postcard and return it to the sender. Comments may be reviewed at the above address from 9:00 a.m. through 5:30 p.m. Monday through Friday. Commenters may also submit their comments electronically. Instructions for electronic submission may be found at the following web address: http://dms.dot.gov/submit/.. The public may also review docketed comments electronically. The following web address provides instructions and access to the DOT electronic docket: http://dms.dot.gov/search/..

FOR FURTHER INFORMATION CONTACT: Mary Bernstein, Director, Office of Drug and Alcohol Policy and Compliance (ODAPC), 400 7th Street, SW., Room 10403, Washington DC, 20590, 202-366-3784 (voice), 202-366-3897 (fax), or

mary.bernstein@ost.dot.gov (e-mail); Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, 400 7th Street, SW., Room 10424, Washington DC, 20590, 202-366-9306 (voice), 202-366-9313 (fax), or bob.ashby@ost.dot.gov (e-mail); or Jim L. Swart, Drug and Alcohol Policy Advisor, Office of Drug and Alcohol Policy and Compliance (ODAPC), 400 7th Street, SW., Room 10403, Washington DC, 20590, 202-366-3784 (voice), 202-366-3897 (fax), or jim.swart@ost.dot.gov (e-mail).

SUPPLEMENTARY INFORMATION:

Background

The Department of Transportation first published its drug testing procedures regulation (49 CFR Part 40) on November 21, 1988 (53 FR 47002), as an interim final rule. The rule was based on the Department of Health and Human Services (HHS) guidelines for Federal agency employee drug testing, with some adaptations for the transportation workplace drug testing program. The Department published a final rule responding to comments on the interim rule a year later (54 FR 49854; December 1, 1989).

The Department added alcohol testing procedures to Part 40 in a February 15, 1994, final rule (59 FR 7340). This rule also modified drug testing procedures pertaining to split samples. Since that time, the Department has amended specific provisions of Part 40 on various occasions (e.g., with respect to non-evidential alcohol screening devices, "shy bladder" procedures).

In the 10 years since Part 40 was first published, the Department has issued a large volume of guidance and over 100 written interpretations, as well as a significant amount of informal advice. Most of this material has not been incorporated into the regulatory text. There have been changes in testing technology, the structure of the drug and alcohol testing business, and the functioning of the Department's drug and alcohol testing programs, making it desirable to update some regulatory provisions. Because the rule was originally based on that of another agency, there are some provisions that never were a close fit for the Department's programs. Moreover, the rule's organization and language do not meet the objectives of the Clinton Administration's current "Plain Language" policies. Under section 610 of the Regulatory Flexibility Act, agencies are directed to review existing rules from time to time with an eye to their effects on small businesses and other small entities.

For all these reasons, the Department decided to review Part 40. As a first step, we issued an advance notice of proposed rulemaking (ANPRM) on April 29, 1996 (61 FR 18713), asking for suggestions for change in the rule. We received 30 comments in response to this ANPRM.

Organization of Draft

Perhaps the first thing readers will notice about this proposal is that Part 40 has been thoroughly restructured, with subparts organized by subject matter area. Compared to the present rule, the text is divided into many more sections, with fewer paragraphs each on average, to make it easier to find regulatory provisions. The proposal uses a

question-answer format, with language specifically directing particular parties to take particular actions (e.g., "As an MRO, you must ..."). We have also tried to express the (admittedly sometimes technical) requirements of the rule in plain language. The Department seeks comment on the clarity, format, and style of the NPRM and solicits suggestions for improving it.

Noteworthy Substantive Changes Proposed

The following section of the preamble lists the NPRM's most noteworthy proposed substantive changes from the existing rule and briefly states the reasons for them.

Interpretations/Exemptions

To avoid confusion and the possibility of overlapping or contradictory guidance, §40.5 spells out specifically the sources and dates of authoritative guidance of the proposed rule. Guidance would come from the Office of the Secretary (OST), either ODAPC or General Counsel's office. It could later be incorporated in written guidance issued by the DOT agencies, though it would be identified as ODAPC/General Counsel's office guidance. Since this proposal is intended to lead to a revised regulation, the language states that only post-issuance guidance or interpretations are valid, since earlier material pertains to the old version of the rule. ODAPC intends to follow a practice of putting new Part 40 interpretations and guidance on the DOT Web site for users' convenience.

This is an OST rule. Therefore, anyone wanting an exemption from it would use the procedures and standards of 49 CFR Part 5, OST's rulemaking procedures. These procedures, rather than those of any of the DOT agencies, would apply to such a request. The proposed section spells out the long-standing procedures of Part 5 for granting an exemption. These standards are intended to preclude "rulemaking by exemption," which is contrary to good rulemaking practice and the Administrative Procedure Act.

Service Agent Assurance

Proposed §40.11 includes new provisions that call for both regulated employers and their service agents to sign a contract provision committing them to compliance with Part 40 provisions. "Service agent" is a new term, intended to encompass participants in the testing process other than employers themselves (e.g., medical review officers (MROs), substance abuse professionals (SAPs), collectors, laboratories, third-party administrators). The Department is using "service agent" as a working term for this collection of participants who provide testing-regulated services to employers. The Department invites suggestions for other terms for this group of service providers.

