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NUCLEAR ENERGY INSTITUTE

**Ralph E. Beedle**  
SENIOR VICE PRESIDENT  
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NUCLEAR GENERATION

March 5, 2001

Ms. Amy Farrell  
Office of Information and Regulatory Affairs  
(3150-0146), NEOB—10202  
Office of Management and Budget  
Washington, DC 20503

SUBJECT: Notice of OMB Review of Information Collection and Solicitation of Public  
Comment on NRC Revisions to 10 CFR Part 26 (66 Fed. Reg. 8812;  
February 2, 2001)

Dear Ms. Farrell:

The Nuclear Energy Institute,<sup>1</sup> on behalf of the nuclear energy industry, submits the following response to the Office of Management and Budget's request for public comment pursuant to the Paperwork Reduction Act (66 Fed. Reg. 8812; February 2, 2001). OMB seeks comment on the burden associated with information collection requirements included in the final rule modifying 10 CFR Part 26, "Fitness for Duty Programs."

The industry believes OMB should not approve the Nuclear Regulatory Commission's (NRC) issuance of the modified Fitness for Duty rule at this point. While the proposed modifications include some changes that will improve Fitness for Duty programs, the rule contains enough significant infirmities to warrant holding its issuance in abeyance until they are adequately addressed.

In particular, and of greatest interest to OMB under the Paperwork Reduction Act, is that the NRC's estimate of burden is wholly incorrect. Industry estimates that the rule

<sup>1</sup> NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, nuclear materials licensees, and other organizations and individuals involved in the nuclear energy industry.

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will cause licensees to expend approximately \$8 million annually rather than foster an industry-wide saving of \$27 million, as the NRC asserts. As is described in the attachment to this letter supporting our recommendation that OMB disapprove issuance at this time, many of these costs

are attributable to information collection costs. The industry strongly believes that the NRC has not demonstrated that the proposed modifications to Part 26 are necessary to protect the public health and safety.

We would be pleased to discuss further the industry's views on the proposed changes to 10 CFR Part 26. Please contact me or Rich Enkeboll at [ree@nei.org](mailto:ree@nei.org) if you desire more information.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Beedle", written in a cursive style.

Ralph E. Beedle

## **Comments of the Nuclear Energy Institute on Proposed Revisions to 10 CFR Part 26, Fitness for Duty Requirements**

### **I. Background**

The NRC promulgated 10 CFR Part 26, "Fitness for Duty Programs" June 7, 1989.<sup>1</sup> The regulations comprising Part 26 are intended to provide reasonable assurance that nuclear personnel are reliable, trustworthy, not under influence of any substance and not physically or mentally impaired in a way that affects their ability to perform their duties. Part 26 covers fitness for duty (FFD) program elements and procedures that licensees of commercial nuclear reactors and those authorized to possess, use or transport formula quantities of strategic special nuclear material must maintain. An appendix to Part 26 sets out guidelines for drug and alcohol testing programs licensees must implement as part of their licensee's FFD programs. Part 26 also includes specific recordkeeping and reporting requirements as well as provision for NRC inspection and licensee audits.

The NRC anticipated that, after licensees implemented FFD programs under Part 26 for a period of time, the agency would conduct an evaluation of the effectiveness of FFD programs and Part 26. The industry and the NRC collected extensive data from 1990 to 1996 on experience with the FFD rule from inspections; periodic license program reports; reports of significant FFD events; industry-sponsored meetings; initiatives by NEI and its predecessor organization, the Nuclear Management and Resources Council, and by the Substance Abuse and Mental Health Services Administration (SAM HSA) (formerly the National Institute on Drug Abuse (NISA)) and its Drug Testing Advisory Board; and current literature.

The NRC published for comment *Proposed Modifications to Fitness for Duty Program*

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<sup>1</sup> 54 Fed. Reg. 24494, June 17, 1989.

