UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In The Matter Of)
)
AMENDMENTS TO 10 CFR PART 21)

UNION OF CONCERNED SCIENTISTS AND
NATURAL RESOURCES DEFENSE COUNCIL
COMMENTS ON AMENDMENTS TO 10 CFR PART 21
AND REQUEST FOR AMENDMENT

Introduction

On October 13, 1978, the Commission took the extraordinary action of making a major amendment to a major nuclear safety regulation without prior public notice. Amendments to 10 CFR Part 21, exempting suppliers of commercial grade components from the regulation, were made immediately effective upon publication in the Federal Register on October 19, 1978 (43 FR 48621). The justification for omitting notice of proposed rulemaking and public procedure thereon was, in large part, allegations by the Staff that:

1. The amendments were not controversial;
2. Continued application of Part 21 could have adversely affected safety, reduced nuclear power plant availability and delayed construction of other plants; and
3. Staff resources would have been adversely affected by the need to act on pending and anticipated exemption requests.

The record of the Staff's activities with respect to these amendments does not support the Staff's allegations.

On October 25, 1978, the Natural Resources Defense Council (NRDC) requested, pursuant to the Freedom of Information Act, all documents related to the amendments to 10 CFR Part 21 which were adopted (Enclosure 1). The Staff's "partial response," dated November 15, 1978, provided some, but apparently not all, documents (Enclosure 2). However, the documents which have been produced show a sharply divergent picture of what has actually occurred from what the Staff alleged.

Background

The regulations in Part 21 were developed to implement Section 206 of the Energy Reorganization Act of 1974. The proposed rule was published for comment on March 3, 1975 (40 FR 8832). The final rule was published on June 6, 1977 (42 FR 28891), and became fully effective on January 6, 1978. The principal thrust of 10 CFR Part 21 was to provide a mechanism for the detection, evaluation and reporting to the Commission of defects[1] in safety-related components. The rules provide that, if the supplier of the component cannot evaluate the safety significance of the defect, the purchaser shall be notified of the defect in order to cause the defect to be evaluated. Knowing and conscious failure to provide the required notice would subject the supplier to a civil penalty of up to $5,000 for

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1/ "Defect" is a term of art defined in 10 CFR § 21.3(d). It includes, for example, deviation from design specifications and incorrect design or construction.

each such failure, not to exceed $25,000 within any period of thirty consecutive days.

It is clear that 10 CFR Part 21 imposed no new safety requirements. These regulations simply required the development of procedures to detect and report failures to adhere to safety requirements imposed by other regulations.

The amendments to 10 CFR Part 21 which became effective on October 19, 1978, exempted suppliers of commercial grade components. Now Part 21 applies only after the commercial grade component is dedicated for use in a safety-related component (i.e., a "basic component").

Comments

The documents relating to the amendments to 10 CFR Part 21 listed in Enclosure 2 have been reviewed by the NRDC and the Union of Concerned Scientists (UCS). Based on our review, we have concluded that the Staff misled the Commission concerning the urgency of, the need for and the safety significance of amendment of 10 CFR Part 21. The bases for this conclusion are set forth below.

Actions of Nuclear Industry. The record indicates that, from the date Part 21 became effective, some segments of the nuclear industry launched a coordinated campaign to shift to lower-tier suppliers the responsibility for quality assurance and for reporting defects. There is little evidence in the record of any bona fide attempt to implement Part 21 correctly by limiting its use to "basic components." Rather, Part 21 was being invoked in "procurement documents" for all components, even when the purchaser knew the component was not safety-related. For examples of this, see documents A-8, A-39, A-44,

and A-82.[2] The result was that Part 21 was being invoked when ordering material "to be used for Hand Rails, Drain Pipe, Identification Tags, etc. (Noncritical) . . . ." (Document A-82). The Staff recognized that such blanket applications of Part 21 were "incorrect" (Document A-8). Nevertheless, the Staff urged amendment of Part 21, in part because it was "causing an adverse effect on the ability to obtain needed items and may increase the costs of [commercial grade] items" (Document A-96). A more accurate description of the situation would be that the nuclear industry was deliberately misinterpreting Part 21 in order to force the Staff to seek the amendment which the Commission eventually adopted.

Safety Significance. All this manipulation by the nuclear industry might be irrelevant if there were, as the Staff asserts, no safety significance to the amendment. In fact the amendment may have a potentially serious impact on reactor safety.

