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UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899-0001

January 23, 1997

Secretary
Nuclear Regulatory Commission
Washington, D.C. 20555-0001
Attn: Docketing and Service Branch
Ref: RIN 3150-AF54 (61FR58346)

Dear Sir:

The attached detailed comments are offered in response to the notice of proposed rulemaking for 10CFR33 (61FR58346). After careful and detailed review of this notice by NIST management, by members of the Ionizing Radiation Safety Committee, and by the Health Physics staff we must conclude that NIST, the radioactive material users' community, and the Nuclear Regulatory Commission are best served by the regulations in their current form. The potential rules, as represented by the various 'questions', and the specific suggested rules clearly present a regulatory scheme that would be less effective in terms of public safety and regulatory effectiveness, more costly in terms of licensee resources, and in certain aspects virtually unmanageable in terms of clear definition of responsibility.

The general result of these 'prescriptive' proposals will be to dilute and diminish the professional management of licensed activities, creating an atmosphere of rote regulatory compliance rather than the professional application of basic principles for public and worker safety. In particular,

- the proposed makeup and responsibilities of the Radiation Safety Committee create an unmanageable structure with confused lines of authority and responsibility that are incompatible with the NIST organizational structures and with general principles of accountability.

- the onerous provisions of the proposed 33.25(b) creates a potential liability for managers that at a minimum will detour any reasonably intelligent person from voluntarily participating in licensee management, *e.g.*, RSC participation, because they will be held liable for actions beyond their control.

In summary we urge you to continue the current licensing practices which allow for the diverse nature of licensees.

Sincerely,

Lyman Pevey
License Manager
Chief, Occupational Health and Safety Division

Chris Kuyatt
Chairman
Ionizing Radiation Safety Committee

Attachment

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NIST

NIST comments on the notice of proposed rulemaking for 10CFR33 (61FR58346).

Background

NIST summary comment: Insufficient information is provided in this notice to demonstrate a need for revising 10CFR33, or in most cases, a need for specific changes suggested in this proposal.

The NRC notes a review of Part 35, and a NUREG published for comment, but does not describe the similar failings or problems between the two programs such that the experience from Part 35 is relevant to Part 33. What elements are similar, what was the success of NRC's response to these problems, and how would this be applied to Part 33 licensees? Given the rather significant difference between the two programs in terms of the use of radionuclides the Part 33 community probably is unaware of the history under the Part 35 program. Further, the discussion as contained in this notice does not relate to, justify, or support the proposed changes to Part 33. While some of the proposed changes are attractive it is our conclusion that Part 33 is effective as currently published and the discussion in this notice does not appear to offer any arguments to the contrary.

It is asserted that the need for a change to Part 33 is reflected by the two ^{32}P events. These two events were so out-of-the-ordinary it is difficult to see how it can be asserted that they are reflective of any aspect of any licensee program. Given the continuing investigation in at least of one of these events it is difficult to make definitive statements about them, but given the nature of these events it would appear that they were deliberate events initiated by one or more individuals in a manner that is totally outside the scope of controls in 10CFR33, unless NRC is intending to change the underlying risk basis for these regulations, such as making the licensee responsible for blatantly criminal acts of its employees. [This latter point is not indicated in this proposed rulemaking.] Further, other than broad generalizations about licensee controls, there have been no licensee controls identified that could have prevented these events. Hence the justification for citing these events in support of the proposed rulemaking is unsupported in this proposal. None of the proposed rule changes are identified as a solution to the problem presented by these events.

If the two ^{32}P events are the most significant that can be identified in support of this proposal there must be a related spectrum of lesser failures identified via the inspection program that could be summarized to support this proposal. Is such data available or is the presumption for a need to revise Part 33 basically anecdotal? As a licensee and as an observer of the regulatory system it is our perception that the current NRC regulatory model has been very successful in effectively and efficiently protecting the public and radiation workers. The combination of the licensing process and an independent inspection process together with flexible, non-prescriptive (*i.e.*, performance oriented) regulations can only be described as a success despite a number of problems over the years. We hope that this 'proposed rulemaking' is simply the public process by which the identified questions can be openly discussed and does not reflect an assessment of failure of 10CFR33.

Requests for Comments on General Considerations

Question 1: Should the responsibilities of licensee management for the radiation safety program be specified in Part 33?