*Requirements.*<sup>2</sup> The NRC stated that the modifications to Part 26 proposed in 1996 would serve four purposes. These were to (1) ensure compatibility between NRC required FFD programs and U.S. Department of Health and Human Services (HHS) testing guidelines, (2) reduce unnecessary burdens, (3) add a limited number of new requirements, and (4) clarify the original intent and overall clarity of the rule.

In response to the 1996 proposed rule changes, NEI, on behalf of the nuclear energy industry, provided extensive comments to the NRC.<sup>3</sup> The industry recommended 22 modifications to improve the proposed rule based on six years of experience with FFD programs. The industry also requested that the NRC withdraw 14 proposed amendments to Part 26 because the proposed changes either would not add to the overall effectiveness of a licensee's FFD program or the additional effort required had not been justified through a thorough regulatory analysis. In addition, the industry suggested that the NRC immediately promulgate, in a separate rulemaking, those revisions to Part 26 deemed to be "non-controversial."<sup>4</sup>

The NRC, however, did not agree to separate the so-called non-controversial amendments (which we believe would have saved commercial power licensees several million dollars per year) from those that the industry did not believe were appropriately imposed on licensees. In fact, the NRC did not issue any proposed modifications to the FFD rule for more than four years. The NRC now is requesting OMB approve the final rule despite the fact that there has been no interim opportunity for the public to comment on the significant changes it contains that were not part of the 1996 proposed rule changes.

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<sup>2</sup> 61 Fed. Reg. 21105; May 9, 1996.

<sup>3</sup> See letter from Ralph E. Beedle to John C. Hoyle, dated August 7, 1996.

<sup>4</sup> The industry made this suggestion, in part, to satisfy the constraints imposed by the NRC's "Backfit" rule. Under the Backfit rule, 10 C.F.R. 50.109, the NRC must determine that there is a substantial increase in the overall protection of public health and safety and that the cost increase is justified for new regulatory requirements or new interpretations of existing requirements that meet certain standards.

## **II. The Proposed Fitness for Duty Rule Does Not Comply with the Paperwork Reduction Act**

### **A. Paperwork Reduction Act requirements.**

The Office of Management and Budget, through its Office of Information and Regulatory Affairs, is responsible for carrying out the dictates of the Paperwork Reduction Act of 1995.<sup>5</sup> The stated purpose of the Act is to ensure federal agencies become more responsible and publicly accountable for reducing the burden of Federal reporting and information collection requirements, requirements on the public. The Act also is intended to reduce the burden on entities subject to such federal requirements by ensuring the greatest possible public benefit from and maximizing the utility of information created, collected, maintained, used, shared and disseminated by or for the Federal Government.<sup>6</sup>

Through enactment of the Paperwork Reduction Act, Congress very specifically set out the evaluation criteria under which federal agencies must determine whether a proposed collection of information should be approved. The criteria include:

- an evaluation of the need for collection of the information
- a functional description of the information to be collected
- a plan for the collection of the information
- a specific objectively supported estimate of burden
- a test of the collection program through a pilot program, if appropriate, and
- a plan for the efficient and effective management of the information to be collected, including resources.<sup>7</sup>

Office of Management and Budget regulations further define "burden" in the context of

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<sup>5</sup> 44 U.S.C. 3503.

<sup>6</sup> 44 U.S.C. 3501(2).

<sup>7</sup> 44 U.S.C. 3506.

the Paperwork Reduction Act. 5 CFR 1305 defines burden as "the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency." The regulation includes in the definition the following actions:<sup>8</sup>

- Reviewing instructions;
- Developing, acquiring, installing, and utilizing technology and systems for the purpose of collecting, validating, and verifying information;
- Developing, acquiring, installing, and utilizing technology and systems for the purpose of processing and maintaining information;
- Developing, acquiring, installing, and utilizing technology and systems for the purpose of disclosing and providing information;
- Adjusting the existing ways to comply with any previously applicable instructions and requirements;
- Training personnel to be able to respond to a collection of information;
- Searching data sources;
- Completing and reviewing the collection of information; and
- Transmitting, or otherwise disclosing the information.