The starting point for assessing the safety significance of the Part 21 amendment is 10 CFR Part 50, Appendix B. That appendix requires establishment of quality assurance programs "to provide adequate confidence that a structure, system, or component will perform satisfactorily in service." In short the QA program is the fundamental mechanism to assure that

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2/ Document identification refers to the document as identified in the NRC response to the NRDC Freedom of Information Act request. That response is attached as Enclosure 2 to this filing.

a nuclear plant will in fact be built and operated in the manner required to justify the finding of adequate protection for the public health and safety.

The purpose of Part 21 was to provide explicit operating requirements for QA programs and to impose penalties for failure to comply as an inducement to compliance. Predictably the imposition of the reporting requirements coupled with the penalty provisions was not popular with the nuclear industry. But Part 21 was in fact not a substantial burden. No penalties were applicable to anyone who failed to report a defect unless the failure were knowing. However, the importance of the Part 21 requirements cannot be overemphasized. By its terms, Part 21 reaches all components which have safety significance and no others. It is further focussed only on those aspects of safety significant components for which defects would be relevant to safety. Thus if the safety function of a bolt is unrelated to the quality of steel used in its construction, then no QA program related to the steel is required under Appendix B and no reporting requirements of Part 21 are applicable. If, however, the quality of the steel is relevant to the safety function of the bolt, Appendix B and Part 21 are both applicable, and they should be.

In a uniquely disingenuous presentation, the Staff alleged that safety would be adversely affected by continued application of Part 21. There is no concrete evidence in the

record to support this allegation.[3] At best, there are unsupported, mostly secondhand, allegations that "[c]ontinued application [of Part 21] may have an undesired effect on the level of safety. . . ." (Document A-96, emphasis added). (For other examples, see Documents A-73 and A-77.) There is no discussion in the record to explain why "continued" application "may" degrade safety, but past application apparently did not, since the Staff issued no show cause orders or took any other steps to correct the safety problems. Thus, under the threat of future adverse effects on safety, but without any specific evidence to support the threat, the Staff recommended amendment of Part 21. In so doing, the Staff ignored its own finding that one of the principal objections to Part 21 was the risk it poses of financial liability (Documents A-26 and A-71). It would appear that, so long as no financial risk attached, vendors were not uncomfortable about certifying compliance with the quality assurance requirements of Appendix B.

The result of the amendments to Part 21 is that the purchaser, even further removed from the manufacture of the component, must attest to the quality assurance of the component and report any defects discovered to the Commission. What is

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3/ The sole exception (Document A-2) pertains to a request for exemption by a byproduct materials licensee before Part 21 became effective. The Staff denied the exemption request (Document A-3).

really occurring is that the purchaser, who has significantly more financial interest in seeing the nuclear plant built, is assuming the burden of Part 21 reporting requirements even though the purchaser is less able than the supplier to detect the defects that must be reported. Of course the goal of Part 21 was to enforce real quality assurance for components, not to find responsibility for components later found to be defective. To fulfill its mission, Part 21 must be made applicable to precisely the class of components which the Part 21 amendment has now exempted. The use of components provided by so-called second choice suppliers could not degrade safety if compliance with the Commission's regulations is adequate to protect the health and safety of the public and if the Staff enforces the regulations. In fact, the second choice suppliers who are willing to accept the financial risks of Part 21 may actually produce better components, evidenced by a better quality control system which allows the supplier to have the confidence to accept the Part 21 regulations.

Staff Perception of the Problem. From the documents released pursuant to the FOIA request and from the public meeting transcript, it can be seen that the principal problem which motivated the Staff to seek this amendment was the fear of having to process numerous exemption requests. The Staff in effect concedes that it could determine on a case-by-case basis whether or not the provisions of Part 21 were being misinterpreted. To fully appreciate the Staff position in refusing to proceed on a case-by-case basis, it is necessary to look carefully at the problem which triggered the exemption requests.

The problem arose where sub-tier suppliers of off-the-shelf components were receiving procurement orders which included Part 21 compliance requirements. These suppliers apparently had no QA program for such components and thus could not implement a program for reporting defects because they could not identify defects (Document A-26). If the component supplied were irrelevant to safety (like equipment I.D. tags (Document A-82)), then the supplier should not be subject to Part 21 or Appendix B (see, e.g., Document A-83). If the component is relevant to safety, there is every reason to impose both Appendix B and Part 21. It is irrelevant that the component supplied is an off-the-shelf item used for many non-nuclear purposes if, when it is used for a nuclear plant, it performs an important safety function. If the supplier of such a component is unwilling to comply with Part 21 because it does not have a QA program which complies with Appendix B, the remedy is not to exempt the supplier from Part 21 but to enforce the provisions of Appendix B and Part 21.

