4.

ATTACHMENT A

4.

August 6, 1971

Mr. W.B. McCool
Secretary of the Commission
U.S. Atomic Energy Commission
Washington, D.C. 20545

Subject: Proposed Rule Making -- 10 CFR Part 50

Dear Mr. McCool:

Reference is made to the proposed rule making, published in the Federal Register, Vol. 36, No. 111, issue of June 9, 1971. The explanatory material and the specific recommendations for amending Section 50.36a of 10 CFR Part 50 have been examined with care and the position stated here results from the consideration of this matter by the Board of Directors at its regular meeting in June.

If, indeed, experience in the operation of light-water-cooled nuclear power plants has shown that it is feasible to maintain conditions which will assure levels of annual exposure as low as five percent of that attributable to the natural background, it is in the public interest to insist that light-water-cooled nuclear power plants be operated in a manner that such low levels be generally maintained. Such a program coincides with the completely defensible recommendation that nuclear programs should be conducted in a way which keeps exposure to radiation as low as practicable.

We may point out, however, that the proposed limit of 5 mrem per year has not been proven practicable under all circumstances and occasional small over runs, while of no biomedical significance, may cause unnecessary controversy. Since, at best, the concept of "low as practicable" is subjective in its interpretation, we feel that some reasonable and controllable latitude in the use of a special dose limitation is desirable.

The prefatory material in the statement in the Federal Register of June 9, 1971 makes it clear that the reason for the proposed change in 10 CFR Part 50 is that experience has shown it to be practical to maintain the low levels proposed in Appendix I, but the language in Appendix I, itself, fails to make a clear statement on this point.

The discussion in the prefatory material includes also the observation that such groups as the NCRP and the ICRP have found no new evidence to indicate that, from a protection standpoint, there is a need for such a pronounced reduction in the standards for exposure of the general population as is stipulated in Appendix I. This point should be emphasized even more strongly. As a matter of fact, the proposed limit of 5 mrem per year is about one thousand times less than the lowest dose level at which injury to man has been observed.

We are concerned that those members of the public, who are unreasonably worried about radiation dose levels caused by proper utilization of radiation sources, will interpret the new rule as an acknowledgement that dose rates any higher than the very low dose rates which are considered practicable in connection with the operation of light-water-cooled nuclear power plants are cause for alarm. The current, excessive apprehension about the validity of presently recommended protection standards will more than likely be intensified unless the announcement makes abundantly clear that the reason for the proposed reduction is not a change in the basic radiation protection standards, but only because experience has shown that it is feasible to expect the operation of light-water-cooled nuclear power plants at the very low level of 5 percent of background.

In view of the above, we believe that the language of the amendment itself should state clearly and emphatically that:

1. The proposed lowering of design factors is not the result of any recently discovered new evidence which would indicate that the current basic protection standards are improper.

2. The new rule applies only to light-water-cooled nuclear power plants and not to nuclear facilities of other types.

We are not of the opinion that the proposal is incorrect, or improper, but the real difficulty is that unless statements of the kind suggested above are made prominently and unequivocably, the Atomic Energy Commission will continue to be subject to unwarranted attack. The time and effort required to parry such attack will impair our capacity to make creditable progress in the task of putting radiation to work for the benefit of all.

Sincerely yours,

Lauriston S. Taylor

LST/jr

5

February 16, 1972

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THE DEVELOPMENT OF RADIATION PROTECTION STANDARDS

Lauriston S. Taylor, President

National Council on Radiation Protection and Measurements

Contents

Attachments

February 14, 1972

THE DEVELOPMENT OF RADIATION PROTECTION STANDARDS

Lauriston S. Taylor, President

National Council on Radiation Protection and Measurements

The Atomic Energy Commission has requested that I discuss the philosophical and practical background for the development of radiation protection "standards" and this I am pleased to do. Since most of the currently acceptable radiation protection standards derive directly or indirectly from the recommendations of the National Council on Radiation Protection and Measurements (NCRP), much of my presentation will relate to the work of the NCRP which began over a decade before the discovery of atomic energy.