NIST Recommendation: No.

As indicated, DG-0005 addresses this issue. Is there any broad scope licensee that the NRC licensing group has licensed that does not meet these provisions? Our experience is that the NRC Part 33 licensing group pretty much gets what it wants and the licensee knows what is wanted via the

Regulatory Guide. If this is the case, how is the regulation defective?

Given the wide variety of licensees, and even broad scope licensees, the current process would appear to be the most flexible from a regulatory point of view. Any prescriptive regulation would have to be a compromise that at best fitted all licensees less effectively and hence served NRC less effectively than the current approach. Thus we would argue against making Part 33 more prescriptive and against adding unnecessary detail.

Question 2: Should the NRC incorporate requirements for the duties and responsibilities of the RSO and RSC?

NIST recommendation: No.
[Observation: This question certainly offers the opportunity to guarantee employment for health physicists, and hence opens the possibility for biased responses.]

The discussion offered by NRC for this proposal does not identify any deficiencies in the current rules. The mere lack of a regulation is viewed by most as a plus. Does NRC have data indicating a difficulty in this area? Our experience in our interactions with the RSO's of other organizations is that they are at least adequately qualified (and usually outstandingly qualified) for the position. The nature of the audience who will respond to this question (*i.e.*, readers of the federal register) is that the NRC will get a very biased response because of this knowledgeable audience. It would seem that this question would be better addressed by a direct sampling process for the result to have any meaning.

A member of the NIST staff, while serving on a committee, has in the past reviewed the CV's of several hundred Certified Health Physicists and can attest that a set of criteria based on some profile of education and experience would certainly exclude some of these highly qualified individuals, ignoring their certification status. Simply stated, while it is easy to write criteria that guarantees a qualified RSO, *e.g.*, a Ph.D. in Health Physics with an ABHP certification, one that simply represents the necessary qualifications that also assures the NRC objective as a function of the full range of types of licensees will assuredly exclude qualified candidates. This would presumably be undesirable.

Question 3: Should specific minimum training and experience criteria for authorized users be incorporated into Part 33?

NIST recommendation: No, NRC should not incorporate specific requirements into Part 33. This should be left to the licensee's Radiation Safety Committee.

What does NRC mean by an authorized user? Is this the person who designs the experiment/usage, formulates the usage procedures including the safety precautions, and obtains all required approvals (sort of like a licensee applicant to NRC); is this a worker who simply uses the material in a knowledgeable way as part of an experiment or established usage protocol while following those established procedures; is this the technician performing manipulations under general supervision; or is it some combination of these? Clearly these are different users with drastically different qualification requirements, depending on the level of activity and proposed usage envisioned. While there are not any specific education and training requirements in 10CFR33 this proposal has not indicated in what manner the basic requirements of 10CFR19 are deficient.

As a licensee we have not had any difficulty under the current regulations of ensuring that proposed users have adequate experience and training. As with all professions users build on experience so that a user needs some related experience to get approval for a higher level of activity or an increased level of usage complexity, and new users are required to have direct supervision. We have

not generated explicit education or training requirements beyond those of 10CFR19, but our subjective application of the 10CFR19 requirements have in general been successful. As an example, the first time worker using relatively low activities of a low toxicity nuclide doing rather simple manipulations would require little beyond very basic knowledge (as prescribed in 10CFR19).

If specific education and training requirements were to be incorporated into 10CFR33 they should identify several kinds of users and should reflect the following aspects of radionuclide usage:

- form - sealed versus unsealed usage is an obvious element for the matrix of experience and education requirements.
- level of activity - clearly, unsealed use of Appendix C quantities handled in a simple manner requires minimal prior experience, while at the other extreme quantities in excess of 10^6 ALI (or those producing dose rates in excess of 100 mrem/h) require substantial experience.
- nature of the unsealed manipulation - simple wet dilutions of even significant activities can be done by minimally trained workers while more complex handling, *e.g.*, powders, elaborate chemistry, requires detailed training and experience.
- authorized scope of usage - a senior user is allowed more flexibility to adjust parameters and experiment techniques while an entry level user has more prescriptive limits in the usage authorization.

Question 4: Should the NRC incorporate specific requirements for inventory and accountability of byproduct material in use, or modify its existing guidance?