The Staff Solution. Inasmuch as the real problem for the Staff was the need to do substantial paperwork to process individual exemptions, it is not surprising that the Staff solution was for the Commission to grant a blanket exemption. Unfortunately the blanket exemption seriously compromises plant safety. According to the Staff, plant safety is preserved because once the component is dedicated to use in a nuclear plant, the provisions of Part 21 become applicable. But is

that applicability likely to be meaningful? We think not. If off-the-shelf bolts are required to have a certain strength which depends in part upon the quality of the steel used in their manufacture, how does the purchaser of the bolts develop a QA program to assure that the bolts have the proper strength? Such a program would depend upon a record of the steel used for making each batch of bolts, a record of the batch of bolts from which the purchased bolt came and a system to assure that the bolts were handled in a way which made it possible to identify their origin. These records must be maintained by the bolt supplier and not the bolt purchaser or the bolt purchaser will have to test the strength of every bolt purchased. The same analysis would apply, for instance, to wire used in a relay or switch, and to relays or switches used in electrical components. What the Staff solution does is substitute the incompetent QA program of the purchaser for the essential QA program of the supplier.

The Process Used. Equally objectionable as the amendment adopted was the process used for its adoption. The Staff claimed to have an urgent need for immediate action requiring the waiver of normal public comment. The justifications given were urgency because of possible disruption in the construction schedule of nuclear plants and the absence of any objection to the proposals.

The reason that the Staff felt a sense of urgency in amending Part 21 was that the Staff had been telling the industry, for at least five months, that Part 21 would be amended on an

"urgent basis" (see Documents A-50, A-51, A-53, A-55, A-58, A-61, A-62, A-63, A-68, A-76, A-80, A-81, A-90, and A-91). In fact, as early as May 1978, the Staff had drafted the amendments, determined that there should be an immediate rulemaking, and begun telling the industry the regulation would be modified. Public notice of such an intent at that time would have provided ample opportunity for any expression of public concern. By deliberately concealing its intentions from the public, by not publicly noticing exemption requests, and by spending over five months preparing the amendment for Commission action, the Staff artificially created the time pressure which it then used as an excuse for Commission action without any prior public notice. Similarly, without any prior public notice of an intent to amend Part 21, it was disingenuous for the Staff to cite the absence of any public objection to a Part 21 amendment as evidence that the public would not in fact object to the amendment. In fact, the Office of General Counsel noted that the case for immediate effectiveness had not been made, that it was likely some members of the public would be interested in commenting on the amendment and that there was an alternative approach which would permit gathering public comment (Document A-92).

There is an additional problem with the reliance on construction schedule disruption as an excuse for the regulatory change. First, as shown above, there was no safety risk to continued use of Part 21 and the assertion that there was had no substantive basis in the record. Second, there is an

important safety risk created by the new amendment which the Staff did not disclose - i.e., the inability of the component purchaser to provide a meaningful QA program with respect to the purchased component. In such a case, the use of a reason for regulatory action which is pertinent only if the Commission is in the business of promoting nuclear power is particularly objectionable. Every Commission regulation has the potential effect of slowing plant construction. It is inappropriate and illegal for the Commission to use that fact to justify reducing the level of public safety, particularly to do so under an immediate effectiveness rule.

The Proper Solution. Viewed most favorably to the nuclear industry, the difficulty with Part 21 implementation was a misunderstanding of its terms and conditions by the industry. The Staff has not attempted to straighten this out but essentially panicked when the exemption requests began to arrive.

The record shows that the General Electric Company was the source of many of the difficulties encountered in implementing Part 21. Some divisions of G.E. flatly refused to supply components if Part 21 was invoked in the procurement document (see Documents A-31, A-35, A-39, and A-49). G.E. decided that it would not supply components under Part 21 unless its suppliers would agree to be subjected to 10 CFR Part 21 (Document A-83).

