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DEFENSE NUCLEAR FACILITIES SAFETY BOARD

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July 2, 1996

The Honorable Robert R. Nordhaus
General Counsel
Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585-0103

Dear Mr. ^{Bob} Nordhaus:

Discussions between our staffs have resulted in numerous changes and improvements to the draft revisions to 10 C.F.R. Part 820, Exemption Relief. DOE's most recent redraft was provided to us for comment on June 17, 1996. A detailed memorandum containing our comments is enclosed. In our view, two key infirmities remain in the current revision of the Notice of Proposed Rulemaking (NPR):

1. A principal legal requirement for granting an exemption to a "generally applicable" safety rule is demonstration of need; that requirement can be met by demonstrating that "special circumstances" exist which justify an exemption. This principle is not adequately preserved by the proposed exemption rule, which, in its current form, waives a showing of need when justified under the "necessary and sufficient" process.
2. Elevation of the "necessary and sufficient" process to a regulatory concept which supports issuance of an exemption is unjustified and unnecessary. The NPR, as written, could cause erosion of critical nuclear safety requirements contained in regulations applicable to defense nuclear facilities. We note the following:
 - The "necessary and sufficient" process is still in the pilot phase and has not been fully approved for use at defense nuclear facilities. See DOE P 450.3 (Jan. 25, 1996).
 - The "necessary and sufficient" process has now been renamed by DOE and is, at best, a vague and, as yet, unproven process for the defense nuclear complex. Thus, the process does not possess the level of tested rigor and formality to qualify for incorporation into a regulatory program.
 - Acceptance of "necessary and sufficient" documentation to fully justify exemptions to substantive safety requirements creates strong incentives for contractors to invoke the process to obtain exemptions from regulations. This contradicts the notion of "generally applicable" safety regulations and causes erosion of the regulatory process without any accompanying safety benefit.

- The “necessary and sufficient” process supplants the special circumstances determination which is a requirement for all exemptions, yet the “necessary and sufficient” process does not require findings on special circumstances.
- There is no need to single out “necessary and sufficient” as a source of documentation which establishes grounds for exemption from a rule. Any process, including “necessary and sufficient,” can generate documentation justifying an exemption.

Frankly, I see no valid purpose or need for inclusion of the “necessary and sufficient” process in this important exemption rule which will affect implementation of all substantive safety rules in the defense nuclear complex. These infirmities can be cured simply by removing reference to the “necessary and sufficient” process. If DOE has to refer to this process for some, as yet, unstated reason, it would be acceptable to the Board to:

1. Identify the “necessary and sufficient” process (by this or its new name) as one of the available means for developing justification documentation;
2. Leave the four criteria in section 820.64 (i.e., in accordance with law, undue risk, consistent with safe operation, and special circumstances) intact regardless of the source of exemption findings.

Rich Azzaro and John MacEvoy of my office will contact Doug Smith to work out these remaining problems, if possible.

Sincerely,



Robert M. Andersen
General Counsel

Enclosure

c: Mr. Mark B. Whitaker, Jr.

DEFENSE NUCLEAR FACILITIES SAFETY BOARD
Office of General Counsel

Internal Memorandum

June 28, 1996

TO: Robert M. Andersen
Richard A. Azzaro

FROM: John A. MacEvoy

SUBJECT: Comments on DOE's June 17 Proposed Change to 10 C.F.R. 820, *Exemption Relief*

I. INTRODUCTION & SUMMARY

DOE provided us with a June 17, 1996, draft notice of proposed rulemaking proposing changes to 10 C.F.R. Part 820, *Exemption Relief*.¹ As with NOPR-2, this proposal addresses some of our previous concerns and introduces additional major concerns. The two major concerns in NOPR-3 are use of the Necessary and Sufficient (N&S) process to supplant determinations required by the proposed (and existing) exemption rule and case law applicable to the DOE rule exemption process, and closely related to this, elevation of the N&S process to regulation status.² This is particularly troubling because the N & S process is a vague and untested pilot program lacking in the formality or content necessary to meet case law criteria for regulatory exemptions. This appears to be a move to enhance the status of the N&S process by prematurely writing it into a regulation.

DOE has no express statutory authority to grant exemptions to its rules. According to the courts, exemption authority is inherent in agency rulemaking authority, but should adhere to certain court-specified criteria. One criterion is that exemptions be granted based on need. Need is shown by factors such as hardship, etc., sometimes called "special circumstances" or "in the public interest." In NOPR-2, DOE proposed to delete the "special circumstance" determination required by DOE's current rules, arguing that its exemption authority comes from statute; therefore, Supreme Court and D.C. Circuit Court criteria are irrelevant. In NOPR-3, DOE gave the appearance of reinstating the special circumstances determination, but in reality, took it away in favor of the N&S process. This is a major concern because the N&S process is not adequate to replace the regulatory special circumstances determination, and as the proposed change stands, the scope of the exemption

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1. This will be identified as "NOPR-3." NOPR-2 is an undated draft Notice of Proposed Rulemaking, received by DNFSB on May 1, 1996, and NOPR-1 is the February 15, 1996, NOPR.
 2. I understand that DOE is about to change the name of the N&S process or substitute an entirely different process, but have not seen this in writing.

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regulation can be changed by changing the N&S process, effectively bypassing regulatory drafting requirements.

In NOPR-2, DOE proposed an automatic extension of time to submit implementation plans required by 10 C.F.R. Parts 830 and 834 if the applicant had initiated or had agreed to initiate the Necessary and Sufficient (N&S) process. NOPR-3 drops this proposal.

