DRAFT SUPPORTING STATEMENT FOR 10 CFR PART 26
FITNESS-FOR-DUTY PROGRAM

(OMB Clearance No. 3150-0146)
Extension Request with Burden Revisions

DESCRIPTION OF THE INFORMATION COLLECTION

The 10 CFR Part 26 information collection requirements apply to all licensees authorized to construct or operate a nuclear power reactor and all licensees authorized to use, possess, or transport irradiated Category 1 nuclear material. There are 72 sites and 2 Category I sites that are required to comply with 10 CFR Part 26. These licensees shall establish, implement, and retain on file for 5 years the records described below. Where there is a retention requirement different from 5 years, it is so stated in the applicable section.

These information collections are necessary to properly manage fitness-for-duty programs and provide information to be used in the development of public policy. The collection of information pertaining to significant fitness-for-duty events is necessary to permit timely evaluation of events that might become problems and that may require a timely response by the NRC staff to ensure that the health and safety of the public is not endangered.

Section 26.6 provides that the Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 26.

Section 26.20(a)-(e) requires that each licensee subject to Part 26 establish and implement written policies and procedures designed to meet the general performance objectives and specific requirements of Part 26. These policies and procedures must address fitness for duty through the following:

> Section 26.20(a): An overall description of licensee policy on fitness for duty.
>
> Section 26.20(b): A description of programs which are available to personnel desiring assistance in dealing with drug, alcohol, or other problems that could adversely affect the performance of activities within the scope of this Part.
>
> Section 26.20(c): Procedures to be utilized in testing for drugs and alcohol, including procedures for protecting the employee and the integrity of the specimen, and the quality controls used to ensure the test results are valid and attributable to the correct individual.
>
> Section 26.20(d): A description of immediate and follow-on actions which will be taken, and the procedures to be utilized, in those cases where employees, vendors, or contractors assigned to duties within the scope of this Part are determined to have been involved in the use, sale, or possession of illegal drugs; or to have consumed alcohol during the mandatory pre-work abstinence period, while on duty, or to excess prior to reporting to duty as demonstrated with a test that can be used to determine blood alcohol concentration.

Section 26.20(e): A procedure that will ensure that persons called in to perform an unscheduled working tour are fit to perform the test assigned.

The requirement is necessary to inform affected individuals with sufficient detail on licensee rules, what is expected of them, and what consequences may result from lack of adherence to the policy. It also provides a description of programs which are available to personnel desiring assistance in dealing with drug problems that could adversely affect their performance and outlines procedures to be utilized in testing for drugs. The requirement also partially meets the legal necessity of providing "prior notice" and having it documented for evidence in legal proceedings.

These records will be maintained until the license is terminated. Superseded records will be retained for 3 years.

Section 26.21(b) requires that appropriate records of policy communications and awareness training be documented and retained for a period of at least 3 years.

This ensures that persons assigned to activities within the scope of Part 26 are provided with appropriate training so that they understand the methods that will be used to implement the policy, the personal and public health and safety hazards associated with abuse of drugs, the effects of prescription and over-the-counter drugs and dietary conditions on drug test results, and the role of the Medical Review Officer (MRO). The requirement also partially meets the legal necessity of providing "prior notice" and having it documented for evidence in legal proceedings.

Section 26.22(c) provides for records of training for supervisors and other personnel to document the conduct of such training. This ensures that such persons have been trained and understand their role in the implementation of the fitness-for-duty program, that they are sufficiently skilled to detect conditions that arise from abuse or presence of drugs, and that the proper action is initiated. These records must be retained for a period of at least 3 years.

Sections 26.23(a) and 26.70(b). These sections permit licensees to accept a fitness-for-duty program administered by their contractors and vendors. Written agreements between licensees and their contractors or vendors will clearly show that the licensee is responsible to the Commission for maintaining an effective fitness-for-duty program. Section 26.70 also permits the NRC to inspect, copy, take copies of any licensee's, contractor's, or vendor's documents related to implementation of the licensee's contractor's, or vendor's fitness-for-duty program under the scope of the contracted activities. The records applicable to these sections must be maintained for the life of the contract.

Section 26.23(b) requires licensees to assure that contractors conduct audits pursuant to Section 26.80.

