

DUKE POWER COMPANY

STEAM PRODUCTION DEPT.

GENERAL OFFICES

422 SOUTH CHURCH STREET

CHARLOTTE, N. C. 28242

P. O. BOX 33189

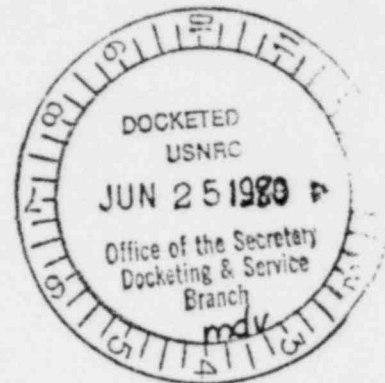
TELEPHONE: AREA 704
373-4011

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PROPOSED RULE

PR-20 (65)
(45 FR 18023)



Mr. Robert A. Purple, Asst. Director
Radiological Health & Safeguards
Standards, Office of Standards
Development
Nuclear Regulatory Commission
Washington, D.C. 20555

Subject: 10 CFR Part 20 - Standards for Protection Against Radiation;
Advance Notice of Proposed Rulemaking.

Reference: Federal Register Notice, Volume 45, No. 56
Thursday, March 20, 1980, Pgs. 18023,-24,-25,-26

Dear Mr. Purple:

Duke Power Company subscribes to the comments submitted to the NRC on this subject by the EEI-Utility Occupational Radiation Standards Group and by the AIF-Subcommittee on Occupational Radiation Protection. We also offer the following comments:

General Comments

We believe that the promulgation of a major change in the Part 20 regulations at this time would be disruptive and not advance the cause of occupational radiation safety. The present 10CFR20 regulations, as amended over the years, have served as the basis for radiation safety programs for all classes of AEC and now NRC licensees. And these regulations have generally done a good job of it; regulators understand them, health physics people understand them and perhaps, most importantly, radiation workers are familiar with and respect them.

It would appear from the outline of the Federal Register Notice for this proposed rulemaking, considering the large number of subjects included, that the NRC intends to write an "encyclopedia" of standards for protection against radiation in revising this Part. The NRC apparently intends to include in this proposed revision the equivalent of every regulatory guide that they ever wrote and ever hope to write on radiation protection.

Since no great need for changes in radiation protection requirements have been identified and recommended by the recognized standards setting bodies, such as the ICRP and the NCRP, a major unilateral change in the Part 20

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regulations by the NRC can only have disturbing and disruptive consequences among all classes of licensees that will take many years to settle out. Therefore, instead of making sudden major changes, the NRC should slowly build on what is now a basic sound structure and reference appropriate documents in the regulations for background information.

The NRC also states in the Federal Register Notice that NRC standards should be consistent with the applicable federal radiation protection guidance and include consideration of the work of recognized national and international advisory organizations. We agree, and state therefore, that the NRC should wait until the BEIR Report findings are available and after EPA guidance is available on allowable occupational dose. We further believe that the ICRP 26 recommendations concerning internal and external dose are of considerable merit and consider them to be appropriate for eventual incorporation into the 10CFR20 Radiation Protection Standards. However, since the NCRP has not yet spoken about the application of ICRP 26 and the practical details by which this can be done have not yet been worked out, and since much detailed consideration needs to be given to this matter, it would be prudent for the NRC to wait until this guidance is available from the NCRP before proceeding with the revision of the regulations.

Our further comments on occupational ALARA/ICRP 26 and internal and external dose aspects of ICRP 26 can be found in Enclosures 1 & 2 of this letter.

Specific Comments

The following comments are identified in accordance with the outline provided in the Federal Register.

Under the section "Essential Elements of the Radiation Protection Standards", a. "Radiological Protection Principles"

- (1) The NRC speaks of a linear relationship without threshold between dose and probability of stochastic effects. It must also be realized that these effects are not real but just an assumption for the purpose of setting radiation protection standards and that a deminimus level of dose needs to be accounted for, or else the linear relationship is absurd and the NRC will be concerned about trivialities forever, i.e., large numbers of people x very small doses = some calculated cancers. Therefore, as far as implementation is concerned, it is necessary to recognize and exempt unimportant doses. The proposed rules should, therefore, include a regulatory dose threshold below which licensees need not concern themselves.