Another concern involves a proposal to raise non-regulatory contractual requirements to the level of regulations for enforcement purposes. Consequently, it is likely that "elevated" requirements associated with waivers granted under the proposed revisions (if promulgated) may not be considered proper agency action and, therefore, would not withstand challenges under currently-accepted case law. Thus, these types of conditions may be unenforceable.

II. BACKGROUND

A. Legal Basis for Granting Exemptions From Regulations

Congress granted DOE authority in the Atomic Energy Act (AEA), to "make, promulgate, issue, rescind, and amend such rules and regulations as may be necessary."³ DOE, under its organic statute (specifically at 42 U.S.C. § 7191) is required to follow Administrative Procedure Act (APA) rulemaking requirements.⁴ However, neither the AEA nor the APA grant express authority to grant general exemptions from regulations. DOE has been expressly authorized some room to maneuver in the rulemaking arena, but under very narrow circumstances, and not in the crucial area of health and safety regulation exemptions. For example, Congress granted DOE authority to waive some rulemaking requirements "where strict compliance is found by the Secretary to be likely to cause serious harm or injury to the public health, safety or welfare"⁵ This applies to the rulemaking process itself, not to the resulting rules. Congress also grants DOE, in 42 U.S.C. § 7194(a), authority to waive rules issued under the Federal Energy Administration Act, the Emergency

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3. 42 U.S.C. § 2201(p). This suggests that Congress intended that DOE develop its health and safety standards in the public view.
 4. Found in 5 U.S.C. § 553. (In this memorandum, "rule" and "regulation" are used synonymously, as are "exemption" and "waiver.")
 5. 42 U.S.C. § 7191(e). This applies to waiver of APA notice and comment requirements when promulgating a rule if necessary for health and safety purposes, e.g., if the delay would result in a threat to health and safety.

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Petroleum Allocation Act of 1973, the Energy Supply and Environmental Coordination Act of 1974, or the Energy Policy Conservation Act, but not rules issued under the AEA. DOE, along with many other agencies including the Nuclear Regulatory Commission (which also promulgates its health and safety rules under the AEA subject to APA requirements), has no express statutory authority to grant exemptions from its AEA-related health and safety regulations.

A small body of case law, including Supreme Court decisions, recognizes that agencies lacking express statutory authority must have the ability to grant exemptions from regulations of general application when special circumstances dictate a need.

Certain limited grounds for the creation of exemptions are inherent in the administrative process, and their unavailability under a statutory scheme should not be presumed, save in the face of the most unambiguous demonstration of congressional intent to foreclose them.⁶

In *United States v. Allegheny-Ludlum Steel Corp.*, 406 U.S. 742 (1972), the Supreme Court addressed the circumstances under which exemptions from regulations are appropriate. The Interstate Commerce Commission had promulgated regulations governing railroad freight car practices in an area where railroad companies had already established voluntary, but marginally effective, codes of practice. The railroads (Appellees) challenged the regulations as unreasonable, and the ICC countered that the Appellees' voluntary practices were inadequate to prevent rail car shortages, and that mandatory enforcement was necessary. Nonetheless, a procedure for exemptions from the regulations was also established because "mandatory total compliance with the rules promulgated would be impossible in view of the tremendous number of units involved" ⁷ In resolving this dispute, the Supreme Court concluded that the regulations were authorized by statute, reasonable, and supported by substantial evidence, noting with favor the exemption procedure. Regarding exemptions, the Supreme Court noted that:

It is well established that an agency's authority to proceed in a complex area . . . by means of rules of general application entails a concomitant authority to provide exemptions procedures in order to allow for special circumstances.⁸

The Court is making a specific and a general point. First, the existence of an exemption process in this case supports the reasonableness of the ICC regulations in question. Second, and more

6. *Alabama Power Co. v. Costle*, 636 F.2d 323, 357 (D.C. Cir. 1979).

7. 406 U.S. at 755.

8. *Id.* (citing *Permian Basin Area Rate Cases*, 390 U.S. 747, 784-86 (1968)) (emphasis added).

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important to this discussion, the Court recognizes that rulemaking authority includes an intrinsic grant of exemption authority to accommodate special circumstances which cannot be predicted in all cases by a rule of general application. The ICC's statutory authority to grant exemptions was not challenged in *Allegheny-Ludlum Steel*, but the Court cites *Permian Basin*, which involves the validity of special exemption processes where no express statutory exemption authority exists. In *Permian Basin*, the need for these exemptions was based on the difficulties faced by smaller gas producers, i.e., special circumstances, in meeting generally-applicable natural gas pricing regulations. The ICC had instituted special exemptions from rules promulgated under a section of the Natural Gas Act that did not authorize exemption or qualification. Nonetheless, the Supreme Court found that "the exemptions created by the Commission for [small gas producers] are fully consistent with the terms and purposes of its statutory responsibilities."⁹ Thus, the Supreme Court recognized an implied grant of exemption authority, in lieu of an express statutory grant, because this authority was necessary to address circumstances that could not be accommodated by a rule of general applicability.

WAIT Radio v. FCC, 418 F.2d 1153, 1157 (D.C. Cir. 1969), *cert. denied*, 409 U.S. 1027, arrived at the same conclusion from a different direction. In *WAIT Radio*, the FCC gave a radio license waiver applicant "perfunctory treatment," dismissing its waiver application without a "hard look." According to the court, even though

an agency may discharge its responsibilities by promulgating rules of general application which, in the overall perspective, establish the "public interest" for a broad range of situations, [this] does not relieve it of an obligation to seek out the "public interest" in particular, individualized cases.¹⁰

According to the court, an agency's waiver process "for consideration of an application for exemption based on special circumstances" is "intimately linked" to its rulemaking authority.¹¹ As in *Permian Basin* and *Allegheny-Ludlum Steel*, the court also linked an agency's waiver authority with the need to accommodate "special circumstances," or in this case, "particular individualized cases."