Section 3508 of the Act sets out the standard upon which OMB is to give its approval to an agency seeking to impose new or additional paperwork requirements. The approval is to be based on an affirmative determination that "the collection of information by the agency is necessary for the proper functions of the agency, including whether the information shall have any practical utility." Section 3508 prohibits an agency from collecting information if it is "unnecessary for any reason."

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<sup>8</sup> Note, however, that time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities (e.g., in compiling and maintaining business records) will be excluded from the "burden" if the agency demonstrates that the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary.

OMB has interpreted the Act to require an agency to demonstrate that it has taken every reasonable step to ensure that the proposed collection of information *is the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives*; is not duplicative of information otherwise accessible to the agency; and has practical utility.<sup>9</sup> Of critical importance in the context of the proposed rule, the regulation also states that "the agency shall also seek to minimize the cost to itself of collecting, processing, and using the information, but shall not do so by means of shifting disproportionate costs or burdens onto the public."

Thus, the standard for approval of additional information collection warrants balancing necessity against the burden on the entities supplying the information. Congress' clear intent was to ensure agencies seeking to impose a burden demonstrate that it is clearly outweighed by the need for the information to be produced and provided.

As will be discussed in detail in the following section, the NRC has not met its required burden under the Paperwork Reduction Act. The NRC incorrectly assessed the burden on the industry occasioned by the increased information collection and reporting requirements of the revisions to Part 26. Certainly, the NRC has not developed a record sufficient to meet the standard of a specific *objectively supported* estimate of burden. Thus, without such an estimate, the NRC could not have appropriately weighed the necessity of the information against the burden of its collection.

B. NRC improperly assessed the need for collection of the information.

The fundamental standard that an agency must meet in instituting new or additional paperwork requirements is that the information must be necessary for the proper functions of the agency. This standard is codified at Section 3508 of the Paperwork

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<sup>9</sup> 5 C.F.R. 1305 (emphasis added).

Reduction Act, as described above. In its transmittal of this rulemaking package to OMB, the NRC justifies the changes in information collection requirements from those in the current rule "as intended to facilitate good management of the licensees programs and ensure proper management of both the internal flow of information and the maintenance of program records." However, the NRC has not demonstrated the need for the additional requirements, especially those that are burdensome.

The following example is particularly instructive. The NRC, through this rulemaking, has changed its interpretation of an existing regulatory requirement that a suitable inquiry, (i.e., or verification of employment history for FFD purposes,) be conducted on all individuals covered by a FFD program. Under the new interpretation, licensees will be required to conduct many more extensive suitable inquiries, ostensibly for the purpose of correcting a failure of FFD programs under the current interpretation of the regulation to identify individuals who are not fit to perform their duties or to have unescorted access to nuclear power plant protected areas. However, the NRC's own compilation of FFD Program Performance Reports for 1999 indicates that there is only a small probability of an unfit individual avoiding detection under the pre-access and for-cause substance testing that is already required by regulation. During the period from 1990, when the FFD rule became effective, through 1999, the overall positive test rate for all tests has averaged 0.94%. Of these positive tests, only 18% of the positive results are obtained from the random testing conducted after individuals are initially cleared for unescorted access to the plant, although random testing constitutes over half of the tests conducted. Therefore, the majority of unfit individuals already are identified by pre-access suitability inquiries or testing. Furthermore, the likelihood that the expanded suitable inquiries as proposed in the new rule would identify individuals with FFD problems that would otherwise go undiscovered has not been demonstrated, and the industry believes that likelihood to be very small.

Prior to OMB approval of the NRC's issuance of the modified FFD rule, the NRC should explicitly demonstrate the need for the additional requirements to protect public health and safety. The industry believes that, particularly for some of the more burdensome



new requirements, it will not be possible to make that showing, and those provisions should be excised from the rule before it is promulgated.