NRC Procedures

In response to a comment from the Nuclear Regulatory Commission (NRC), the proposed rule would permit an entity which has employees covered by both DOT and NRC testing requirements to use either agency's procedural requirements.

§40.33 What requirements must a collector meet?

(a) To be a collector, you must do the following:

(1) Read the drug testing procedures in this part and the current "DOT Urine Specimen Collection Procedures Guidelines" and attest in writing to your understanding of them. (The "DOT Urine Specimen Collection Procedures Guidelines" is available at ODAPC, Department of Transportation, 400 7th Street, SW., Room 10403, Washington DC, 20590.) **[new]**

(2) Be trained to proficiency on collection procedures in this part by another person(s) sufficiently knowledgeable in the applicable collection procedures of this part to be able to evaluate the collector's performance. **[40.23(d)(1)]**

(i) The person providing the instruction must provide written documentation that you have demonstrated proficiency in collections under this part by your completing five consecutive error-free trial collections. **[new]**

(A) The five trial collections must include both uneventful and problematic examples.

(B) In addition to two uneventful collection scenarios, one must address insufficient quantity of urine, one the temperature out of range, and one in which the employee refuses to sign the CCF.

(ii) The person providing the instruction will monitor, evaluate, and attest whether or not the trial collections are "error-free." **[new]**

(iii) The person providing the instruction must emphasize that you are responsible for maintaining the integrity of the collection process, ensuring the privacy of employees being tested, and avoiding conduct or statements that could be viewed as offensive or inappropriate. **[40.23(d)(1)]**

(3) Meet the requirements of paragraph (b)(2) of this section by [date six months from the effective date of the final regulation], if you were a collector prior to [effective date of the final regulation]. Meet the requirements of paragraph (b)(2) of this section prior to your first collection, if you become a collector after [effective date of the final regulation]. **[new]**

(4) Receive additional training, as needed, to ensure proficiency as the technology you use changes.

(5) Be retrained to proficiency if you make a mistake in the collection process that has caused a test to be canceled. **[new]**

(i) This retraining must be provided and your proficiency documented in writing by a person sufficiently knowledgeable in the applicable collection procedures of this part.

(ii) The instruction need only be in the general area of your deficiency that caused the test to be canceled.

(iii) As part of the retraining, you will have to demonstrate your proficiency in the collection procedures of this part by completing three consecutive error-free trial collections before you conduct another DOT collection of a safety-sensitive employee.

(iv) The person providing the instruction will monitor, evaluate, and attest whether or not the trial collections are "error-free."

(b) As a collector, you must be retrained in the elements of paragraph (a) of this section by [date one year from the effective date of the final regulation], or two years from the date you became a collector, whichever is later, and once every two years, thereafter. **[new]**

(c) As a collector, you must maintain all documentation of training/retraining as long as you serve as a collector. **[new]**

§40.35 What requirements must organizations employing collectors meet?

This section becomes effective [date six months from the effective date of the final regulation]. **[new]**

(a) As an organization employing the collector (e.g., a transportation employer, third-party administrator, occupational health clinic), you must maintain in your files the following information:

(1) A signed statement by the collector that he or she has read and understood the drug testing procedures in this part and the current "DOT Urine Specimen Collection Procedures Guidelines"; and

(2) A signed statement by an official of the organization that the collector has received training/retraining and has demonstrated proficiency as required by this part.

(b) You must retain these signed statements as long as the person performs collector functions for the organization and for 2 years after the person ceases to perform these functions for the organization.

(c) You must provide to collectors the name and telephone number of a designated employer representative (DER) to contact about any problems or issues that may arise during the collection process. **[new]**

§40.37 Where is other information on the role of collectors found in this regulation?

You can find other information on the role and functions of collectors in the following sections of this part:

§40.1 - coverage.
§40.3 - definition.
§40.43 - steps to prepare and secure collection site.
§§40.45 - 40.47 - use of CCF.
§§40.61 - 40.63 - preliminary steps in collections.
§40.65 - role in checking specimens.
§40.67 - role in directly observed collections.
§40.69 - role in monitored collections.
§40.71 - role in single specimen collections.
§40.73 - role in split specimen collections.
§40.75 - chain of custody completion and finishing the collection process.
§40.191 - action in case of refusals to take test.
§40.193 - action in "shy bladder" situations.
§§40.197 - 40.199 - collector errors in tests, effects, and means of correction.