In so doing, the court in *WAIT Radio* put a lower bound on an agency's discretion to process waivers. At a minimum, waivers based on special circumstances must be given a hard look. Later in its opinion, the court put an upper bound on the waiver process:

9. 390 U.S. at 786-87.

10. *WAIT Radio* at 1157.

11. *Id.*

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The court's insistence on the agency's observance of its obligation to give meaningful consideration to waiver applications emphatically does not contemplate that an agency must or should tolerate evisceration of a rule by waivers. On the contrary a rule is more likely to be undercut if it does not in some way take into account considerations of hardship, equity, or more effective implementation of overall policy, considerations that an agency cannot realistically ignore, at least on a continuing basis. The limited safety valve permits a more rigorous adherence to an effective regulation.¹²

Thus, addressing particular factors, such as hardship, equity, etc., should keep the agency from swinging to the extreme of granting excessive waivers. (In our discussions we have consolidated the particular factors and special circumstances warranting an exemption with the considerations to be evaluated in granting the exemption under the single term "special circumstances.")

DOE's exemption authority for AEA-related health and safety regulations derives from the courts' recognition of implied authority, and so must conform to the courts' standards. It appears that Congress also recognized this case law doctrine. As stated above, Congress granted DOE express authority to grant exemptions from regulations promulgated under statutes other than the AEA. This authority is limited to those exemptions that "may be necessary to prevent special hardship, inequity, or unfair distribution of burdens" ¹³ This is fully consistent with the standard in *WAIT Radio*.

Other criteria established by the courts for granting exemptions from regulations include the following.

12. *Id.* at 1159. Other courts, in addressing health and safety issues, have taught these principles. For example, in *Delta Air Lines v. U.S. Federal Aviation Administration*, 490 F. Supp. 907, 916 (N.D. Ga. 1980), the court addressed excessive exemptions from air line pilot medical requirements. Noting that the FAA's client was the public, not the airlines or the pilots, the court stated that the public interest "requirement assures that the objective of the Act and Regulations (to promote air safety) will not be defeated and further assures that the Regulations themselves will not be rendered meaningless by virtue of constant and *pro forma* exemptions." The court also stated that "exemptions should be used sparingly and only in very limited and unusual circumstances." *Id.* (citing *Utah Agencies v. CAB*, 504 F.2d 1232 (10th Cir. 1974), and *Island Airlines, Inc. v. CAB*, 363 F.2d 120 (9th Cir. 1966)).

13. 42 U.S.C. § 7194(a).

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- Exemptions cannot contravene statutory requirements;¹⁴ thus, exemptions from AEA health and safety requirements must be shown to not sacrifice adequate protection or violate other statutory requirements.
- The exemption process is formal and rigorous.

An applicant for a waiver “faces a high hurdle, even at the starting gate. ‘When an applicant seeks a waiver of a rule, it must plead with particularity the facts and circumstances which warrant such action.’”¹⁵

The agency must indicate “fully and carefully the methods by which, and the purposes for which, it has chosen to act, as well as its assessment of the consequences of its [exemption] orders for the character and future development of the industry.”¹⁶

“Sound administrative procedure contemplates waivers, or exceptions granted only pursuant to a relevant standard -- expressed at least in decisions accompanied by published opinions, especially during a period when an approach is in formation, but best expressed in a rule that obviates discriminatory approaches.”¹⁷

DOE, in the oil energy (non-nuclear) arena, has established some regulations and agency case law for exemptions which are consistent with federal and Supreme Court requirements.

- “An application for an exception [from oil pricing regulations] may be granted to alleviate or prevent serious hardship or gross inequity.”¹⁸

Gross inequity is present if:

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14. *E.I. Du Pont de Nemours & Co. v. Train*, 430 U.S. 112 (1977).
 15. *WAIT Radio*, 418 F.2d at 1157 (quoting *Rio Grande Family Radio Fellowship, Inc. V. FCC*, 406 F.2d 664 (D.C. Cir. 1968), emphasis added).
 16. *WAIT Radio* at 1156.
 17. *Id.* at 1158-59 (emphasis added).
 18. 10 C.F.R. § 200.55(b)(2), DOE evaluation of exception applications.

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The purpose of the regulatory provision involved would be distorted by strict application of its literal provisions; or

A firm is uniquely affected by a regulatory provision and is thereby experiencing a disproportionate burden relative to other similarly situated firms; or

Application of a regulatory provision frustrates the realization of a major national policy objective.¹⁹

- Exception relief is not appropriate where future difficulties are merely speculative.²⁰

Thus, in this area DOE has chosen considerations which are of the same nature as the special circumstance criteria seen in DOE's current nuclear health and safety exemption rule (see summary *infra*), other agency exemption rules, and applicable case law.

B. DOE's Current Exemption Rule

As a prerequisite to issuing an exemption, the current DOE regulation²¹ requires a determination that an exemption:

1. Would be authorized by law;
2. Would not present an undue risk to the environment or the health and safety of workers or the public;
3. Would be consistent with the safe operation of a DOE nuclear facility; and
4. Involves special circumstances, including:
 - a. Application of the requirement would conflict with other requirements;
 - b. Application of the requirement in the particular circumstances:
 - would not serve its underlying purpose,
 - is not necessary to achieve its underlying purpose, or

19. William Foster Cockress, Jr., *Federal Regulation of Energy: The Exceptions Process*, 7 Transp. L.J. 83, 91 (1975).

20. See *OKC Corporation*, 2 FEA ¶ 80,604 (June 5, 1975); 7 Transp. L.J. at 90.

21. 10 C.F.R. § 820.62.