Section 26.24(a) requires chemical testing to provide the licensee a means to deter and detect substance abuse. In this regard the licensee shall implement chemical testing programs that require:

(1) Testing within 60 days prior to granting of unescorted access to protected areas;
(2) Unannounced tests imposed in a random manner at a rate of 50% for licensee, contractor and vendor employees;
(3) Testing for-cause, i.e., as soon as possible following any observed behavior, incidents or credible information indicating possible substance abuse.
(4) Follow-up testing on an unannounced basis to verify continued abstention from the use of substances covered under Part 26.

Although no records are required by this section, these requirements influence the records that are made to meet the testing validity standards set forth in Appendix A.

Section 26.24(d)(1) provides for licensee conduct of initial screening tests of an aliquot provided, among other requisites, that licensee staff qualifications are documented and quality control procedures include certain specified controls.

Section 24.24(d)(2)(iii) requires, immediately upon receipt of a negative report, the removal from the tested individual's personnel record or other records any matter which could link the individual to a temporary suspension and Section 26.24(d)(2)(iv) requires the one-time development, and subsequent use, of a notification letter for the purpose of providing a written statement to a tested individual, whose preliminary onsite test is positive, but not confirmed by the MRO, that the records have not been retained and that the temporary removal or suspension or other administrative action will not be disclosed. This ensures that the reputations and careers of those individuals are not jeopardized. No report is made to NRC of this notification.

Section 26.24(e) requires the MRO to notify licensee management of positive test results. The current rule does not require written notification; however, that is the general practice since such test results cause an adverse personnel action.

Section 26.25 requires each licensee to maintain an employee assistance program. The employee assistance program staff shall inform licensee management when a determination has been made that any individual's condition constitutes a hazard to himself or herself or others. This section also requires that the licensee's employee assistance staff inform licensee management when a determination has been made that any individual's condition constitutes a hazard to himself or others.

Section 26.27(a)(1), and (2) and (3) requires a licensee, prior to the initial granting of unescorted access to a protected area or the assignment to activities within the scope of Part 26 to any person, to obtain a written statement from the individual as to whether activities within the scope of Part 26 were ever denied the individual. This is accomplished by checking a few boxes on a form and signing the individual's name. A suitable inquiry is then conducted to verify the information. Records regarding persons denied unescorted access or removed under

the provisions of Part 26 are made available in response to a licensee's, contractor's, or vendor's inquiry supported by a signed release from the individual. This will assist the licensee to determine if persons should be granted or denied unescorted access in accordance with a fitness-for-duty policy. No report is made to the NRC.

Section 26.27(b)(2) requires, at a minimum, that at the first confirmed positive drug test by an individual conducting activities covered by Part 26; plans for treatment, follow-up testing, future employment, and rehabilitation be developed; and that management and medical assurance of the individual's fitness for duty be obtained before the individual is returned to duty.

Section 26.27(b)(4) requires that unescorted access can only be granted to an individual who has been removed from the activities covered by Part 26 for 3 years or more after satisfactory management and medical assurance that the individual has abstained from drugs for at least 3 years and is fit to perform those activities; that any individual reinstated under these conditions be given unannounced follow-up tests to verify continued abstinence; and that any subsequent involvement with illegal substances results in permanent denial of unescorted access. These records are maintained until the license is terminated.

Section 26.27(c) requires that refusal to provide a specimen for testing and resignation prior to removal be recorded as removals for cause. These records must be retained for the purpose of meeting the requirements of 10 CFR 26.27(a).

Section 26.27(d) requires a licensee to notify the NRC when an NRC employee may be under the influence of any substance, or is otherwise unfit for duty. This ensures that the NRC can take appropriate actions as necessary.

Section 26.28 requires each licensee, contractor, or vendor implementing a fitness-for-duty program under 10 CFR 26.23 to establish a procedure for its employee to appeal a positive alcohol or drug determination.

Section 26.29(a) and (b) requires that each licensee subject to Part 26, who collects personal information on an employee for the purpose of complying with part 26, shall establish and maintain a system of files and procedures for the protection of the personal information.

In order to ensure the protection of information, the licensee shall not disclose the personal information collected and maintained to persons other than assigned MRO's, other licensees legitimately seeking the information as required by part 26 for employment decisions and who have obtained a release from current or prospective employees or contractor personnel, NRC representatives, appropriate law enforcement officials, the subject or his or her representative, or to those licensee personnel who have a need to have access to the information in performing assigned duties. These records are maintained until the license is terminated.