I shall divide the discussion somewhat arbitrarily into three parts:

1. Comments on 10CFR Part 50
2. The Historical Development of Radiation Protection Standards
3. Scientific Basis for Protection Standards

1. COMMENT ON PROPOSED CHANGES 10 CFR PART 50

The specific question of the proposed changes in 10 CFR Part 50 has been responded to by the NCRP in its letter of August 6, 1971 and this is included here for purposes of presenting a complete view of our position. (See Attachment A)

Many of us feel a bit of sadness when we come to realize that unsupportable and unreasonable political and public pressures, and government reaction to them, are forcing industry, the economy and, indeed our whole society into taking actions for which there is such

limited scientific basis. For nearly 4 decades we have lived within a structure of radiation protection standards. For exposures within the limitations, even when they were six times higher than today, we have yet to identify - individually or statistically - any injury to man attributable to radiation exposure.

The basic standards that we know today, for either the radiation worker or the general population, are much below the lowest dose giving an observable effect on children and adults - doses of the order of 20 rads, or usually greater, delivered essentially in a single exposure. There are statistical data showing possible effects from single short exposures of the foetus of the order of 1 rad, delivered at specific times, but there appears to be some question as to the validity of the conclusions. There are vast amounts of data showing no observable effects in the low dose region.

It is because of this lack of positive knowledge in the low dose region that the NCRP and other radiation protection bodies have taken the unusual precaution of using the "lowest practicable" concept which is, I believe, unique to the radiation field. An argument favoring use of the concept is that radiation effects may have long latent periods and very long-range genetic effects. But radiation isn't all that unique. There are other potential pollutants with proven effects - that have a long latent period and genetic effects.

The "lowest practicable" concept was intended to be used with judgment, common sense and reason. Perhaps we were naive enough 20 years ago to think that such factors could be applied in a useful way. But, recent attempts to legislate judgment, common sense and reason into monolithic laws and regulations seem to have destroyed the basic concept itself.

Population Exposure

In principle, we concur with the AEC in its proposed use of the "lowest practicable" concept for population exposure. In practice, we believe that there has been over-reaction to the public clamor and we question the practicability of a dose limit of 5 mrems in a year. Of course this might be a design goal, but under any regulatory process it also then becomes a control goal. If the regulator argues that this can be used with some flexibility he seems to be abandoning the theory of regulations, which must be go or no-go, and returning to reason. But why not apply a little reason first and then not be trapped into endless exceptions, interventions and all the problems that needlessly restrictive standards inevitably bring upon us?

5 mrems in a year is certainly a reasonable and rational goal if it can be attained at reasonable and acceptable cost and can be reasonably and rationally measured and controlled. We question the practicability, especially of the latter.

The number 5 becomes a rigid, magic number in spite of some provisions in the proposed rule that seem to allow for real or projected overruns. Past experience, however, indicates that the problem is not that simple; a real or projected value of 4.99 mrem in a year is "good" and a value of 5.01 is "bad". Somebody, whether the regulator or a citizen, is certain to lack a sense of proportion and object to the latter figure even to the point of attempting to stop a vital plant or facility. The guidance outlined in Section III and IV of the proposed rule-making seems basically satisfactory - but only provided it remains as guidance and the objective levels do not become rigid control levels.

The implications arising from the attempted use of the "least practicable" concept in regulations are of concern to the NCRP. It is generally accepted that laws or regulations should be uniform in their application to all within their jurisdiction. Indeed this is one of the prime virtues of laws or regulations. The "low as practicable" concept, however, has merit precisely because it allows deviation from the radiation protection standards which are, indeed, designed to be applicable to all. The attempt to specify by regulation what is "least practicable" appears to be an unfortunate melding of concepts which vitiates the merits on each side. It undoes the assured uniformity of regulations because deviation on a case-by-case basis would appear essential, and yet removes from those subject to the regulation, the responsibility for ascertaining what need be done to meet the "least practicable" criteria.