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- would result in resource impacts which are not justified by the safety improvements;
or
- c. Application of the requirement would result in a situation significantly different than that contemplated when the requirement was adopted, or that is significantly different from that encountered by others similarly situated; or
- e. The exemption would result in a health and safety benefit that would offset any detriment that would result from the exemption; or
- f. Circumstances warrant temporary relief while good faith action is taken to achieve compliance; or
- g. Other material circumstances exist which were not present when the requirement was adopted for which it would be in the public interest to grant an exemption.

DOE's current regulatory criteria for making the exemption determination are consistent with those set forth by the courts as factors to be considered in the exemption process.

III. DISCUSSION

The exemption rule revision proposed by DOE in NOPR-3 raises a number of major concerns, all of which relate to increasing the potential to abuse the regulatory process through manipulation of the exemption process. DOE's historical abuse of regulatory exemptions borders on legendary, albeit in the non-nuclear energy regulatory arena. (DOE has essentially no nuclear health and safety regulations on which to base any meaningful analysis of exemption.)

[C]reating a board or permitting an official to grant exceptions from the rules has resulted in a subversion of the rulemaking process in at least two agencies. The subversion in both the Federal Aviation Administration and the Department of Energy occurred in two distinct ways. First, it occurred when the agencies used the exceptions process as an arena in which to formulate and announce new policies and directions for the agency. Second, the rulemaking process was weakened when these agencies granted exception requests excessively. This resulted from their failure to heed the statutory and regulatory requirements for exception proceedings and granting relief and their distortion of the role of the exceptions process in relation to rulemaking.²²

22. Elise Friedbauer Lambrou, *Comment, The Exceptions Process: Administrative Counterpart to a Court of Equity and the Dangers It Presents to the Rulemaking Process*, 30 Emory L.J. 1135, 1138 (1981) (footnotes (continued...))

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This is the backdrop against which we view DOE's proposal to revise its nuclear health and safety exemption rule. DOE has demonstrated a tendency to abuse the exemption process, which suggests that we view current attempts to "streamline" the exemption rule with caution. Furthermore, one commentator who studied DOE's previous attempts to streamline its (non-nuclear) exemption process, concluded that anything but streamlining occurred.

The inappropriately liberal granting of exemption relief by . . . DOE encouraged exception requests and may have led to an overload of cases. The overload in turn led to "rubber stamp" approvals and arbitrary decisions. In terms of the DOE, the backlog of cases caused delay and meant that the individual for whom the process was designed -- the person caught in unforeseeable circumstances suffering serious hardship -- could not get prompt relief.²³

Specific major concerns are as follows.

A. Special Circumstances

10 C.F.R. § 820.62(d), regarding the "determination of special circumstances," would be superseded by:

reliance on the documentation and justified finding made and approved pursuant to the Necessary and Sufficient Process that compliance with the regulatory requirement for which

22. (. . . c o n t i n u e d)
omitted). This is not an isolated observation. See, for example, Peter H. Schuck, *When the Exemption Becomes the Rule: Regulatory Equity and the Formulation of Energy Policy Through an Exceptions Process*, 1984 Duke L.J. 163 (1984). ("[T]he exceptions process became a fig leaf concealing the incompetence, indecision, and political weakness of the DOE's regulatory apparatus." *Id.* at 286.)

23. 30 Emory L.J. at 1156 (footnotes omitted). This occurred in commercial oil industry regulation, not nuclear safety, and arose because DOE granted liberal exceptions rather than revising rules to accommodate situations applicable to a range of regulated companies.

Broad objections to the effects of a particular regulation upon all those required to adhere to the regulation are properly considered in the content of a petition for rulemaking

Commercial Bottle Gas, [1979 Transfer Binder] *Energy Mgmt.(CCH)* (4 DOE) ¶ 81,140, at 83,077 (September 27, 1979).

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the exemption is requested is not necessary in order to ensure adequate protection for workers, the public and the environment.²⁴

This says that special circumstances need not be addressed as part of the regulation exemption process if the bases for the exemption request were prepared under the N&S process. This is exactly where we were with NOPR-1, which also was unacceptable. If a contractor engages in the N&S process, the effect of the exemption process as proposed is to reduce all regulations to below the level of mandatory guidelines, not even equivalent to NRC Regulatory Guides. This is because DOE may now substitute other methods of compliance with no showing other than adequate protection and compliance with the law. NRC Regulatory Guides require at least a showing of equivalent methods to comply with the regulation. DOE's proposed change does not require even that. This proposal has the potential to subvert DOE's health and safety regulations.