Section 26.71 requires each licensee and each contractor or vendor implementing a licensee approved program to:

(a) retain records of inquiries that result in the granting of unescorted access (i.e., background checks). These records must be maintained for 5 years to facilitate suitable inquiries under Section 26.27(a) and because individuals can be denied unescorted access to the protected area or removed from activities within the scope of Part 26 for a period of up to 5 years.

(b) retain records of confirmed positive test results and the subsequent personnel actions. These records support the suitable inquiries requested by Section 26.27(a). This permits the evaluation of program performance and the correction of any program weaknesses so identified. These records also must be retained for 5 years for the same reasons provided above with Section 26.71(a).

(c) retain records of persons made ineligible for assignment to activities within the scope of Part 26 who have been involved in the sale, use, or possession of illegal drugs while within a protected area. This requires licensees to retain records of persons made ineligible for 3 years or longer until the Commission terminates each licenses under which the records were created. These records are needed to facilitate inquiries from other licensees required by Section 26.27(a) to determine if a person had been made ineligible for assignment to activities within the scope of 10 CFR 26.

(d) collect and compile fitness-for-duty program performance data, and submit to the NRC biannually. This data includes statistics pertaining to drug testing, management actions, management actions on appeals and their resolutions, and for those licensees who choose to exercise the option of temporarily removing an individual as permitted by 10 CFR 26.24(d)(2), data on reporting of test results by process stage. This data will enable proper analysis and assist NRC staff in determining actions needed to correct program weaknesses and revise public policy. This data and analysis must be retained for 3 years.

Section 26.73 requires each licensee to inform the NRC Operations Center by telephone within 24 hours of discovery of significant fitness-for-duty events. This will enable the NRC staff to evaluate the event and determine whether immediate actions by the staff are warranted.

Section 26.73(d) requires each licensee to certify to NRC that their fitness-for-duty programs are implemented. This one-time reporting requirement provided to NRC the necessary background information that all programs were in place and implemented on schedule. This requirement would also apply to any new licensees subject to Part 26. No new licensees are anticipated.

Sections 26.80(a) and (c) requires each licensee subject to part 26 to conduct an audit of their fitness-for-duty program nominally every 12 months. Results and recommendations of the audit must be documented and reported to senior corporate and site management. Resolution of audit findings and corrective actions must be documented. These documents must be retained for 3 years. This audit documentation will help ensure identification and resolution of program weaknesses and help NRC determine what corrective actions are necessary.

Appendix A sets forth the minimum standards for alcohol and drug testing; it emphasizes the procedures and records (chain-of-custody, quality control, etc.) for ensuring the integrity of the test results, and the process for reporting and evaluating test results. The Appendix is an adaption of the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (53 FR 11970). The documentation and reporting are consistent with Federal standards and are needed to ensure that test results are valid and defendable in any legal proceeding.

Specifically, the standards in Appendix A contain reporting and recordkeeping requirements as listed in Attachment 3.

A. JUSTIFICATION

1. Need for and Practical Utility of the Collection of Information

The regulations in 10 CFR Part 26 establish requirements for licensees authorized to operate nuclear power reactors and licensees authorized to use, possess, or transport irradiated Category 1 nuclear material to implement a fitness-for-duty program. The general objective of the program is to provide reasonable assurance that licensee personnel will perform their tasks in a reliable and trustworthy manner and 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. Included in this general objective is the goal of achieving a drug-free workplace and a workplace free of the effects of such substances.

The NRC has adapted pertinent parts of the Health and Human Services (HHS) Guidelines concerning drug testing programs for application to the nuclear industry.

This supporting statement is designed to provide a comprehensive overview of the information collection requirements contained in 10 CFR Part 26. The information collection requirements fall into three categories:

a. Written policies and procedures and associated records to facilitate proper management of the fitness-for-duty program. Included are records of training, program audits, contract provisions and certain protected information used to ensure that those persons who tested positive, were removed for cause, or whose fitness for duty has been questioned, are not returned to duty until they have corrected their problem.

b. Telephonic reports of significant fitness-for-duty events made within 24 hours of the event.

c. Collection and analysis of fitness-for-duty program performance data.

2. Agency Use of Information

The NRC will use the required records and reports for one or more of the following purposes:

a. To determine if there are problems requiring timely action by the NRC staff. NRC responses vary depending upon the circumstances but could include immediate telephone contact with the licensee to discuss the event or site inspection.

b. To monitor compliance with 10 CFR Part 26.

c. To perform empirical evaluations of this evolving discipline in support of any future considerations. This would include analyses of trends and lessons learned.