Under "identification of the basic radiation protection principles which are derived from the assumptions such as:"

- Item (1), The NRC states that no practice or operation involving exposures to radiation should be adopted unless its introduction produces a positive net benefit. We would assume that the NRC means to interpret this, as meaning, the operation of a nuclear power reactor produces electricity which is a positive net benefit and not as each possibility for exposure that occurs in the plant, which would result in an impossible accounting task.
- Item (2), The NRC states that economic and social factors need to be taken into account in interpreting ALARA. We state that the social factor to be considered is the need for electric power; and the fact that the establishment of a man-rem figure by the NRC for a given type of facility would also not give appropriate consideration to the social and economic differences between them, such as union vs. non-union situations as well as the ethnic characteristics of the work force which may cause significant differences from facility to facility. Therefore, we ask the NRC not to establish a collective dose limit but to rely instead on the fact that if all the individual doses are maintained ALARA then the sum or the collective dose will therefore be ALARA.
- Item (4), Licensees should not be required to defend the NRC dose standards. In this particular case, any dose figures that appear in 10CFR20 and the application of these figures should be explained by the NRC and this in turn could be passed along to people in training courses.

Under item b. "Standards for Individual Occupational Exposures":

- Item (1), Numerical dose limits. The NRC should be aware of the fact that they cannot simply adopt the ICRP 26 recommendations without extensive interpretation on a practical level as to how these recommendations are to be applied. That is, for example, they will need to specify an exact mechanism for the summation of internal and external doses as well as an exact means for the determination or measurement of the internal dose. They will also need to make sure that this system will work before they require its use.
- Item (2), Special groups should be limited to pregnant women and minors.
- Item (3), The present regulations cover controls for transient workers that have recently been issued. These appear to be adequate and should be given a chance to work.

Item (4), (5), & (6). It may be appropriate to add this guidance to the standards providing they are based on ICRP and NCRP guidance and are appropriate. Flexibility is needed in regard to allowable doses for lifesaving and in regard to any occupational exposure penalty.

Under Item c. "Standards for Exposures of the General Public":

Consider present EPA guidelines in formulating these standards as well as Appendix I to 10 CFR Part 50. It might be more appropriate to put various items such as siting considerations and emergency dose limits in the appropriate Parts of the Title 10 regulations rather than in Part 20.

Items (6), (7), & (8). It would be appropriate to have these figures in the regulations providing they are soundly based technically and address deminimus.

Item d. "Requirements for a Radiation Protection Program":

It would appear that all items in these categories should be written as objectives, not as detailed procedures. Many industry standards now cover these areas. They should perhaps better be located in other Parts of the regulations also.

Under the section "Areas in Part 20 That Need Improvement", sub-heading (a) "Radiological Protection Principles":

Item (2), The NRC states that quantitative occupational ALARA guidelines should be established wherever possible and that collective doses should be addressed. We would remind the NRC that various studies have shown that any attempt to significantly decrease the individual dose limit, for example, would lead to an increase in the collective dose at a nuclear power plant, and that the significance of collective dose as well as individual dose is tied largely to risk considerations and to the linear extrapolation. Our concern here is whether or not there are really any biological effects at the low occupational dose levels that actually occur. It would also appear that if the dose for each individual at a nuclear facility were maintained ALARA, then the summation of doses, i.e., man-rem or person-rem, would by definition be ALARA. It would, therefore, be inappropriate to establish by regulation a definite man-rem figure for a given facility or for each given type of facility throughout the country. This would be arbitrary and without meaning.

Under sub-heading b. "Standards for Individual Occupational Exposure":

Item (1), The NRC states that present Part 20 does not preclude radiation exposure as high as a total of 17 rem of combined internal and external dose to the whole body in a single year, showing then a summation of 5 rem internal plus 12 rem external doses. Although Part 20 does not preclude such exposure, such a combined internal and external dose of this magnitude is obviously not a general practice and would occur with rare exception, if at all. We might remind the Commission here that the ICRP 26 recommendations, although establishing a limit of 5 rem per year, essentially as the sum of both internal and external doses, also permits in some few cases, doses of up to 10 additional rem in a year and 25 additional rem of occupational exposure in a lifetime (essentially replacing the 5(N-18) formula).