1. Exemptions Must Be Based On Need

Our position on the criteria for granting exemptions is straightforward and generally accepted by federal agencies: An exemption should be granted if there is a need for the exemption and if the law is not violated.²⁵ Need is dictated by the specific fact pattern driving each exemption request; a fact pattern that we call "special circumstances" but could just as well call "in the public

24. NOPR-3, proposed 10 C.F.R. § 820.62(d).

25. *See, e.g.*, 10 C.F.R. § 205.55(b)(2), DOE regulation for evaluation of exception applications (application may be granted to alleviate or prevent serious hardship or gross inequity); 32 C.F.R. § 626.14, DOD Biological Defense Safety Program ("Ensure the existence of necessary and compelling reasons before granting waivers"); 40 C.F.R. §§ 750.11 and 750.31, EPA PCB and toxic substances exemption rules (quantify economic consequences of compliance, show no "unreasonable risk" to health and environment); 40 C.F.R. § 403.13, EPA waste pretreatment standard variances (show factors fundamentally different from those considered by EPA in establishing the standards to be waived); 49 C.F.R. § 555.5, exemptions from motor vehicle safety standards (show hardship or other bases); 40 C.F.R. § 30.1003, deviations from EPA assistance agreements (justification of why the deviation is necessary); 40 C.F.R. § 763.173, asbestos regulations (show that substitute material is inadequate and that asbestos is not an unreasonable health risk in the specific application); 14 C.F.R. § 11.25, FAA regulations (show public interest as well as no adverse safety effect); 29 C.F.R. § 1905.10, OSHA (show inability to comply and how employees are protected from hazard); and 10 C.F.R. § 50.12, NRC production and utilization facilities (specific special circumstances must be shown).

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interest."²⁶ Statutory compliance is addressed by criteria ensuring adequate protection (or no undue risk -- the terms are synonymous) and "in accordance with the law."

Nuclear health and safety rules are generally applicable requirements which DOE considers necessary to carry out its mandate under the Atomic Energy Act ("AEA"). Further, DOE considers rules to be important requirements.

By issuing DOE Nuclear Safety Requirements through the rulemaking process, DOE is sending a strong message that it believes these requirements are important to nuclear safety and that exemptions should only be granted if they do not unduly jeopardize health and safety.²⁷

Accordingly, DOE should not readily waive its health and safety requirements. However DOE recognizes that it must accommodate situations where it is not practical or possible to comply with a rule.

[S]ituations could arise where compliance with a DOE Nuclear Safety Requirement would be inappropriate, impractical or impossible. Exemption relief in such situations might be appropriate if the relief would not be contrary to the intent of the DOE Nuclear Safety Requirement and would not endanger the environment or the health and safety of the public or facility workers.²⁸

This statement, which is DOE's current regulatory position in its own words, also reflects our position and that of the courts. With NOPR-3, DOE is attempting to bid a hasty retreat from this position. According to DOE, these changes "protect the integrity of the Necessary and

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26. As discussed, *supra*, courts have viewed certain exemption criteria with approval, e.g., hardship, equity, more effective implementation of overall policy, circumstances substantially different from those considered in the rulemaking proceeding. These are representative. DOE must identify criteria relevant to its policies and interests.
27. 58 Fed. Reg. 43,680, 43,685 (August 17, 1993), DOE statement of considerations published with the current exemption rule.
28. 58 Fed. Reg. 64,290 (December 9, 1991), DOE notice of proposed rulemaking accompanying publication of the current exemption rule for comment.

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Sufficient process”²⁹ and move “away from the ‘one size fits all’ approach toward a tailored approach that recognizes the differences among the diverse DOE facilities.”³⁰ DOE’s abhorrence of overly-broad rules is understandable. Unfortunately, DOE is bolstering the questionable integrity of the Necessary and Sufficient process, which creates an expectation of easy exemptions, at the expense of the actual integrity of the regulatory process. Rather than nullifying the effect of its rules, DOE should consider a tailored approach to rulemaking, such as that adopted by EPA or NRC.³¹ This would minimize reliance on exemptions or a N&S process to correct poorly-drafted rules. That, however, is a topic beyond the scope of this analysis.

2. Statutory Authority to Grant Waivers

In support of its proposal to eliminate special circumstance determinations, DOE argues that its authority to grant waivers is granted by the AEA and APA. Thus, exemption requirements need only conform to statutory authority; case law is not controlling. This argument is not persuasive.

As noted, *supra*, DOE has no express statutory grant of authority to waive to its nuclear health and safety regulations. NRC corroborates this conclusion and confirms that under the AEA and APA, any exemption authority comes from court-recognized need for an exemption process, subject to clearly-stated limits such as a recognition of special circumstances.³²

The courts have cited several permissible rationales for the granting of exemptions. In *U.S. v. Allegheny-Ludlum Steel Corp.*, *supra*, the Supreme Court cited “special circumstances” as a rational for granting exemptions. In *WAIT Radio*, the D.C.

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29. Statement by Doug Smith, DOE OGC during telephone conference with Richard A. Azzaro and John A. MacEvoy.
30. NOPR-2 at 4.
31. NRC, for example, has divided its rules up into parts (e.g., 10 C.F.R. Parts 30, 40, 50, 60, 70) that apply to various types of facilities and materials. Many specific NRC regulations incorporate inherent flexibility to accommodate levels of risk for specific facilities. See, for example, 10 C.F.R. § 70.22(i). In this manner, NRC regulates a vast array of licensees ranging from owners of large nuclear power plants to possessors of small laboratory sources, without undue reliance on an exemption process to tailor its regulations. It is doubtful that DOE faces as broad a range of radioactive hazards and source terms as that faced by NRC, yet DOE claims it needs to rely on an exemption process (including the N&S process) to tailor its rules to its diverse facilities. It is more likely that DOE needs an effective rulemaking apparatus and more dedication to the regulatory process.
32. 50 Fed. Reg. 50,764 (1985), final exemption rule.

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Circuit believed that an exemption or waiver provision might account for considerations of "hardship, equity, or more effective implementation of overall policy."³³

Granting exemptions based only on "in accordance with the law," "adequate protection," and "consistent with safe operation" fails to recognize the "special circumstances" criterion established as an integral part of the court-recognized authority to prevent excessive use of waivers.