C. NRC improperly assessed "burden" on the industry.

The proposed changes to the FFD rule will result in significant additional costs to licensees while providing only minimal or no safety benefit. Contrary to the NRC's assertion that the changes to the FFD rule will yield a \$27 million savings to the industry, the industry has concluded that the rule annually will cost licensees approximately \$80,000 per unit and a total of \$8 million annually on an industry-wide basis.

The industry has identified many instances in which the proposed changes to the FFD rule will result in increased costs to licensees not justified by an overall public health and safety benefit. While not an exhaustive list, the following examples are illustrative of the NRC's failure to comply with the Paperwork Reduction Act, and provide evidence sufficient for OMB to withhold approval at this time. The first example involves revisions to 10 CFR 26.27(a). This regulation specifically addresses the information a licensee must obtain from individuals during the pre-access clearance process, the requirement for the licensee to then conduct a suitable inquiry to verify the accuracy of the information obtained from the individuals. Thereafter we discuss the burdens associated with a proposed medical determination of FFD if concerns are raised in information provided by the individual or in the suitable inquiry. The third example concerns those rule changes regarding institutionalizing inconsistencies between NRC imposed requirements for FFD programs and other federal FFD programs. Finally, we discuss the specific requirement to audit HHS certified laboratories as another example of the failure to meet the Paperwork Reduction Act need and burden criteria.

(i) Proposed requirement to conduct suitable inquiries for employment less than 30 days.

The NRC defines "suitable inquiry" to mean a best-effort verification of employment

history for the past five years through contacts with previous employees to identify prior FFD problems. The requirement that the licensee conduct suitable inquiries is found in 10 CFR 26.27(a)(3) of the new rule (10 CFR 26.27(a)(2) in the prior rule). The language of the rule and the definition of suitable inquiry do not explicitly specify whether suitable inquiries must be conducted for all periods of employment or whether there is some period of such a short duration that it does not warrant a suitable inquiry.

The general industry practice now is not to conduct suitable inquiries for periods of less than 30 days. This practice is based on the industry's understanding that the NRC intended suitable inquiry requirements to be aligned with those of the NRC mandated access authorization program.<sup>10</sup> In adopting the existing FFD rule, the NRC did not assign any cost to its then-new requirement for the suitable inquiry for FFD purposes on the basis that licensees already conduct those background checks in their access authorization programs.

The 1996 proposed rule clarified Section 26.27 by stating that suitable inquiries need not be conducted for any period of 30 days or less that the individual was not covered by an FFD program to meet the requirements of the regulation. The proposed final rule has deleted this clarification, providing an explanation that reinterprets the regulatory language to affirmatively require suitable inquiries for even periods shorter than 30 days. This new interpretation of the regulatory language will significantly affect licensee conduct of these programs. In making this change, the NRC did not properly assess the associated burden on licensees.

The NRC has concluded that there is no burden resulting from this change. The NRC's determination of no burden apparently is premised on the assumption that conducting a suitable inquiry for each short period of employment and unemployment does not

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<sup>10</sup> In adopting Part 26, the NRC recognized that it would be most efficient if, in the course of conducting background checks, a single call could be made to a person's previous employer, or other reference, in which both the required FFD and access authorization inquiries could be made. Further, the NRC endorsed NUMARC 89-01 which specifies that verification of employment history include verification of employment periods of 30 days or more and that activities during interruptions of employment in excess of 30 days must be verified. See Reg Guide 5.66, NUMARC 89-01, Section 6.2.1.

change current practice. That premise is wholly incorrect. In fact, the industry's calculated costs for this change will be significant. As the NRC itself has recognized, many of the employees in the nuclear industry have been employed many times during the past five-year period of employment history mandated by 26.27(a)(4). This is particularly true for craft and trade workers. Requiring suitable inquiries to include each short period of employment and unemployment will require licensees to employ or contract for additional staff to perform a much larger number of suitable inquiry evaluations. Because most licensees rely, at least in part, on a limited number of background investigation and self screening companies to perform suitable inquiries, these companies are not likely to be able to quickly process the significant increase in suitable inquiries generated by the "less than 30 day" requirement.