Item (3), It would be appropriate to add standards applicable to emergency or planned overexposure situations; however, they should be based on ICRP, NCRP, and EPA guidance.

Under sub-heading c. "Standards for Exposure of the General Public":

Item (4), Emergency plan and item (5) environmental monitoring might better be relocated in other Parts of the regulations.

Under sub-heading d. "Requirements for a Radiation Protection Program":

Item (1), The basic elements of an acceptable radiation protection program should perhaps be listed in the regulations or presented as objectives rather than as detailed procedures.

Under sub-heading e. "Reporting Requirements":

Item (1), The NRC states that reporting of routine internal exposure should be required. One might ask "why, if they are low, should they be reported?" On the other hand, if reports are required, the NRC would have to give detailed procedures for the determination of such dose (or exposure) so that all licensees can report them in the same manner, for example, a mechanism to convert mpc-hours to dose. Again, if the sum of the fractional intakes is less than say 10% of the annual limit of intake, then perhaps it can be ignored as a de minimus dose.

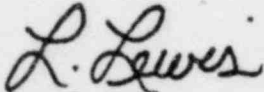
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Under sub-heading f. "Miscellaneous"

- Item (1), NRC questions the adoption of the SI units. The SI units are not understandable to the public let alone technical people, and there have been many problems in the adoption of such units. This system is not in favor in Europe where they are now used.
- Item (2), Concerning performance standards. The only comment is that the NRC should not require state-of-the-art measurements for every figure but the accuracy and reliability should be appropriate to its significance. Appropriate ANSI standards should be referenced.
- Item (3), States that the technical bases for numerical limits should be readily identifiable. To this we whole heartedly agree and request that the NRC follow this for all numerical limits it may add to the regulations.

Thank you for giving us the opportunity to comment upon the proposed regulatory changes. We expect that the NRC will appropriately consider them.

Sincerely yours,



Lionel Lewis
System Health Physicist

LL/scd

OCCUPATIONAL ALARA ASPECTS/ICRP 26

One of the major areas for revision of the Part 20 regulations appears to be enforceable ALARA applied to external and internal exposure utilizing the framework of the ICRP 26 Recommendations.

There are many philosophical considerations in regard to occupational ALARA. One of these is the relative importance of collective dose versus individual dose, which appears to be tied to the dose limit for individual occupational exposure. Various studies have shown that any economic attempt to significantly decrease the individual dose limit at a nuclear power plant, for example, would lead to an increase in the collective dose. The second is, the significance of collective dose versus individual dose, which is also tied largely to risk considerations and to the linear extrapolation. In other words, the collective dose risk, and the magnitude of risk for individual dose, depends on whether or not there are really any biological effects for occupational exposure at these low dose levels.

The requirement to maintain doses ALARA also requires that the social and economic aspects of the exposure be taken into consideration. It would appear, therefore, that if the dose for each individual at a nuclear facility were maintained ALARA, then the summation of doses, i.e., man-rem or person-rem, would, by definition, be ALARA. It would therefore, be inappropriate to establish, by regulation, a definite man-rem figure for a given facility or for each given type of facility throughout the country. The establishment of a man-rem figure for a given type of facility would also not give appropriate consideration to the social and economic differences between them,

such as union vs. non-union situations, as well as the ethnic characteristics of the work force, which may cause significant differences from facility to facility.

On the other hand, ICRP 26 may indeed be a positive step in the right direction. However, since the NCRP hasn't yet spoken authoritatively on the significance of or the application of the ICRP 26 recommendations, then it would appear appropriate and suitable for the NRC not to take action on this until the NCRP has completed their review and published their recommendations.

One very difficult area in regard to enforceable ALARA or any ALARA program appears to be the economic value of a man-rem of exposure. It appears that one would have to perform a cost-benefit evaluation for each exposure, where previously under the earlier principle of as-low-as-practicable (ALAP) each evaluation was done on the basis of professional judgement which was not quantifiable or enforceable. However, recent studies have shown that the economic value of a man-rem is perhaps non-quantifiable or at least extremely difficult to evaluate. It would appear that this is an ambiguous and difficult area in which to establish regulations, and therefore, any value chosen by the NRC would not be technically based but arbitrary.