> NIST recommendation: No, these procedures should be left for the licensing and inspection process. However NRC should establish a quantitative level below which the licensee is not required to perform centralized accounting, *i.e.*, the licensee is only required to maintain accountability at the user level.

This topic raises the greatest possibility of being a needless manpower drain of radiation protection resources. While the regulations clearly require, and there is a clear need to, *control* all licensed material there is clearly a difference in the degree of austerity needed between low-level, low-toxicity sources and the opposite extreme. Given the added variable of a wide variety of kinds of licensees we judge that this issue is best left to the licensing and inspection process. Any sort of comprehensive rule is certain to be inadequate for a significant number of licensees.

Specific issues of concern are:

- how is a source accounted for, particularly those with short half-lives and those that are difficult to assess or to detect independently?
- how does the licensee distinguish between user accountability and control for authorized sources and central accounting and systemic control for all licensee sources?
- should sources of less than a certain half-life, *e.g.*, 18 days (10% of 180 day accounting period), be exempt from central accounting? A suggested wording is if the activity of the source 15 days after acquisition is less than some value, *e.g.*, a fixed activity like 10 µCi or less than the Appendix C value, central licensee accounting is not required. This has the attributes that: (1) recognize that the user is not likely to lose track of a source immediately after acquiring it, and (2) provides flexibility for short half-life materials, particularly those made at research reactors or milked from longer-lived precursors.
- should sources of less than a certain activity, e.g., Appendix C quantities or quantities less than 1% of the license limit, be exempt from central accounting and only be subject to periodic user audits of accounting?
- if NRC requires accounting for unsealed sources, what are the precision criteria to be? Allocation (*i.e.*, extracting portions of the source) and accounting precision is highly variable among

different kinds of users, particularly those doing 'relative' experiments. Even the step of establishing an arbitrary precision value will necessitate additional work for some users simply to demonstrate compliance to those (possibly arbitrary) criteria.

5. Should the NRC consider the risks associated with internal exposure pathways separate from those for external radiation?

NIST recommendation: Most emphatically, no.

The 10CFR20 revision which rectified this historical error should not be undone. In virtually all cases generic internal dose modeling is an overestimate of the individual's exposure. And in the cases specifically cited the dose estimates were certainly as good as external dose estimates in analogous events. If anything, under the current rules internal dose risks for the typical worker are more realistically estimated than external exposures (by the very definition of these doses in Part 20) so that added special considerations for internal exposure are not needed.

On the other hand if NRC has some mechanism, or can sponsor research that will identify a mechanism that would assist the licensee in distinguishing inhalation versus ingestion uptakes based on routine bioassay data it would help identify events similar to those previously discussed.

6. Are there other specific aspects of DG-0005 that should be codified?

NIST recommendation: No.

7. Should broad scope licensees be allowed to make changes in their radiation safety program similar to 50.59?

NIST recommendation: Yes, depending upon the nature of the rule implementation.

Under our current license as structured by NRC we have

- a section in the application that represents boilerplate conditions,
- a section that represents implementation of those conditions and which may be changed by NIST, subject to annual notification to NRC,
- a license conditions document issued by NRC,
- and implementing procedures that can be changed subject to approval by the RSC.

If this proposal would remove one of those layers there would be a benefit, albeit a minor one since we are talking basically about the elimination of 6 or 8 pages of material. Presumably this proposal would necessitate a more complex 'license conditions' document from the NRC, comparable to the Part 50 'Technical Specifications'. We suspect that for most facilities this would be a wash, *i.e.*, of no significant advantage.

A possible significant disadvantage would be that while it would reduce the licensing workload at NRC, it would increase the inspection workload of a basically paperwork activity thereby decreasing inspection time of 'real' licensee activities.

8. Should the different types of broad scope licenses currently in Part 33 (Types A, B, C) be deleted and replaced with a single type?

No additional comment.

9. Should a category of "master materials licenses" be created?

NIST recommendation: No, if this category would apply to NIST as we are currently licensed.

This would seem a matter of simple practicality. How many licenses does NRC have that fit this category? Is the tradeoff of creating a different regulatory framework justified by other resource savings? This proposal does not offer any information of this sort.

For NIST, and probably for most licensees this is an academic issue. The added layer of bureaucracy is a clear detraction from choosing this category unless the licensee is a very large, and probably multistate organization. And in that event, the idiosyncrasies of the different states are an added distraction to this option unless the licensee is like the examples cited, *e.g.*, exempt from state licensing by virtue of being a federal entity.