Thus, as described above, the increase in the number of suitable inquiries required is likely to result in increased delay between the time of hiring the worker and clearing the worker for unescorted access. This delay could markedly raise labor costs as the worker is typically "on the clock" from the time of hire until completion of the job.

Perhaps most compelling, is that the increased delay between hiring and commencement of work—thereby affecting date of completion—could adversely impact a plant's outage schedule, resulting in the very significant financial impact. Statistical data from one industry member demonstrates that, for calendar year 2001, a delay in the completion of an outage will result in a *per day* cost increase of \$750,000-1,000,000.

The NRC's analysis of burden not only is incorrect, in our view, but the bases for its analyses have not been sufficiently explained. In pertinent part the NRC has stated that its decision to withdraw the clarifying provision is "based on information obtained after publication of the proposed rule." The NRC further states that "licensee FFD personnel have indicated to the NRC that adverse FFD information is frequently obtained through checks of employment of 30 days or less," and "licensee FFD personnel also pointed out that under the proposed rule, employees could conceal their

FFD problems by ensuring that their employment at any one site is less than 30 days.”

Contrary to this explanation, historical data demonstrates that current suitable inquiries are sufficient to protect the public health and safety and that there will be no additional benefit to pursuing employment of “less than 30 days” as the NRC now would have licensees do. Licensees believe it will be of no additional benefit largely because such inquiries only have to be performed on a “best efforts” basis. Given that most employers have policies prohibiting the release of any meaningful employment information about former employees or are at least reluctant to release much more than dates of employment, position and salary range, licensees do not believe that the additional suitable inquiries will yield the kind of information being sought.

(ii) Medical determination of fitness for duty by a licensed physician.

Proposed 10 CFR 26.27(a)(4) would require a medical determination of fitness be performed on all individuals with a history of substance abuse. Such a determination would be required to include completion of a record of the determination. This provision is unnecessary and creates a significant burden that the NRC improperly has refused to consider.

Section 26.4 of the proposed rule now includes in the definition of “history of substance abuse” “any legal or employment action taken for alcohol or drug use.” Thus, even a single conviction for driving while intoxicated would meet the definition of a history of substance abuse. In addition, section 26.27(a)(4) of the proposed rule requires that, before being assigned to licensed activities, where there is a concern about an individual's history of substance abuse, it must be evaluated by a licensed physician to determine whether the individual meets FFD program standards. This also necessitates the individual being entered into a follow-up testing program.

The requirement for a medical determination is not justified. The current approach in the nuclear industry is to allow experienced administrative staff to evaluate such

convictions along with other information about the individual to determine whether there is a need for further action, beyond the required psychological evaluation and drug and alcohol test. In general, a single conviction without other indications of a substance abuse problem, would not require further action. The rate of positive random drug and alcohol tests in the nuclear industry has been less than one half of one percent of the hundreds of thousands of tests. After a decade of mandatory FFD testing, no evidence has been uncovered to support the conclusion that additional medical determination in proposed 26.27(a)(4) would be of significant benefit. The current system of pre-employment drug and alcohol testing and psychological evaluation has been effective in assuring that the industry work force is relatively free of drug and alcohol abusers. Requiring a medical determination of the fitness of individuals simply because they meet the broad new definition of a history of substance abuse, has little potential to increase the effectiveness of the current system.

Licensees estimate proposed section 26.27(a)(4) will require a medical determination for approximately 10 percent of the applicants. Although the industry estimates vary somewhat, the annual cost *per reactor* unit will be approximately \$10,000, i.e., a total of approximately \$1,000,000 for the nuclear power industry. This includes increased costs for the licensed physician on an hourly basis and payment to the worker on an hourly basis while the evaluation is being performed. In addition, there will be additional overhead costs for such activities as arranging the additional interviews with physicians, documenting the results and maintaining those records. The need to enter the individual into the follow-up program also will increase costs for the licensee.