3. Reduction of Burden Through Information Technology

At the current time, no licensees submit the information electronically. Most licensees collect and store fitness-for-duty data electronically.

The NRC has no objection to NEI or another industry group creating an electronic mail system acceptable to the NRC for submitting information in an acceptable data collection format. The NRC will continue to capitalize on information technology for improving information access, information distribution, and public interaction. However, the NRC will not eliminate paper in favor of electronic communication without full consideration of the public's ability to access information electronically.

4. Effort to Identify Duplication and Use Similar Information

The collection of information required by 10 CFR Part 26 does not duplicate any other requirements for collection of information.

5. Effort to Reduce Small Business Burden

This information collection does not affect small businesses.

6. Consequences to the Federal Program or Policy Activities if the Collection is Not Conducted or is Conducted Less Frequently

The reporting of significant events is limited to telephone reports on as "as-needed" basis. A frequency of approximately 6 months is established for collection, analysis and reporting of program performance data. Without these records the licensee and the NRC would be unable to analyze and take appropriate actions necessary to correct program weaknesses and to take other corrective actions.

7. Circumstances Which Justify Variation from OMB Guidelines

Retention of certain records in excess of 3 years has been deemed necessary to ensure that the health and safety of the public will not be adversely affected. These records are specified above under the description of the information collection.

8. Consultations Outside the NRC

The requirements in 10 CFR Part 26 are discussed on a continuing basis with the Nuclear Energy Institute (NEI), Substance Abuse and Mental Health Services Administration (SAMHSA) and licensees individually and at industry-wide meetings.

Opportunity for public comment has been published in the Federal Register.

In an SRM dated December 4, 2000, the Commission approved final rule changes to 10 CFR Part 26, “Fitness-for-Duty Programs” (SECY-00-0159) that were intended to reduce unnecessary regulatory burden on licensees. Major comments were received on the final rule that stated that the rule would result in additional costs, rather than savings for licensees, that the rule language was unclear, and that requirements for Part 26 and Part 73.56 were not consistent. The NRC has withdrawn the final rule to resolve commenters’ concerns.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

Section 26.71 requires each licensee to collect personal information for the purpose of complying with 10 CFR 26. However, the licencee is required by Section 26.29 to maintain a system of files and procedures for the protection of the personal information. Personal and sensitive information will not be reported to the NRC by the licensee. Under Section 26.25, Employee Assistance Program staff will provide confidential assistance except where safety considerations must prevail and when the Employee Assistance Program counselor believes that a worker’s condition poses a hazard to himself or herself or others. Otherwise, voluntary self-referrals to the Employee Assistance Programs are treated confidentially and are not reported to management. Furthermore, that information would not be available for disclosure in response to an inquiry of previous employers.

To assure the protection of an individual temporarily suspended under the provisions where subsequent testing does not confirm the basis for such removal, 10 CFR 26.24(d)(2)(iv) requires the licensee to eliminate from its records any matter that could link the individual to a temporary removal or

suspension or other administrative action, prohibits the licensee from disclosing the matter, and requires the licensee to provide the individual with a written statement of these measures and other related matters. NOTE: The licensee is prohibited from retaining a copy of the document provided to the individual.

11. Justification for Sensitive Questions

Section 26.27(a) requires each licensee to obtain a written statement concerning substance abuse history and to conduct an inquiry to determine the validity of that information. This information is needed to determine if there are any past actions that may be indicative of an individual's future reliability and trustworthiness that could adversely affect their ability to safety and competently perform their duties. Individual names are not required in reports submitted to the NRC in accordance with 10 CFR 26.73(a) and (b), and 26.71(d).

12. Estimate of Industry Burden and Burden Hour Cost

Industry costs associated with the information collection requirements contained in 10 CFR Part 26 are provided in Table 1, Attachment 1.

Licensees currently have fitness-for-duty programs in place that adhere to industry guidance. These programs include written policies and procedures and contract provisions which establish fitness-for-duty agreements between the licensee and contractor or vendor; the minor changes to contracts that may be needed in a few instances are deemed insufficient to quantify as a burden.

Burden estimates are based, in part, on discussions with nuclear utility employees and on estimates of NRC personnel familiar with the records and reports required by 10 CFR Part 26.