10. "Multi-site" licenses.

No comment.

11. What balance should be maintained between a performance-based and a prescriptive approach to regulating broad scope licensees?

The balance should lean as far towards performance-based as possible. Given the wide variety of licensees in the U.S., any prescription rule is an ill-fitting shoe for some, if not many, licensees. Only the fourth element, *i.e.*, an intolerable outcome, should be the determining factor in necessitating a prescriptive rule. The NRC regulatory process has demonstrated remarkable effectiveness and success, even in view of noted failures. While it is always worthwhile to review and refine a successful product it should be recognized that 10CFR is just that, and sweeping changes in regulatory philosophy are not needed.

Specific Examples of Possible Regulatory Language:

NIST recommendation: These draft suggestions have significant problems, as indicated in the comments below. In most cases we recommend against adopting these suggestions.

Item 2- A.U.: The definition of 'authorized user' is simplistic in that it does not reflect the spectrum of different types of users and the different qualification requirements. In particular it does not distinguish between users with different levels of authorized use, either in usage complexity or activity level. It has the detrimental implication that all *authorized users* are the same by virtue of being so labeled by this NRC rule. **This term is best left undefined.**

Item 2- RSC: The definition of RSC is deficient in that a committee neither develops nor administers. This definition conflicts with management responsibilities. A committee reviews and approves. Further, 'responsibility for approval' is unclear in a similar manner. That is, does NRC intend that the committee personally and *a priori* review and approve each and every proposal and radionuclide order or does NRC intend that the committee oversee a program conducted by the RSO and reviewed by the committee on a regular and timely basis for accomplishing this? In the former case for large programs the committee will have a fulltime workload, and hence cannot be constituted of representative members as NRC specifies in the proposed rules since those people have other jobs.

Item 2 - RSO: The definition should read "... the individual, identified on the license, responsible for the development and administration of the licensee's radiation safety program." At smaller facilities the person qualified to be the RSO in terms of education and experience may have other primary job

functions and in that instance may not directly oversee "day-to-day operations." The essential element is the person who administers the program, *i.e.*, has authority to hire, fire, approve fund expenditures, etc.

Item 3: The requirement to "maintain adequate safeguards against ... loss of records" is unreasonable. While a failure-free program is always a desirable objective some sort of reason must apply in judging failures. A single failure should not represent a programmatic failure, which position this rule would mandate. We suggest changing 'adequate' to 'reasonable' if this proposal is to be retained.

More generally, this proposal represents an unneeded, added regulatory layer. NRC already has requirements for records in certain specific areas, specifies retention requirements, and can issue citations for the lack of those records. What is the legal necessity for another nail?

Item 4(a): see the earlier comment. In summary, deletion of the specific B and C categories would result in a loss of clarity for a reader of the regulation. The current rule provides a sense of scale that the proposal loses. The proposal gives the impression that NRC is treating multicurie licensees and microcurie licensees the same.

Item 4(b): As defined this has no impact on most Type A broad scope licensees, unless the underlying NRC intent is to force most current Type A licensees into this category. In that case it represents an unneeded and unnecessary added administrative workload for those licensees in that it would mandate another layer of bureaucracy. Please clarify NRC's intent. No data is presented to demonstrate that this licensing category would serve any useful purpose other than to codify an existing NRC practice, which if currently legal needs no further codification.

Item 5(a):

- Section 30.32(g) forces many usages to be treated as unsealed sources, results in a significant loss of credibility among the users in terms of perceived risk, and results in an unneeded expenditure of scarce radiation safety resources. For example, a liquid in a sealed glass vial certainly does not meet the Part 32 criteria for a sealed source but clearly is not an unsealed source and containment failure is easily recognized by a knowledgeable user. Surveillance procedures for unsealed sources are clearly inappropriate for such a source usage. **Sealed sources under Part 33 licenses should be defined as sources that are adequately contained for their intended use.** This is not the same (and should not be the same) as Part 32 sealed sources and need not have the same performance requirements. Such sources under a Part 33 license, as opposed to a Part 32 license, are subject to a higher quality continuing surveillance and in general are used by more knowledgeable users. NRC should take this opportunity to recognize this and explicitly exclude 30.32(g) from applying to Part 33 licensees.