It is hoped that some of the underlying reasoning leading to the statements above, may be made more clear by the discussions to follow.

2. HISTORICAL DEVELOPMENT OF RADIATION PROTECTION STANDARDS

Early NCRP Activities*

The National Council on Radiation Protection and Measurements is just rounding out its forty-second year of operations. The manner in which it was formed, and its mode of operation during these 42 years bears importantly on the nature of its philosophy, workings and output. It shows also how the NCRP has evolved to meet new requirements and changing demands in its role as an organization providing scientific

*A fairly complete review of the historical development of radiation protection standards has just been published and it is suggested that reference be made to it. (1)

and the ICRP reduced the basic permissible level for radiation workers to 5 rem/year for whole body exposure, blood forming organs and gonads. For other individual organs the permissible dose was left at 15 rem in a year, or 26 rem in a year.

At the same time, a permissible dose of 0.5 rem/year was recommended for individuals in the general population. This was consistent with the 1949 recommendation of the NCRP that individuals in the general population not be allowed to receive more than 1/10 of the basic permissible dose for radiation workers. For purposes of control, an average value of about 1/3 of the individual value, or 0.17 rems/year (170 mrems/year) will generally insure that no individual in the general population receives a dose which exceeds 0.5 rem/year.

Beginning in 1957, the Joint Committee on Atomic Energy held a series of hearings relating to radiation protection standards. These clearly brought out the fact that the standards being used by the Federal Government were based entirely on the recommendations of the NCRP and the ICRP. It appeared to be an anomalous position, for the government to find itself operating under standards over which it had no control. As a result, the Federal Radiation Council was established by Executive Order and by an amendment to the Atomic Energy Act of 1954 that was prepared by the Joint Committee. After nearly a year of study with the aid of a considerable number of experts from around the country, the Federal Radiation Council adopted a set of basic standards which did not differ significantly from those the NCRP had developed in 1949 and modified in 1957. Essentially these same standards hold today.

1959: Because of the growing concern about the possible exposure of the population as a whole to radiation, the NCRP established an

Ad Hoc Committee to examine the question of somatic effects of irradiation of large population groups. The general philosophy developed by that group was reviewed by the whole membership and most of it has been fairly consistently followed ever since. Among its recommendations were the following:

1. It was agreed that there was not sufficient evidence to establish dose response curves for somatic effects at low doses and so in the absence of such information it was proposed that a proportional relationship between dose and effect be postulated and that the effect be independent of the dose rate or dose fractionation.
2. On the basis of the model noted above, or any other nonthreshold assumptions regarding dose-effect relationship, it was agreed that even the smallest dose might be associated with some risk. Under such circumstances, the exposure of the population to any increase in radiation should not occur unless there is reason to expect some compensatory benefits.
3. Because it was not possible to make accurate estimates of hazards or benefits of a specific level of radiation doses, especially at low doses, it was recommended, pending the development of more precise information, that the population dose limit for man-made radiation be based on or related to the average natural background level.
4. The Committee emphasized that under any acceptable postulates, the biological effect does not suddenly

change from harmless to harmful if any particular permissible dose is exceeded. Any permissible level which may be chosen is essentially arbitrary and every effort should be made to keep the radiation doses as far below the permissible level as practicable.

1971: With the publication of Report No. 39 on Basic Radiation Protection Criteria, the NCRP completed a ten year study and review of the basic radiation protection criteria. Taking into consideration all of the new evidence which had been developed, especially during the past decade, and for reasons explained in the report, the Council continues to use the linear, no-threshold model to give an upper limit for dose effects in the very low dose regions. On this basis, or any other, it believes, in the light of our current knowledge, that the currently recommended limits for population exposure are reasonable and defensible in terms of risk and benefits derived.