3. Case Law Requires a Need for an Exemption

DOE also argues that federal and Supreme Court case law on exemptions resulted from suits against agencies that were reluctant to grant exemptions without statutory authority. Thus, according to DOE, discussions of special circumstances, hardship, equity, etc., were dicta and not particularly relevant to the holdings. This is, again, another flawed argument.

None of the three leading cases cited *supra*, i.e., *Permian Basin*, *Allegheny-Ludlum Steel* and *WAIT Radio*, involved agencies that would not have granted waivers but for court intervention. In *Permian Basin* the Supreme Court upheld the ICC's decision to grant waivers based on "particular individualized cases" in spite of a lack of statutory authority. It was not necessary for the Court to direct the ICC to institute a waiver procedure. In *Allegheny-Ludlum Steel*, the Supreme Court upheld a regulation challenged as unreasonable for the reason, *inter alia*, that an exemption process existed to address special circumstances. Again, it was not necessary for the Court to direct the ICC to institute a waiver procedure. In *WAIT Radio*, the court admonished the FCC for a perfunctory review of a waiver request, and remanded for a "hard look." The court then established upper and lower bounds on agency discretion for granting exemptions based on special circumstances, naming some circumstances it viewed with favor as part of an exemption determination. Thus, the cases did not stand for the principle stated by DOE, and the need for a showing of special circumstances is intimately linked to the implied authority to grant exemptions.

33. 50 Fed. Reg. 16,506 (1985), U.S. Nuclear Regulatory Commission Notice of Proposed Rulemaking to amend its exemption rule, 10 C.F.R. § 50.12. This is particularly relevant because NRC also promulgates its health and safety regulations under AEA authority.

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4. DOE Contends That NRC Violated Case Law Until 1985

Also in support of its position on special circumstances, DOE argues that the NRC's current exemption rule was not driven by *Allegheny-Ludlum Steel* or *WAIT Radio* because it did not comply with these cases (decided in 1972 and 1968, respectively) until 1985 when it published its current version of its exemption rule, 10 C.F.R. § 50.12. This is not correct. Prior to the 1985 version of its exemption rule, the NRC required determinations that exemption requests were in the public interest. This required consideration of special circumstances, although not in those words. In the prior version of its exemption rule, the NRC:

staff would evaluate an exemption request to determine if there was a justifiable reason for the proposed exemption and, in addition, whether adequate protection of the public health and safety would be maintained if the exemption were granted.³⁴

The "justifiable reason" is another way of saying that special circumstances dictated a need for the exemption. When promulgating the current exemption rule, the NRC decided to change the name of the determination, and specify a number of factors to be considered.

[T]he public interest determination consists of the consideration of the special circumstances that justify the exemption. Therefore, "special circumstances" is a more appropriate terminology for this standard.³⁵

B. The Necessary & Sufficient Process is Inadequate to Supplant Portions of the Exemption Rule

On the face of the proposed rule the N&S process is incorporated into the proposed exemption rule to (1) allow the decisionmaker to rely in full on findings in the N&S process to support the determination of adequate protection,³⁶ and (2) to supplant the special circumstances determination.³⁷

34. 50 Fed. Reg. 16,506 (1985) (proposed exemption rule).

35. 50 Fed. Reg. 50,764 (1985) (final exemption rule).

36. The proposed change reads:

In making the determinations required by subparagraphs (a)(2) and (3) [adequate protection and consistent with safety], the responsible Secretarial Officer may rely

(continued...)

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This raises a number of serious legal and logical concerns. Further, using the N&S process to justify an automatic exemption from important (court-required) determinations under the exemption rule, and unnecessarily and improperly elevating the status of the process to regulation level, can provide a false expectation to contractors that the N&S process is a "fast track" to regulatory exemptions.

1. Reference to N&S is Unnecessary

DOE has chosen to single out the N&S program as a source of findings for the exemption determination to be made by the Secretarial Officer. In reality, there are no restrictions on the sources of information that may be used by the decision maker to arrive at a final determination; therefore no need exists to specify any process, including N&S. Exemption applications and their bases/findings can originate with a regulated entity independent of, or as part of, any organized effort, including the N&S process. If the exemption application is complete, regardless of its source (i.e., N&S or otherwise), the decisionmaker may rely on the findings as the single source of information to be considered. For DOE to elevate this obvious point to regulation status, and only identify the N&S process, is unnecessary and misleading. It goes without saying that DOE may base its determination in full on N&S process findings, or any other findings, provided they adequately address the exemption criteria in 10 C.F.R. § 820.62. It is surprising that DOE chose to single out the N&S process, which at its current stage of development is vague, is not yet cleared for use at

36. (...continued)

in full on the documentation and justified finding made and approved pursuant to the [N&S] process that compliance with the regulatory requirement for which the exemption is requested is not necessary in order to ensure adequate protection for workers, the public and the environment.

Proposed 10 C.F.R. § 820.62(b).

37. The proposed change reads:

The determination required by subparagraph (a)(4) [special circumstances] is not required for a [sic] exemption decision made by the responsible Secretarial Officer in reliance on the documentation and justified finding made and approved pursuant to the N&S process. . . .

Proposed 10 C.F.R. § 820.62(d).

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defense nuclear facilities,³⁸ and does not address the criteria in 10 C.F.R. § 820.62 which must (as the existing and proposed regulations both require) be addressed by other, non-N&S, exemption applications. Thus, even if a reason existed for identifying a specific process in the exemption rule, it is not clear why this particular process was chosen.