- Presumably the circular reference created by 30.33(4) does not cause Parts 32,34-39 to apply to Part 33 licensees. If this is not the case, then additional time is requested to evaluate the impact of those sections on Part 33 licensees.

Item 5(b): This in essence prohibits a new organization from acquiring a Type A license, regardless of the education and experience of its staff. Given that it is people who are essential to an acceptable program this requirement should include a provision based on the RSO and RSC experience base. While such applications are probably a rare event there is no reason stated in this proposal to arbitrarily exclude them.

Item 5(c): Presumably 'previous experience' includes the previous experience of the licensee's personnel, both in terms of a new license (see comment above) and in terms of a license renewal.

Item 5(h)(10): This is a much more comprehensive requirement than that required by 10CFR19 where only appropriate training is required. If something different from Part 19 is intended then more detailed discussion of this requirement is needed. If only the Part 19 requirement is intended then that should be explicitly stated to avoid conflicting interpretations of the rule. In particular this requirement seems to be targeting non-users who are simply in some general (undefined) area near authorized work. The Part 19 requirement achieves this more directly and simply unless the intent is to require training for persons in unrestricted areas, in which case this proposal is fundamentally defective. On the other hand if the intent is to prescribe what areas are to be included in the licensee's Restricted Area this proposal lacks clarity to that effect.

Item 5(h)(13): This looks like an authorization for a Part 33 licensee to perform a limited decommissioning of a previously licensed activity site, *e.g.*, a lab. If this is what is intended this is a significant, positive change to the rule. Our previous experience is that it took 3 years to release a single, one-room lab via the current NRC processes, during which time it stood idle. **NIST recommendation: Highly desirable.**

Item 6: As long as extensive revisions are being considered we suggest that some of the restrictions posed in 33.17 are unreasonable and serve no public interest. For example, 33.17(a)(2) prohibits activities covered by Part 34. But in fact any Part 33 licensee having a reasonable activity gamma source can easily and safely conduct a radiography experiment at the licensee facility. Presumably what NRC is concerned about is extensive commercial operations conducted at non-licensee owned facilities. Rather than putting such a comprehensive trap in the rules for the licensee why not be more specific in the exclusion? For parts 36 and 39 it is more difficult to hypothesize a reasonable Part 33 activity, but that does not mean that they do not exist. Why needlessly complicate the life of a Part 33 licensee, particularly those with limited geographical sites?

Item 6: Regarding a(3), activities for which a license is needed under Part 35 are prohibited. So why is this clause needed? Facilities doing animal research, or even those doing *in vitro* work, label chemicals and process them in a manner that is effectively equivalent to making them suitable for human use. We collect and distill tritiated water as part of our environmental sampling program, which end result is clearly suitable for human use. Is this prohibited? Many other innocuous examples could be cited. If the act of administering is prohibited unless one has a Part 35 license, then why is this rule needed? Again, it is useless baggage that just complicates the rules. [Note: At another organization one of our staff encountered this clause well into a research project, and got a waiver from NRC via a simple letter with no restrictions other than to prohibit human use.]

Item 6: Regarding (b)(2), (a)(2) clearly prohibits Part 35 (human use) activities but (b)(2) proceeds to address restrictions on medical use by the Part 33 licensee. Something in clarity is being left to the imagination of the reader. If this is intended to cover the situation when NRC issues a waiver, then presumably this condition can be applied as part of the waiver process. Again, deleting (b)(2) would further simplify the rule.

Realizing that there are Part 33 licensees doing Part 35 activities we suggest that to clarify Part 33 NRC:
(1) maintain the current prohibitions in Part 33, delete all references to human use, and address these needs via the regulatory exemption process, or
(2) do (1) together with a change to Part 35 to incorporate Part 33 requirements for those Part 35 licenses needed Part 33 latitude, or

(3) write Part 33 to explicitly allow Part 35 activities when certain NRC specified conditions are met. The current phrasing is "neither fish nor fowl" but looks like a fosh or a fiwl.

Item 6: Suggest changing "...or the name ... changes" in (c) to "..or the person changes." Presumably name changes due to marriage or other personal events are not a crucial regulatory issue, plus the rules should be gender neutral. In fact a slight rewording of (d)(1) would allow most of (c) to be deleted, further simplifying the rule. For example, add to (d)(1) "...before naming, reassigning, or replacing ...".