With one or two exceptions, the Council has found no reason to change the recommendations which were last modified in 1957. The principal change from the earlier recommendations was in a reduction of the dose limit for individual organs of exposed population groups to a value of 0.5 rem in any one year, which is the same as the earlier allowance for the whole body or the critical organs. The change was made in the absence of any new evidence indicating increased hazards of the radiation over those presumed previously; it was done as much to simplify the structure of the basic protection standards as for any technical reason. At the same time, it was pointed out that there might be situations when this objective could not reasonably be achieved, in which case the use of higher levels could be examined on a case-by-case basis.

It should be emphasized, however, that the Council still believes that radiation exposure of people should be held to a reasonable minimum which may indeed be below the basic protection standards in many instances. On the other hand, it is not believed that the basic standards should themselves be changed on the basis of any scientific evidence that we have at hand, and we should avoid the establishment of unnecessarily severe standards. The effects of radiation, if any, at the very low doses being considered in connection with certain types of reactor operations, will be so small as to be statistically undetectable by any means that we know of today. Samples much larger than the total population of the United States would be required to achieve a statistically significant answer (3). If there is any risk at these low doses it is so small as to be undetectable; in time we may very well find out what the basic radiobiological phenomena are and how to assign values to any effects that may be found.

2. SCIENTIFIC BASIS FOR PROTECTION STANDARDS

The Risk Philosophy

Because all radiation uses are not equally important, or exposure of all persons equally acceptable the NCRP, in the 1940's, first presented the philosophy of "balancing" risks against benefits for radiation. It was realized at the time that a balance could not be expressed in any quantitative way, and in fact no generally accepted system exists even today in spite of efforts by many groups to try to find tangible base lines upon which to make the necessary comparisons. At the same time, it has been possible to greatly reduce radiation exposure of the individual and the public in a variety of situations.

While we still do not see a quantitative means for balancing risks against benefits, it is possible to assign dollar costs to the achievement of given levels of radiation. But to make any kind of risk evaluation it is necessary to develop models or assumptions which, while they themselves may be unproven, nevertheless provide some estimate of the upper level of risk for a given exposure (4) (5). Such a model was proposed for use by the NCRP by one of its Ad Hoc Committees in 1959, since which time it has provided a base for its subsequent philosophical approach to the radiation protection problem (6). But the apparent limitations of any such models have to be constantly borne in mind, so that they do not come to be thought of as facts in themselves but rather as a base-point from which various judgments can be evaluated.

An example would be the model or assumption of a strict linear relationship, without threshold, between dose and effect from high doses where radiation effects can indeed be evaluated, to low doses where it has not yet been possible to study sufficiently large samples of exposed people to arrive at a statistically significant evaluation. It is well known that such a simple relationship usually does not hold, and that simple extrapolations from high-dose effects to low-dose effects are most likely to err in varying degrees on the safe side; that is, the effects at low dose and low dose-rates will almost certainly be less than predicted on a basis of simple extrapolation. Such a model ignores the existence of dose-rate effects

and, hence, biological recovery in a bio-system exposed to radiation. Nevertheless the model is useful for giving some kind of upper limit of dose effect.

The requirement to use such theoretical models is brought about by the absence of adequate knowledge of biological effects at very low doses and low dose-rates and it is this absence (brought about because the incidence of effects is so low, that even when looked for carefully cannot be detected even in a very large population) that presents the great dilemma as far as a purely scientific development of radiation protection standards is concerned. Carrying application of the linear dose-effect model to the extreme would mean that everything involving the direct or indirect use of radiation or radiation as a by-product would have to be abandoned or some risk accepted. Even naturally occurring radiation would have to be considered as dangerous. For many reasons this is an unacceptable situation, and it is therefore necessary to apply educated judgment as to what would be acceptable. As I and others have been pointing out for many years, other elements that enter the judgmental determinations should be those of an economic, political, medical, legal, moral, and survival nature (7).