13. Estimate of Other Additional Costs

NRC has determined that the storage and equipment costs per foot are approximately $45. The quantity of records to be maintained is roughly proportional to the recordkeeping burden. Based on the number of pages maintained for a typical clearance, the records storage costs has been determined to be equal to 0.0004 percent of the recordkeeping burden cost. Therefore, the storage cost for this clearance is estimated to be $3,421 (57,018.6) hours X $150/hour X 0.0004).

14. Estimated Annual Cost to the Federal Government

The total estimated annual cost to the Federal Government is expected to be $74,925 as shown in Table 2, Attachment 2. This cost is fully recovered through license fees assessed to NRC licensees pursuant to 10 CFR Parts 170 and 171.

15. Reasons for Change in Burden or Cost

The burden for two Category I sites that are required to comply with 10 CFR Part 26 have been added to the clearance. Cost has been adjusted based on NRC's current licensee rate.

16. Publication for Statistical Use

The NRC has published an annual report (NUREG.-5758, Volumes 1 through 6) that summarizes the results of the drug and alcohol testing programs submitted semi-annually by each licensee. The data for CY 1996 and 1997 were published in Information Notice 98-39.

17. Reason for Not Displaying the Expiration Data

The information collection requirements are contained in the Code of Federal Regulations. Amending the Code to display information the current expiration data could be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

None.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this information collection.

TABLE 1
10 CFR PART 26 - FITNESS-FOR-DUTY PROGRAM

Estimate of Burden Required of Industry - **RECORDKEEPING**

SUBSECTION	NO. OF SITES	BURDEN PER SITE/HRS.	TOTAL BURDEN/HRS.	TOTAL COST x $150
26.20 (a)-(e) Written policies and procedures (maintenance)	74	1	74	$11, 100
26.21(b) and 26.22(c) Training records	74	120	8,880	$1,322,000
26.23(b), 26.28 and 26.70(b) Contract provisions (maintenance)	74	.5	37	$5,550
26.24, 26.29(a) and (b) and 26.71(a)(b)(c)(d) Records concerning persons tested positive, removed for cause, and related matters	74	12	888	$133,200
26.24(d)(2)(iv) Notification of Suspension (one-time development)	4	1	0*	0
26.24(d)(2)(iii) and (iv) Records being destroyed (2 per site)	4	.4	1.6	$240
26.25 Maintain employee assistance program	74	2	148	$22,200
26.27(a)(1), (2) and (3) and 26.27(c) Written statement for individual	74	5.0	370	$55,500
26.27(b)(2) Minimum requirements for a first confirmed positive drug test	74	16	1184	$177,600

*None expected

TABLE 1 - RECORDKEEPING (Continued)

SUBSECTION	NO. OF SITES	BURDEN PER SITE/HRS.	TOTAL BURDEN/HRS.	TOTAL COST x $150
*26.71(d) Modification to Program performance data Report Form (one-time development by NEI)	N/A	N/A	N/A	N/A
26.71(d) Collection of performance data	74	20	1,480	$222,000
26.23 and 26.80 Audits	74	36	2,664	$399,600
TOTAL			15,726.6	$2,358,990
Appendix A Records concerning collection & Testing of specimens	74	558	41,292	$6,193,800
TOTAL RECORDKEEPING			57,018.6	$8,552,790

*Complete

TABLE 1
10 CFR PART 26 - FITNESS-FOR-DUTY PROGRAM

Estimate of Burden Required of Industry - **REPORTING REQUIREMENTS**

SUBSECTION	NO. OF SITES	REPORTS PER SITE	BURDEN PER SITE/HRS.	TOTAL BURDEN/HRS.	TOTAL COST x $150
26.6 Exemption applications	2	1	16	32	$4,800
26.24(d)(2)(iv) Notification to individual	4	20	.1	8	$1,200
26.24(e) MRO to notify licensee management	74	15	.25	277.5	$41,625
26.25 Licensee notification by EAP staff	18	1	.5	9	$1,350
26.27(d) Fitness of NRC employee notification	74	None anticipated	.5	0	0
26.71(d) Program performance data	74	2	40	5,920	$888,000
26.73 Reports of significant events	74	1	.25	18.5	$2,775
26.73(d) Certify implementation of program (complete)	74	0			0
TOTAL REPORTING REQUIREMENTS				6,265	$ 939,750
TOTAL RECORDKEEPING				57,018.6	8,552,790
TOTAL BURDEN/COST				63,283.6	$ 9,492,540