(b) As a collector, you must do the following before each collection:

(1) Secure any water sources or otherwise make them unavailable to employees (e.g., turn off water inlet, tape handles to prevent opening faucets);

(2) Make sure that the water in the toilet is blue;

(3) Make sure that no soap, disinfectants, cleaning agents, or other possible adulterants are present;

(4) Inspect the site to make sure that no foreign or unauthorized substances are present;

(5) Tape or otherwise secure shut any movable toilet tank top, or put bluing in the tank;

(6) Make sure that undetected access (e.g., through a door not in your view) is not possible; **[40.25(b)(1)-(2)]**

(7) Secure areas and items (e.g., ledges, trash receptacles, paper towel holders, under-sink areas) that appear suitable for concealing contaminants; and **[new]**

(8) Recheck items in paragraphs (b) (1) through (7) of this section following each collection to ensure the site's continued integrity. **[new]**

(c) If the collection site uses a facility normally used for other purposes, like a public rest room or hospital examining room, you must, as a collector, also make sure before the collection that:

(1) Access to collection materials and specimens is effectively restricted; and

(2) The facility is secured against access during the procedure to ensure privacy to the employee and prevent distraction of the collection site person and limited-access signs are posted. **[40.25(b)(2)]**

(d) As a collector, you must take the following additional steps to ensure security during the collection process:

(1) To avoid distraction that could compromise security, make sure you have only one employee under your supervision at any time. **[40.25(d)]**

(2) To the greatest extent you can, keep an employee's collection container within view of both you and the employee before and after the employee has urinated. **[40.25(g)]**

(3) Make sure you are the only person in addition to the employee who handles specimens before they are secured in the shipping container. **[40.25(d)]**

(4) In the time between when the employee gives you the specimen and the time you seal the specimen, remain within the collection site. **[40.25(f)(25)(ii)]**

(5) Maintain personal control over each specimen and CCF throughout the collection process. **[40.25(f)(25)(i)]**

(e) If you are operating a collection site, you must prevent unauthorized personnel from entering any part of the site. **[40.25(d); subparagraphs new]**

(1) The only people you are to treat as authorized persons are employees being tested, collectors and other collection site workers, DERs, employee representatives authorized by the employer (e.g., employer policy; labor-management agreement), and representatives of DOT.

(2) You must make sure that all authorized persons are under the supervision of a collector at all times when permitted into the site.

(3) You may remove any person who obstructs, interferes with, or causes a delay in the collection process. **[new]**

(4) You must make sure that no one except the employee, collector, and monitor or direct observer enters the room in which urination occurs.

(f) If you are operating a collection site, you must minimize the number of persons handling specimens. **[40.25(k)]**

§40.45 What form is used to document a DOT urine collection?

(a) The Federal Drug Testing Custody and Control Form (CCF) must be used to document every urine collection required by the DOT drug testing program. The CCF must be a seven-part carbonless manifold form. (The CCF is available at U.S. Government Printing Office, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954.) **[40.23(a)(1)(i)]**

(b) As a participant in the DOT drug testing program, you may not modify or revise the CCF except as follows:

(1) You may include other information needed for billing or other purposes necessary to the collection process. **[40.23(a)(1)(ii)]**

(2) The CCF must include the employer's name, address and telephone number, which may be preprinted, typed, or handwritten. In addition, a consortium's or third-party administrator's name, address, and telephone number may be included. **[comment]**

(3) Instead of printing the entire pages of the CCF in the colors specified by HHS, you may use white pages with clearly discernible borders in the specified color for each page. **[comment]**

(4) As an employer, you may add, in the "Remarks" section of the CCF, the name of the DOT agency under whose authority the test occurred. **[comment]**

(5) As a collector, you may use a CCF with your name, address, and telephone number preprinted but under no circumstances are any signatures to be added before the collection event. **[comment]**

(c) Under no circumstances may the CCF transmit personal identifying information about an employee (other than a social security number or other employee identification number) to a laboratory. **[40.23(a)(1)(ii)]**

(d) As the collector, you must make sure that medical information about the employee (e.g., medications the employee has taken) appears only on the copy of the CCF given to the employee. **[40.23(a)(1)(iii)]**

(e) As an employer outside the United States, you may use a foreign-language (equivalent) version of the CCF approved by ODAPC (e.g., in French for use in Canada or Spanish for use in Mexico). **[new]**

§40.47 May employers use the CCF for non-DOT collections or non-Federal forms for DOT collections?

ATTENDANCE LIST
NRC AND NEI MEETING
MARCH 23,2000

ON MARCH 23, 2000, THE FOLLOWING INDIVIDUALS ATTENDED THE MEETING BETWEEN THE NUCLEAR REGULATORY COMMISSION AND NUCLEAR ENERGY INSTITUTE HELD IN ROOM T-3B45 OF TWO WHITE FLINT BUILDING, ROCKVILLE, MARYLAND.

Name	Organization	Phone
Richard Rosano	NRC/NRR	301-415-3282
Jesse Arildsen	NRC/NRR	301-415-1026
Robert Skelton	NRC/NRR	301-415-3309
Ray Hsu	NRC/NRR	301-415-3212
David Orrik	NRC/NRR	301-415-3213
Barry Manili	NRC/NRR	301-415-2912
Garmon West	NRC/NRR	301-415-1044
Brad Baxter	NRC/NRR	301-415-1088
Elaine McNeil	NRC/NRR	301-415-2932
Dennis Gordon	NRC/NRR	301-415-1162
Al Tartiff	NRC/NRR	301-415-3814
Sandra Frattali	NRC/NRR	301-415-3730
Joe Birmingham	NRC/NRR	301-415-2829
Harold Christensen	NRC/NRR	301-415-1031
Kathryn Winsberg	NRC/OGC	301-415-1641
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