Item 6: Presumably the licensee has the authority to appoint an interim RSO due to the loss of the current RSO for reasons outside the control of the licensee, pending approval from the NRC of the new RSO.

Item 6: It would be interesting to hear the legal argument why (d)(2) and (d)(3) are needed when these acts, by a simple reading of 10CFR, would appear to be a violation in and of themselves. When NRC issues a license limiting what a person can own, possess, transfer, etc., etc., is the inference in this proposal that there is some way to read that limit in a manner that one can exceed it? If so, then the inference to be drawn from this section is that NRC is only really limiting licensees as prescribed by (d)(2) and (d)(3). If not, why is this needed?

Item 7: Regarding (b),

- there are a significant number of persons currently certified by the American Board of Health Physics who do not meet this degree requirement (either having no degree or the degree is in a non-science area), but who most of us would consider to be highly qualified to be RSO's. This rule needlessly excludes such qualified persons from this position.
- other degree areas are a fruitful source of health physicists, *e.g.*, math, law, and should be recognized.
- note that the OPM requirements for designation as a Health Physicist contain exceptions to these requirements. Does this proposed rule mean that a person classified as a Health Physicist by the U.S. Government, even at a high grade level, might not qualify as an RSO? If this rule stands, will NRC initiate the needed changes to the OPM standards?
- there are clearly more limited license types, even broad license types, that do not need even the five year experience requirement, assuming these licensees are not covered by another Part.

We suggest that these qualification requirements be applied to broad licenses "...of significant scope or complexity..." and that for simpler applications persons with "...more limited experience and education will be approved by NRC upon application and review of their qualifications."

Item 7: We suggest that 33.21(c)(2) is an unnecessary detailing of the RSO responsibilities, particularly in terms of how the RSC will accomplish their regulatory responsibilities. Simply requiring the licensee to accomplish specified tasks should be all that NRC prescribes. More detail reduces the ability of the licensee to accomplish the required tasks efficiently and effectively. Similarly regarding (c)(3), 10CFR20 already requires an annual review, to which this condition presumably refers. Who performs the review should be left to the licensee management to determine. For a large licensee this might best be done by a separate review group. This narrow prescriptive approach limits licensee flexibility. If this phrase is retained (highly undesirable in our view) NRC should clarify what is intended by the difference in wording between this and the Part 20 requirement.

Item 7: Regarding 33.22,

- the required makeup of the RSC is such that committees of enormous size are not only likely, but guaranteed. Such unwieldy groups in no way add to safety effectiveness and more likely will detract from it. They simply become bureaucratic logjams. While we see no solution to the generic identification of organization elements as cited in the rule, a simple solution would be to include the phrase "a committee of 5 persons (or more at the licensee's discretion) representing the major users of ...". Even this number is large for small, limited activity licensees where such a committee would probably represent all the users talking to themselves. More desirable is the phrase "... an appropriately constituted group, representative of licensee usages, of a minimum size for effective oversight ...".

- for a small organization having the RSO as a mandatory member of the committee is a necessary requirement just to ensure adequate expertise on the RSC. But for very large licensees the RSO and the RSC should be independent, with the RSO as an ad hoc, non-voting member of the RSC. A large organization in this context is one with at least 20-40 independent users across at least 8-10 organizational elements. While there might not be very many licensees so classed, they should have the flexibility of organizing their RSC as an independent policy and oversight group. The rule should permit this flexibility.

- again, the reference to 'medical, broad scope licensees' is confusing given the presumption that such activities are licensed under Part 35. If Part 33 and 35 are used conjunctively for medical licensing this should be clarified.

- the (a)(2) requirement for quarterly meetings is excessive for many licensees. This should be left for determination as part of the licensing process. For smaller licensees where the involved individuals see each other regularly anyway an annual meeting is probably all that is necessary. Requiring committees to meet just to satisfy a regulatory requirement when there is nothing substantive to discuss is needless regulation.

- regarding the excessive detail in(a)(3), *i.e.*, "each member shall be provided ... a copy of ...", one wonders at the NRC experience that led to this sort of micromanagement. This sort of detail should be left to a regulatory guide, or covered by some generic statement like "...committee activities will be conducted in a normal, businesslike manner", leaving the licensee to detail the administrative aspects of the committee activities.