TABLE 2
10 CFR PART 26 - FITNESS-FOR-DUTY PROGRAM

Estimate of Cost to the Federal Government

SUBSECTION	TIME/YEAR	NUMBER OF RECORDS/REPORTS	STAFF HOURS
26.20(a)-(e) Written policies and procedures	2 hours/site	1/site	2.0 hrs.
26.21(b) and 26.22(c) Training records	2 minutes/individual	1500 ind/site x 5% sample	2.5 hrs
26.23 and 26.70(b) Contract provisions	10 minutes/contract	12 contracts/site x 25% sample	0.5 hr.
26.73(d) License certification	1 time	1/site	No longer applicable
26.23 and 26.80 Audits	30 minutes/report	12/site x 25% sample 1.5 hrs.	
26.29 and 26.71 Records concerning persons tested positive, removed for cause, and related matters	10 minutes/person	15 persons/site/year	2.5 hrs.
26.71(d) Program performance data	15 minutes/report	2/site	0.5 hr.
26.73 Reporting significant events	4 hours/event	1 report/site/year (~70/year for industry)	4.0 hrs. 13.5 hrs/site

Annual cost = 13.5 hrs/site x 37 sites (estimated number of inspections) = 499.5 x $150/hr. = $74,925

APPENDIX A

REPORTING AND RECORDINGKEEPING REQUIREMENTS

Subpart A - Section 1.1 specifies applicability requirements

A.1.1(2)	Inform NRC within 60 days of implementing any deviations from guidelines.

Subpart B - Scientific and Technical Requirements

Section 2.1 specifies requirements for the substances

B.2.1(c)	Establish testing procedures.

Section 2.2 specifies requirements for general administration and testing

B.2.2(a), (b) and (d)	Develop and maintain documented procedures for collection, shipment, and accession of urine and blood specimens which shall include: use of the chain-of-custody form (copies, distribution, retention); specimen laboratory labeling; and written procedures, instructions, and training guidelines (content and distribution).

Section 2.4 specifies specimen collection procedures

B.2.4(c)(1)	Post public restroom to avoid access during testing.
B.2.4(d)	Execute chain-of-custody forms
B.2.4(g)	Label on sample and in permanent record book shall identify individual.
B.2.4(g)(4)	Individual must sign consent-to-test form, list medications and over-the-counter preparations used in last 30 days.
B.2.4(g)(9)	Collection site person must note unusual behavior or appearance in permanent record book and on chain-of-custody form.
B.2.4(g)(11)	If insufficient sample, collection site person must contact authority to obtain guidance.
B.2.4(g)(15)	Collection site person must note unusual urine inspection findings in permanent record book.
B.2.4(g)(22)	Collection site person must label urine sample with date, identification number, and any other required information.
B.2.4(g)(23)	Individual shall certify by initialing label.
B.2.4(g)(23)(i)	Individual shall certify urine sample is his on chain-of-custody form or in permanent record book.
B.2.4(g)(23)(ii)	Allows individual to provide information on medications on chain-of-custody form.
B.2.4(g)(24)	Collection site person shall enter in the permanent record book all identifying information for each specimen and sign the book next to the identifying information.
B.2.4(g)(25)	Supervisor in drug testing program shall review and concur in advance to obtain a urine specimen under direct observation based on the belief the individual may alter or substitute the sample.
B.2.4(g)(26)	Collection site person shall complete a chain-of-custody for aliquot and split sample and certify proper completion of the collection.

B.2.4(h) Collection site person shall label samples and document on change-of-custody forms.

B.2.4(i) Collection site person shall sign and enter the date specimens were sealed for shipment.

B.2.4(j) If individual fails to cooperate in urine collection, collection site person shall inform the Medical Review Officer (MRO) and document the non-cooperation in the permanent record book and on the specimen custody and control form. The MRO shall report failure to cooperate to management.

Section 2.5 provides guidelines for HHS - certified laboratory personnel

B.2.5(a)(4) HHS-certified laboratory qualified person shall document laboratory personnel's in-service training, review work performance, and verify skills.

B.2.5(a)(5) HHS-certified laboratory qualified person shall be responsible for keeping procedures manual maintained. This individual shall review, sign and date the manual whenever new or modified procedures are placed into use, or a new individual assumes responsibility for management of the laboratory. Copies of all procedures and dates when in effect shall be maintained.

B.2.5(a)(6) HHS-certified laboratory qualified person shall be responsible for maintaining the quality assurance (QA) program to ensure proper performance and reporting of test results and documenting quality control (QC) characteristics of each test or test system.