2. Complete Reliance By Secretarial Officer is Unacceptable

If, by authorizing the Secretarial Officer to “rely in full on the documentation and justified finding made and approved pursuant to the [N&S] Process,” DOE intends to free the Secretarial Officer from further analysis, we must oppose this provision. This provision could be interpreted to mean that the Secretarial Officer can rely on the justification and approval provided by the N&S process and need not perform an independent evaluation. If so, this is unacceptable because it:

- a. violates the rule as written and as proposed, that “[t]his authority may not be further delegated,”³⁹ and this would amount to a *de facto* delegation,
- b. relies on an as-yet flawed N&S program for the findings and justification, and
- c. violates a “requirement” in the N&S manual that

Approval does not constitute approval of exemptions from standards in applicable laws and regulations For DOE nuclear safety regulations, an exemption request, and the justification contained therein, will be processed in accordance with 10 CFR 820.⁴⁰

“Processing” must accomplish more than just a rubber-stamp approval of an N&S justification, or this N&S Manual paragraph, coupled with the proposed new 10 C.F.R. § 820.62(b) amounts to little more than a circular sham process.

These “flaws” referenced in the above discussion (2(b)) have been discussed *supra* and are further discussed below.

38. “Effective immediately, all Department Elements are authorized to use the ‘Closure Process for Necessary and Sufficient Sets of Standards’ except for defense nuclear facilities.” DOE P 450.3, January 25, 1996, DOE Policy authorizing use of the N&S process for standards-based environment, safety and health management.

39. 10 C.F.R. § 820.61.

40. DOE M 450.3-1, Chapter II § 7.b.(2), January 25, 1996.

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3. "Reliance In Full" Violates the Proposed Rule

The proposed rule requires a determination that special circumstances exist prior to granting an exemption.⁴¹ The proposed rule also waives the special circumstances determination if the N&S process provides the findings and justification for the exemption. Thus, on the one hand, an exemption application must not be approved if it fails to address special circumstances, and on the other hand, special circumstances are not required of the N&S exemption application. Keeping in mind that the N&S process does not address the special circumstances set forth in the proposed (and existing rule), the automatic exemption for the N&S exemption application is illogical and violates the rule.

4. DOE is Using the N&S Process to Subvert the Regulatory Process

As discussed above, DOE has already improperly proposed to use the N&S process to bypass the special circumstance determination required by the courts, in violation of its own proposed (and existing) rule. If DOE succeeds in elevating the N&S process to the level of a regulation without pursuing the required APA notice and comment process, it will be able to, in effect, change the regulatory criteria required for exemption approval by changing the N&S process. We will be left with the curious circumstance that exemption requests originating outside the N&S process will be required, by regulation, to meet one set of criteria, but N&S exemption requests will be "required" (in the DOE administrative sense) to meet a set of internal, policy-based, criteria. This is internally inconsistent and not in keeping with a regulatory process under the APA.

5. The N&S Process Does Not Define a Necessary & Sufficient Requirement Set

In NOPR-2, DOE references DOE Manual 450.3-1 as the documented N&S process. As Draft M 450.3 now stands,⁴² the N&S process does not require a special circumstances determination. In fact, although M 450.3-1 directs DOE personnel to identify, confirm, and approve a necessary and sufficient set of standards, it provides essentially no information regarding what a necessary and sufficient set of standards is, nor does it identify (or direct the reader to) what constitutes adequate protection. Without more, the N&S process of Draft DOE M 450.3-1 is wholly inadequate to supplant major portions of the current exemption regulation, which currently includes,

41. Proposed 10 C.F.R. § 820.62(3) (existing § 820.62(d)).

42. DOE draft M 450.3-1, January 24, 1996.

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inter alia, special circumstances determinations.⁴³ One questions why this, a non-regulatory and as yet untested system, would be prematurely incorporated into a formal regulatory exemption provision which applies to generally applicable regulations.

6. Independence is Lacking in the N&S Process

Independent involvement is essential to the integrity of the exemption process. Yet the proposed revision seems to discourage independence in favor of the N&S process, which has few requirements for independent evaluation. The N&S process in its current form requires no independence in the overall exemption process (N&S plus section 820) between the contractor, party making the finding, party accepting the finding and the line organization making the final exemption determination.

This relates back to the ground rules for the exemption process itself, which under *WAIT Radio* at 59 is "a standard . . . best expressed in a rule that obviates discriminatory approaches." Under the N&S process as documented in DOE M 450.3-1, the Approval Authority approves the N&S set of standards justified by the Identification Team. The Approval Authority is designated by the

43. DOE has proposed to define the N&S set of requirements as

the set of standards approved by the Department to be adequate to protect workers, the public and the environment by means of the Necessary and Sufficient process.

This definition is circular and attempts to define only a sufficient set, not a necessary and sufficient set. Until officially defined by DOE, I suggest we define a Necessary and Sufficient set to be the following:

A requirement is to be included in the N&S set if it is necessary for adequate protection of worker and public health and safety. If not necessary, but desired to achieve a certain level of excellence, it should be an optional member of the set (and so marked).

The set of necessary requirements is a sufficient set if the totality of the necessary requirements, when properly implemented, will provide adequate protection.

To illustrate, each requirement in a set of "N" requirements may be necessary to provide adequate protection (i.e., it is not an unnecessary requirement), but may not be sufficient. An additional set of "S" requirements is needed to make the set of "N + S" sufficient to provide adequate protection. The set of "N + S" requirement would then be a necessary and sufficient set.