In addition, the cost could be greater, depending on the ultimate determination of the meaning of a vague and unexplained requirement in proposed section 26.4 that the "qualifications [of the licensed physician] for making the determination are related to the fitness issues presented by the patient." If this requires that the physician be more specialized than current Medical Review Officers, the expense could be even greater than the estimate above.

Another likely expense, not included in the above estimate, arises from the fact that licensees generally do not have licensed physicians readily available at their sites. At some sites, a physician is present on a part-time basis, while at others employees who require a medical evaluation must go to an off-site location. In either of these circumstances, the added requirements for medical determinations will result in significant delays in putting new employees to work. At a minimum, such delays result in the licensees bearing the costs of salary for the employee while they are unable to work. More importantly, at times such delays can delay needed work activities and thereby reduce the availability of the power plants to generate power.

Even where an individual's history justifies evaluation of their propensity toward substance abuse, there is little or no justification to require such an evaluation to be done by a licensed physician. The pre-employment evaluations covered by proposed section 26.27(a)(4) are not like the usual circumstance in which current NRC FFD regulations require a determination by a Medical Review Officer. Now, the Medical Review Officer is normally called upon to determine whether there is an alternative medical explanation for a positive drug or alcohol test. Such a question does require a licensed physician. In contrast, however, licensees normally rely on licensed psychologists to evaluate the psychological fitness of candidates and employees whose fitness is questioned. If there were reason to evaluate the suitability of a candidate because of a history of substance abuse, the evaluation could be more efficiently and effectively done by the licensed psychologist who otherwise would be called upon to evaluate the individual's psychological fitness. Requiring a separate evaluation by a licensed physician is duplicative and an unjustified added expense and complication.

- (iii) Compatibility between NRC required fitness for duty programs and HHS testing guidelines.

The NRC states that one of the four primary objectives of the proposed Part 26 rule changes is to ensure compatibility between NRC required FFD programs and HHS testing guidelines. In fact, the NRC has not accomplished this objective. Rather, the

proposed rule revisions create increased burden on licensees by revising Part 26 in ways that specifically deviate from HHS testing guidelines and other federally required FFD programs but have shown no compelling need to do so.

The NRC maintains an opiate cutoff level of 300 ng/ml. By contrast, the HHS opiate cutoff level is 2000 ng/ml. This 2000 ng/ml applies to individuals covered by FFD programs required under Department of Transportation regulations, including such safety-dependent occupations such as pilots, air traffic controllers and aircraft dispatchers under the Federal Aviation Administration's supervision. The Department of Transportation (DOT) adopted the lower opiate threshold accepted by the HHS. When deciding to adopt HHS's opiate cutoff level, DOT emphasized that it is essential for their testing procedures to remain consistent with the HHS Guidelines, as Congress provided in the Omnibus Transportation Employee Testing Act of 1991. They relied on HHS's rationale that the less stringent standard is sufficient to identify heroine use and to ensure an adequate level of safety.

When increasing its opiate cutoff level, HHS stated that the goals of the revised testing policy "are to substantially reduce the total number of specimens laboratories report positive for opiates that Medical Review Officers verify as negative, to shift the emphasis of testing for opiates back to the proper deterrence and detection of heroin use, and to reduce any unnecessary/excessive costs to drug testing without compromising the original drug deterrent objectives."<sup>11</sup> The Agency explained that since the purpose of the workplace drug testing program is to deter and detect use of illegal drugs, establishing the testing cutoff levels for opiates at these higher levels will eliminate the identification of most individuals who are legitimately taking prescription medications that contain morphine or codeine or have ingested poppy seeds.