B.2.5(f) Laboratory personnel files shall include resume of training, experience, certificate or license, references, job descriptions, records of performance evaluations and advancements, incident reports, competency test results.

Section 2.6 provides guidance for licensee testing facility personnel

B.2.6(c) Licensees' testing facility personnel files shall include resume of training, experience, certificate or license, references, job descriptions, records of performance evaluations and advancements, incident reports, competency test results, and data to support determinations of honesty and integrity.

Section 2.7 specifies laboratory and testing facility analysis procedures

B.2.7(a)(1) Maintain documentation of individuals accessing HHS-certified laboratory licensee's drug testing facility, including dates, entry times, and purpose.

B.2.7(a)(2) Date, purpose, and individual handling shall be documented on chain-of-custody form each time specimen is handled or transferred. Authorized technician shall sign and complete chain-of-custody forms for specimens/aliquots as they are received.

B.2.7(b)(1) Laboratory personnel shall report within 24 hours to licensee and note on the chain-of-custody form any evidence of tampering or discrepancies in information in comparing specimen containers to form information. Indications of tampering at a licensee's testing facility shall be reported to senior licensee management within 8 hours.

B.2.7(d) Any evidence of adulteration, dilution, detected drugs or metabolites shall be reported to the MRO.

B.2.7(e)(1) If licensees use more stringent drug cutoff levels, results shall be reported for both HHS-approved and more stringent levels.

B.2.7(f)(1) Negative testing results from second screening shall be reported to licensee.

B.2.7(f)(2)	All positive testing results from second screening shall be recorded. If licensees use more stringent drug cutoff levels, results shall be reported for both HHS-approved and more stringent levels.
B.2.7(g)(1)	HHS-certified laboratory shall report test results to licensee's MRO within 5 working days. Before reporting, review and certify. Report shall identify substances tested for, whether positive or negative, cutoff levels, licensee's specimen number, and laboratory's specimen identification number.
B.2.7(g)(3)	MRO may obtain from, and the laboratory shall provide, quantification of test results.
B.2.7(g)(5)	Laboratory shall send certification to MRO with copy of signed chain-of-custody form and copy of test report.
B.2.7(g)(6)	HHS-certified laboratory and licensee's testing facility shall provide to licensee FFD coordinator monthly statistical summary of urinalyses and blood sampling without personal data. Report shall contain, for initial testing, number of specimens received, reported out, and screened positive, and for confirmatory testing, number of specimens received and number confirmed positive.
B.2.7(g)(7)	Statistical summary report shall include statistics for HHS guidelines and any more stringent licensee guidelines. Upon request by NRC or the licensee, testing facilities shall make available quantitative results for all samples.
B.2.7(g)(8)	Retain urine or blood specimen records for a minimum of 2 years.
B.2.7(j)	Quantitative results of any second testing process from split samples shall be made available to the MRO and the tested individual.
B.2.7(m)	Prior to awarding a contract for drug testing, licensee shall evaluate procedures of the laboratory drug testing program.
B.2.7(n)	HHS-certified laboratories and licensee's testing facilities shall maintain for 2 years documentation on all aspects of the testing process. Documentation shall include personnel files for individuals having access to specimens, chain-of-custody documents, QA/QC records, procedure manuals, all test data and calculations, reports, performance records, and hard copies of computer data. Specimen records under challenge should be maintained indefinitely.
B.2.7(o)(1)	Each laboratory and licensee's testing facility shall have a procedure manual which includes test principles, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, method sensitivities, cutoff values, reporting methods controls, criteria for unacceptable specimens and results, remedial actions, reagents, expiration dates, and references. Copies of all procedures and date of effect shall be maintained as part of the manual. Retain superseded material 3 years.
B.2.7(o)(2)	Standards shall be labeled as to content and concentration and dates when received, prepared or opened, placed in service, and expiration date.
B.2.7(o)(3)(i)	Pipettes and measuring devices shall be certified for accuracy and checked periodically.
B.2.7(o)(3)(iii)	Written procedures for instrument set up, normal operation, major troubleshooting and repair, schedule for checking operation, tolerance limits for function checks. Records on preventive maintenance.
B.2.7(o)(4)	Written procedures for actions when systems are out of acceptable limits or errors are detected. Documentation that procedures are followed and corrective actions taken.

Section 2.8 specifies quality assurance and quality control requirements

B.2.8(a) HHS-certified laboratory and licensee's testing facility shall have and maintain QA procedures for all aspects of the testing process, including reporting and documentation.