- the functions prescribed in (b)(1) are in essence management responsibilities. If the committee has these responsibilities what is management's role in the conduct of the radiation protection program? Note further that when a committee is responsible for something no one is responsible. These responsibilities to ensure the requirements of 20.1101 are met should be changed to audit and review functions.

- the requirements of (b)(1)(ii) are particularly onerous for large programs unless this rule is interpreted as to allow the committee to delegate these responsibilities in combination with some sort of audit process. If not, then only people with nothing else to do will be appointed to the RSC. That is, the RSC will not be able to retain the more highly qualified staff in the organization.

- to expand on the foregoing comment, the greater the number of specific functions detailed for direct committee involvement increases the likelihood that the more qualified staff members will not have time to participate in committee activities. This rule should permit delegation of accomplishment of various tasks subject to review by the RSC.

Item 7: Regarding 33.23,

- this rule is strongly endorsed.

- we presume that (b) simply requires an internal organizational statement, not an expression of this in the license application. This permits administrative flexibility in keeping such a document up-to-date.

- item (a)(4) borders on conflicting with management prerogatives since it gives the committee authority to "...initiate ... or provide corrective actions." The RSC authority should be limited to

approving measures proposed by management and otherwise prohibiting licensed activities until satisfactory measures are in place.

Item 8: It is not clear how 33.25(a)(1) adds anything to the requirements of 10CFR19, other than being more specific in several details. If this detail is needed why not put it in Part 19 since it applies equally well to other parts of 10CFR? On the other hand this is just one example of a litany of details required by Part 19 that could be listed. Why this one? If NRC judges that Part 19 should be more explicit we suggest that it be revised. Another issue is that burying training requirements in parts other than Part 19 without at least a cross-reference simply creates confusing regulations.

Item 8: Regarding 33.25(b), as worded this is unreasonably onerous. Incorporating into the federal regulations a statement of responsibility for actions beyond the reasonable knowledge and control of the licensee seems like it should be in violation of some law, if not the constitution. Some appropriate legal qualification limiting the scope of this open-ended rule is desperately needed for this rule.

Item 9: Regarding the proposed 33.59,

- if NRC is going to incorporate provisions analogous to 50.59 which provide the licensee flexibility for keeping license documents up-to-date, then it would seem reasonable to extend the licensed period of licenses issued under Part 33 in a similar manner, *e.g.*, 20 years. This would have the obvious benefit of reducing paperwork and NRC overhead for these types of licenses. On the other hand, if the period is not extended then what is the benefit to the regulatory process to add the extensive paperwork and formalism posed by (b)(1) in this proposed rule?
- (b)(2), while obviously analogous to 50.59, incorporates a more stringent, *i.e.*, 30 day, reporting requirement. Our current license only requires an annual report for similar actions and 50.59 similarly requires an annual report. We urge that this be changed to an annual reporting requirement.
- in (a) it is unclear how the licensee can change the facility in a manner that it is "less restrictive than the regulations". The regulations control sources, processes, and uses. The structure of this sentence needs clarification. If this is a null requirement it should be deleted. If NRC has specific examples in mind, please cite these to clarify the meaning of this requirement.
- (c) would seem to be self-evident. Is it necessary to clutter the rules with such statements? Further, it is redundant with the exclusion in (a), *i.e.*, "unless the proposed change involves a specific license condition". Such redundancies simply create potential for conflicting interpretations as well as needlessly adding bulk to the rules.

Summary

In summary, we are sympathetic with a number of the proposed rule changes. However the documentation accompanying these proposed changes in general are not supportive of these proposals, either specifically or even in broad generalities. It would appear that NRC has some underlying motivation and justification for these proposals other than the few extraneous events mentioned in the Supplementary Information section. The licensee community would benefit by seeing these, and could more effectively comment on these proposals with this information in hand.

We presume given the preliminary nature of this proposal, the proposed rule's obvious need for extensive revision, and its significant impact on a large number of NRC licensees, that the revised version will be submitted to the public for further comment. Preferably, given the foregoing, NRC would arrange a series of local meetings around the country to determine the underlying need for a change before devoting significant resources to a proposed rule. This, together with a clear definition of the underlying purpose of the proposal, will allow a more effective rule to be produced.