The NRC regulations indicate that the cut-off levels are subject to change in response to industry experience and changes to the HHS Guidelines.<sup>12</sup> The HHS Guidelines expressly modified the opiate cut-off level, and absent any "industry experience", the NRC should conform to this standard as well. The NRC has not justified the need to impose more stringent requirements for nuclear workers. The industry notes in this context that the reduced limit of 300 ng/ml increases costs to licensees because many HHS certified laboratories charge more to process samples to detect a 300 ng/ml level of opiate than to detect the HHS cutoff level.

(iv) Requirement to audit HHS certified laboratories.

The NRC also requires licensees to audit HHS certified laboratories as part of the requirement to audit all contractors and vendors that provide services to implement FFD elements. The NRC has not articulated a compelling basis to require licensees to audit laboratories subject to strict HHS certification requirements. The rigorous HHS requirements ensure a sufficient level of accuracy and reliability through their certificate of accreditation regulations. The certification process includes a detailed biennial application renewal process (including updating the names and qualifications of all

<sup>11</sup> Mandatory Guidelines to Federal Workplace Drug Testing Programs, 62 Fed. Reg. 51118 (Sept. 30, 1997).

<sup>12</sup> 10 C.F.R. Part 26 Appendix A (2000).



personnel, the names and number of tests performed annually, and the methodologies for each test procedure), proficiency test sampling, as well as access and reporting requirements to the HHS at their discretion.

Additional NRC auditing will only duplicate laboratory personnel training and testing requirements. Similarly, it lacks logic to require licensees to audit the HHS certified laboratories ordinarily used, but not require audits for "different" HHS certified laboratories selected by workers for testing split specimens.<sup>13</sup>

### **III. Conclusion**

The NRC has been given broad authority to protect public health and safety by regulating activities of those entities licensed to possess or use nuclear material. However, the NRC's regulatory authority is neither limitless nor unfettered. In fact, the agency's authority to regulate is constrained by applicable laws, e.g., Administrative Procedure Act, the Paperwork Reduction Act, and the Regulatory Flexibility Act. These laws were enacted to ensure that federal agencies do not exceed their authority and do not regulate without appropriately considering those public policy issues Congress deemed important.

In the case of the Paperwork Reduction Act, Congress directed federal agencies to weigh, among other things, the need for new or additional information collection and recordkeeping requirements as well as the burden such requirements would impose on affected entities, i.e., in this instance, the regulated industry. As is evident from the discussion above, the FFD rule imposes significant information collection and recordkeeping requirements that do not significantly, if at all, advance FFD programs. In addition, the NRC has largely or completely discounted licensee input regarding the economic and administrative burdens created by the cited provisions. Thus, in failing

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<sup>13</sup> SECY-00-0159, p. 50.

both to adequately justify the need for the proposed regulatory changes to achieve FFD program objectives, and to objectively support its estimate of burden, as required by the explicit language of the Paperwork Reduction Act, the NRC has not met its legal obligation under the Act. As such, we strongly urge OMB to remand the proposed rule to the NRC for its further consideration in light of these inadequacies.

OMB also should withhold its approval of the proposed FFD rule based on public policy considerations. On January 20, 2001, Andrew Card, Assistant to the President and Chief of Staff, issued a Memorandum to executive departments and agencies setting out the new Administration's regulatory review plan. This memorandum identified a number of procedural steps federal agencies were to take to allow the incoming Director or Acting Director of OMB to review proposed regulations. The penultimate paragraph of the memorandum sets out the objectives of the regulatory review plan as achieving "sound regulatory practice and the avoidance of costly, burdensome or unnecessary regulation." And, as is squarely on point for the instant rulemaking, the memorandum states that "independent agencies are encouraged to participate voluntarily in this review." Thus, based on the very criteria stated in Mr. Card's memorandum and the public policy considerations underlying the Administration's regulatory review plan, OMB should not approve the NRC's proposed FFD rule at this time.