"Adequate protection" is a difficult concept to define, but I fail to see how an N&S set can be defined without knowing what constitutes adequate protection. DOE should define this term at a minimum for the purpose of implementing the N&S and exemption processes.

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Convened Group. The Convened Group represents the Agreement Parties, and the Agreement Parties include the Customer Organization, which is the organization responsible for doing the work to be subjected to the selected set of requirements. Thus, the organization responsible for the work participates in selecting the people who justify and approve the applicable set of requirements. Nothing in the N&S process requires the justifiers to be independent of the approvers. Nothing in NOPR-3 requires evaluation by an organization independent of the organization responsible for the activity. In short, as written, the proposed rule and draft manual chapter do not preclude the same person from proposing an exemption, preparing the justification for the exemption, and approving the justification (upon which the Secretarial officer "may rely in full").

This is not a rule that obviates⁴⁴ discriminatory approaches. With only a minor change to the proposed rule DOE could ensure that exemption determinations require approval by organizations independent of the line organization responsible for the activity and those responsible for justifying and approving the basis for the exemption request.

C. DOE Must Evaluate More Than Adequate Protection

Limiting the exemption determination to a level of adequate protection may result in granting a waiver that undermines the very purpose of the rule, since rules may require adherence to a standard beyond adequate protection.

DOE's regulatory authority under the AEA goes beyond the adequate protection standard. DOE is to:

establish by rule, regulation, or order [agency order, not DOE safety Order], such standards and instruction to govern the possession and use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property"⁴⁵

Therefore, the waiver must be evaluated against the underlying policy of the rule. This, however, is one of the determinations to be deleted by NOPR-3 in favor of the N&S process. NRC, which also is subject to the same provision of the AEA, decided that (1) rules must of necessity be

44. *Obviate*: to prevent or counteract by anticipating. *Webster's II, New Riverside University Dictionary*, 1988.

45. 42 U.S.C. § 2201(b) (emphasis added).

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more specific than requiring adequate protection, and (2) the specific objective of the regulation must be ascertained as part of the waiver process.⁴⁶

If DOE changes section 820 to require no more than adequate protection, all resulting requirements will have no more purpose than adequate protection. In effect, DOE is claiming that only one regulation needs to exist (and presumably only one DOE safety Order requirement), and all it need say is "Provide Adequate Protection." DOE does not believe this to be true because a comprehensive (and frequently updated) set of rules and Orders exists. Why then would DOE propose an exemption rule that would allow its substantive regulations to be nullified?

D. Automatic Extensions For Implementation Plans

In NOPR-2, DOE had proposed automatic extensions of time for implementation plans when due dates were specified in the associated regulations (10 C.F.R. Parts 830 and 834). The extension would have amounted to six months to a year.⁴⁷ DOE contended that this would have no effect on safety because the rule compliance date (as opposed to the implementation plan due date) was not automatically extended. In response to our concern that, based on observed performance, an implementation plan delay would unavoidably delay the implementation date, DOE removed this provision from the proposed rule. DOE now plans to extend the implementation plan due dates as part of the substantive rules which require the implementation plan. While this removes the consideration from the proposed exemption rule, we must watch for these changes in the other rules.

46. In commenting on the need for special circumstances determinations, the NRC noted that its proposed exemption rule:

addresses situations where alternative or compensatory means exist to achieve the underlying purpose of the regulation. This would allow an exemption request to be considered where it could be shown that satisfactory alternative or compensatory mechanisms exist to achieve the regulatory purpose. It must be understood here that the underlying purpose of the rule should be something more specific than achieving adequate safety protection. Otherwise all of the safety requirements in 10 CFR Part 50 become subject to open litigation, and the exemption process becomes open ended. Rather, the specific objective of the regulation must be ascertained from the rule itself or the underlying rulemaking proceeding"

50 Fed. Reg. 16,506.

47. The proposed extension is for eighteen months following publication of the substantive rule. Thus, if the rule requires an implementation plan six months after the rule publication date, the automatic extension would add one year.

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E. Exemption Conditions May Not Be Enforceable

In the proposed new section 820.62(b):

A decision to grant an exemption on the basis of paragraph (b) of this section shall be conditioned so as to require compliance with

(2) if alternative nuclear safety standards are not specifically identified in the documentation, all of the nuclear safety standards in the [N&S] Set.⁴⁸

If invoked, this section will attempt to convert all N&S requirements, many of which are contractual requirements, into regulatory requirements, subject to enforcement under the Price-Anderson amendments of the AEA. Even though DOE will issue the exemption as a Final Order (in the APA sense), which is enforceable under the AEA,⁴⁹ DOE may not be successful in enforcing non-regulatory contractual requirements elevated to a regulatory level. APA formality may be required prior to enforcement of these requirements, such as adjudications or hearings for conditions imposed by orders (e.g., compliance orders, exemption orders) and notice and comment for requirements to be enforced as rules.

DOE argued that this proposed change was intended to point out that regulatory requirements in S/RIDS and contracts were imposed as conditions of the exemptions. Therefore, only regulatory requirements would be enforced. But, if that were true, the proposed change would not be necessary, since regulatory compliance would be required except for the exempted rules.

48. Less awkward wording could be used.

49. Specifically, 42 U.S.C. § 2282a(a), which authorizes civil penalties for violation of, *inter alia*, an applicable order related to nuclear safety. (Distinguish an order commanding an action or granting a right, i.e., a Final Order as defined in 10 C.F.R. § 820(a)(v)(C), from a DOE Safety Order, which is a procedure or policy document more in the nature of an unenforceable regulation.)