B.2.8(c)(3) Document implementation of procedures to ensure "carryover" does not contaminate an individual's specimen.

B.2.8(d)(3) Periodically document linearity and precision of controls for confirmation tests.

B.2.8(e)(4) Licensee shall make a signed and dated record of investigative findings and corrective actions taken by laboratory for unsatisfactory performance testing results. Send report to NRC within 30 days. NRC shall ensure notification of the finding to DHHS.

B.2.8(e)(5) If a false positive administrative error, immediately notify NRC. If error may have been systematic, licensee may require review and reanalysis of previously run specimens.

B.2.8(e)(6) If a false positive technical or methodological error, licensee shall require laboratory to submit to licensee all QC data from the batch with the error and require retesting of the batch. Retesting should be documented by responsible management.

Section 2.9 specifies requirements for reporting and review of results

2.9(a) MRO shall review results prior to transmitting results to licensee management.

2.9(b) MRO shall examine alternative medical explanations for any positive tests, including interviews with the individual, review of individual's medical history or other biomedical factors.

2.9(c) Following verification of positive test results, the MRO shall notify applicable employee assistance program and appropriate management.

2.9(e) If positive test is questioned and the individual requests it, MRO may authorize a reanalysis of original aliquot or stored sample.

2.9(g) Licensee shall maintain records that summarize any negative findings based on scientific insufficiency, but shall not include personal data.

<u>Subpart C - Employee Protection</u>

Section 3.1 specifies requirements for protection of employee records

3.1 Licensee contracts with HHS-certified laboratories and procedures shall require test records to be confidential.

Section 3.2 specifies individual access to test and laboratory certification results

3.2 Individual may request in writing personal testing records and relevant laboratory records.

[7590-01-P]

U. S. NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: U. S. Nuclear Regulatory Commission (NRC)

ACTION: Notice of pending NRC action to submit an information collection request to OMB and solicitation of public comment.

SUMMARY: The NRC is preparing a submittal to OMB for review of continued approval of information collections under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. The title of the information collection: 10 CFR Part 26, “Fitness for Duty Program”

2. Current OMB approval number: 3150-0146

3. How often the collection is required: On occasion

4. Who is required or asked to report: All licensees authorized to construct or operate a nuclear power reactor and all licensees authorized to possess, use, or transport unirradiated Category 1 nuclear material.

5. The number of annual respondents: 74

6. The number of hours needed annually to complete the requirement or request: 63,284 (6265 hours of reporting burden and 57,019 hours of recordkeeping burden)

7. Abstract: 10 CFR Part 26, “Fitness for Duty Program,” requires licensees of nuclear power plants and licensees authorized to possess, use, or transport unirradiated Category 1 nuclear material to implement fitness-for-duty programs to assure that personnel are not under the influence of any substance or mentally or physically impaired, to retain certain records associated with the management of these programs, and to provide reports concerning significant events and program performance. Compliance with these program requirements is mandatory for licensees subject to 10 CFR Part 26.

Submit, by (insert date 60 days after publication in the Federal Register), comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the draft supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1 F23, Rockville, MD 20852. OMB clearance requests are available at the NRC worldwide web site: http://www.nrc.gov/public-involve/doc-comment/omb/index.html. The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions about the information collection requirements may be directed to the NRC Clearance Officer, Brenda Jo. Shelton, U.S. Nuclear Regulatory Commission, T-6 E6, Washington, DC 20555-0001, by telephone at 301-415-7233, or by Internet electronic mail at INFOCOLLECTS@NRC.GOV.

Dated at Rockville, Maryland, this 12th day of April 2002.

For the Nuclear Regulatory Commission

(Original signed by)
Beth C. St. Mary, Acting NRC Clearance Officer
Office of the Chief Information Officer

Comments and questions about the information collection requirements may be directed to the NRC Clearance Officer, Brenda Jo. Shelton, U.S. Nuclear Regulatory Commission, T-6 E6, Washington, DC 20555-0001, by telephone at 301-415-7233, or by Internet electronic mail at INFOCOLLECTS@NRC.GOV.

Dated at Rockville, Maryland, this 12th day of April 2002.

For the Nuclear Regulatory Commission

(Original signed by)
Beth C. St. Mary, Acting NRC Clearance Officer
Office of the Chief Information Officer

*See Previous Concurrence

ACCESSION NUMBER: ML020710049 (DRAFT)

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