The Staff informed the Commission that "[t]he problems being encountered in the implementation of 10 CFR Part 21 may be considered to be associated with the 'learning' of a new regulation, i.e., the industry may find a way to properly

and appropriately implement 10 CFR 21." (Document A-96). The record indicates that this was a correct observation. The Staff was aware that G.E. experienced no difficulty in implementing Part 21 when the requirements of Appendix B to 10 CFR Part 50 were applicable. Rather, such difficulties arose, and properly so, when the supplier was not following the Quality Assurance Requirements of 10 CFR 50, Appendix B (Document A-26). Furthermore, a large number of the procurement difficulties encountered by licensees such as Virginia Electric and Power Company were resolved by determining that Part 21 had been incorrectly invoked on non-safety items, by purchasing an alternate component, or by further discussion with the supplier (Document A-83).

What is required is a clearly articulated policy about the applicability of Part 21 which stresses its functional nature and decries the mindless application of it to all components irrespective of their use. In addition the Commission could allow the Staff to approve an exemption from Part 21 for any supplier if the purchaser demonstrated that it could implement an effective QA program that would detect any and all safety deficiencies in the purchased component and that it would assume the responsibilities imposed by Part 21. The recalcitrance of the industry and the Staff averson to paperwork and to producing a clear articulation of the requirements of Part 21 should not be the excuse for an amendment that undermines the purposes of the statute and of Part 21.

We therefore urge the Commission to repeal the amendments to Part 21 set forth in the Federal Register on October 19, 1978 (43 Fed. Reg. 48621), to reimpose the original requirements of Part 21 and to direct the Staff to immediately begin a program to improve the understanding of Part 21 and to process exemption applications based on the criteria discussed above.

Conclusion

There is obviously more to this proceeding than a mistaken amendment to a regulation. The Staff presentation to the Commission was clearly an adversary presentation during which the Staff skillfully used its presumed expertise, humor and the selective emphasis of record facts to persuade the Commission to do something it should not have done and to do it in an inappropriate manner. It is important that the Commission take steps to reduce the risk created by the Staff acting in an adversarial fashion. To this end, we propose that the Commission adopt the following modifications in the policy applicable to consideration of regulatory actions:

1. All proposed regulations be preceded by an advance notice of intent to develop a regulation. This would have produced a public notice no later than June 1978.
2. Staff proposals for regulations be treated no differently from those generated by the public - i.e., a Staff submittal of a proposal to the Commission should trigger a Federal Register notice and opportunity for public comment on the

Staff proposal. Only after receipt of the public comment should the Commission take action on the proposal. The Staff proposal could be treated as the proposed amendment, provided its publication did not represent a prejudgment of the merits by the Commission.

If these simple rules had been followed here, the present controversy would not have reached this unfortunate status.

Respectfully submitted,

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
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DRAFT

IDENTICAL LETTER SENT TO

Toby Moffett, Chairman
Subcommittee on Environment, Energy and Natural Resources
U.S. House of Representatives
cc: Rep. Paul McCloskey

John D. Dingell, Chairman
U.S. House of Representatives
cc: The Honorable Clarence J. Brown

Gary Hart, Chairman
Subcommittee on Nuclear Regulations
Committee on Environment and Public Works
United States Senate
cc: Sen. Alan Simpson

The Honorable Morris K. Udall, Chairman
Subcommittee on Energy and the Environment
Committee on Interior and Insular Affairs
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Enclosed for your information are copies of a Notice of Denial of Petition For Rulemaking in Docket No. PRM 2-8, Union of Concerned Scientists and Natural Resources Defense Council, Inc., to be published in the Federal Register. The petition filed on March 2, 1979 was contained in a letter commenting upon certain amendments to 10 CFR Part 21, "Reporting of Defects and Noncompliance." The petition requested the Commission to adopt the following procedures: 1) all proposed regulations should be preceded by an advance notice of intent to develop a regulation, and 2) Staff proposals for regulations should be treated procedurally no differently from those generated by the public.

Notice of receipt of the petition was published in the Federal Register. Three letters of public comment were received, all of which dealt only with that part of the petitioner's letter concerning the amendment to 10 CFR Part 21. No comments were received regarding petitioner's suggestion to revise NRC procedures for handling Staff-proposed regulations.

For the reasons stated in the enclosed notice, the Commission has concluded that the petition should be denied.

Sincerely,

Howard K. Shapar
Executive Legal Director

Enclosure: Notice of Denial of Petition for Rulemaking

cc: Rep. Steven Symms

Enclosure "E"