If, however, the NRC wants to move ahead in regard to enforceable ALARA at this time, it may be appropriate to require a defined regulatory ALARA Program which would state the basic principles and considerations involved. This program then could be subject to review and approval by the NRC staff for licensing purposes and/or by the Inspection and Enforcement Division personnel.

Under Section d-4 of the proposed regulations entitled "Requirements for a Radiation Protection Program," item (4) ALARA program requirements, it would appear that the NRC is preparing to move right ahead. If this is done, then the program requirements should be listed as objectives and not as detailed procedures. On the other hand, in that section of the proposed regulations under "Areas in Part 20 That Need Improvement," item (2) states that, "Quantitative occupational ALARA guidelines should be established wherever possible for NRC licensed facilities, [and] "Collective doses should be addressed." Again, we believe that such guidance would be arbitrary. Item (4) of this same section states that "Special provisions to limit collective doses should be considered." Again, we wish to remind the NRC that the summation of individual ALARA doses, i.e., the collective dose, should, therefore, also be considered as ALARA.

To reiterate some of the above comments taking into consideration the fact that the NRC believes that the new Part 20 regulations should be "readily inspectable and enforceable", we state that performance standards are needed rather than detailed procedures. The NRC also states in the proposed rule that these standards should be "consistent with the applicable Federal radiation protection guidance and include consideration of the work of recognized national and international advisory organizations." We agree, and again we want to emphasize that since the NCRP has not spoken as to the means for the application of ICRP 26 and particularly, in this instance as it applies to enforceable ALARA, that the NRC should wait to utilize this guidance when available.

Regulatory Guide 8.8, Rev. 3, speaks appropriately to ALARA and its implementation.

L. Lewis
Duke Power Co.

INTERNAL AND EXTERNAL DOSE ASPECTS/ICRP 26

The NRC proposes to also adopt the ICRP 26 recommendations that relate to the use of effective dose equivalents concerning dose limitations for combined internal and external exposures. Again, all of the philosophical arguments presented in the comments concerning occupational ALARA apply here also.

It is stated in the proposed rules that "Present Part 20 does not preclude radiation exposure as high as a total of 17 rem of combined internal and external dose to the whole body in a single year," showing then, a summation of 5 rem internal plus 12 rem external doses. Although Part 20 may not preclude such exposure, a combined internal and external dose of this magnitude is obviously not a general practice and would occur with rare exception, if at all. We might remind the Commission here that ICRP 26 recommendations, although establishing a limit of 5 rem per year, essentially as the sum of both internal and external doses, also permits in some few cases doses of up to 10 additional rem in a year and 25 additional rem of occupational exposure in a lifetime.

If the NRC decides to move ahead and establish regulations concerning the adoption of the ICRP 26 recommendations despite the fact that the ICRP and NCRP have not yet provided effective guidance on how these recommendations ought to be interpreted on a practical level, then the NRC should consider the fact that they will need to establish in the regulations an exact mechanism for the summation of internal and external doses as well as an exact mechanism for the determination or measurement of the internal dose.

One means of doing this for internal dose would be to sum the total MPC-hours of exposure for each individual over each quarter and over each year and convert these by some appropriate mechanism to a whole body dose equivalent figure. ICRP committee 2 has attempted to do this by converting former MPC's over to "annual limits of intake", which, in this proposed regulation, it appears that the NRC is also considering using (although we understand with reductions in some cases).

The use of such a mechanism as "annual limit of intake" by licensees would require much detailed monitoring, accounting, and exposure control work. Such detailed work, however, would not appear to be appropriate or necessary for nuclear power licensees since internal exposure is a very small part of the total dose received by any individual.

We basically believe that the ICRP 26 recommendations concerning internal and external dose have considerable merit and are appropriate for eventual incorporation into the 10CFR20 radiation protection standards. However, the practical details by which this can be done have not been worked out yet by the NCRP and much detailed consideration needs to be given to this aspect. It would, therefore, appear prudent for the NRC to wait until the detailed interpretations and practical applications are available before they incorporate ICRP 26 into the regulations.