The assumption of the model of a linear no-threshold relationship between dose and effect, and the consequent conclusion that however small the dose there may be some effect, marks a major deviation from the approach generally used in the field of toxicology. In that field, it has been customary to study the effects of some toxic agent down to the point where they could no longer be observed, using reasonably large numbers of experimental animals, and then set a permissible level or its equivalent at some reasonable fraction of that low level.

This has been a generally satisfactory practice, although, occasionally the levels have been revised downward or even upward depending upon new evidence or the need for the use of a toxic agent despite some risk.

Adoption of a linear no-threshold model places us on the horns of a dilemma. While it is a useful concept for scientific discussion if its significance and particularly its limitations are appreciated, its projection into the public domain without qualification, leads to the inescapable conclusion that any exposure to radiation, no matter how, when, or at what rate, must produce some cumulative and deleterious effect. It helps little that these limitations may be understood within scientific and technical discussions since this is not understood or appreciated by the general public and its simple application leads to apprehension. It is by virtue of the treatment of these models as though they were indeed established facts, that the problem has been presented to the public in such a way as to confuse and disturb it.

Factors Involved in Radiation Protection Standards

It must be clear that there is no simple solution to the problem of establishing protection standards as far as either the technical or non-technical input is concerned. The discussion above has touched upon some factors; others might be clearly desirable but are impracticable, thus resulting in compromise. Probably the most important source of information that we would turn to would be observed biomedical effects of radiation on human beings. There is of course an enormous amount of this for high doses but the data are minimal or absent at low doses. Second to this source of information are data on biomedical effects obtained through laboratory experiments.

Another item would be the importance of the need for a radiation use or its acceptance as a by-product in the first place. Because certain uses have appeared to be very important and at the same time difficult to carry out without any exposure, some latitude in the standards must be considered. A good example of this was the early exceptions for people working with radium where large exposures were allowed for the hands, etc. However, as technology improved it was found that the same operations could be carried out effectively without such extra allowance of exposure, and the standards were made more restrictive. A number of such instances will be found over the forty years that NCRP recommendations have been in existence.

Still another item of consideration has been the capability to provide protection at what is considered to be reasonable cost and minimal interference with the application. Here again there have been exceptions in the past which have been changed as our technology has improved. It is obvious that all of these questions involve not only scientific and technical input but also value judgments gained by extensive experience.

I suppose it can be argued that we have not considered moral, religious, economic, or political aspects of the problem, just to name a few, and yet even this would not be strictly correct. All of these questions have been constantly in the minds of the people developing our standards, but in most situations we are still faced with the problem of how to evaluate, say a political consideration, as against a biomedical consideration. At the present time informed judgment, alone, can be of assistance here. Informed judgment has played a role and as new social values have become evident the informed judgment has frequently been modified one way or another.

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(3) Weinberg, A.M. Letter to Editor, Science 174, 546 (Nov. 5, 1971).

(4) Permissible Dose from External Sources of Ionizing Radiation, NCRP Report No. 17, (NBS-HB-59), 1954.

(5) Taylor, L.S. Radiation Exposure as a Reasonable Calculated Risk, Health Physics 1, 62 (1958).

(6) Somatic Radiation Dose for the General Population--Report of the Ad Hoc Committee of the National Committee on Radiation Protection and Measurements (May 6, 1959), Science, 131, 482, 1960.

(7) Taylor, L.S. Radiation Exposure and the Use of Radioisotopes (UNESCO Lecture), Impact 7, 209 (1957).

(8) Regulation of Radiation Exposure by Legislative Means, NCRP Report No. 19, (NBS-HB-61), 1955.

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low values, (~0.03 mR). Nevertheless, the traveler may be unwilling to subject himself to this kind of risk even though he may incur a risk of ten times this amount each hour of flight due to radiation simply while traveling at the altitude of conventional jet planes. (Exact comparisons are risky.) Here is a situation where people over age 45 might accept such checking without qualms but where the effects, if any, would be greater on the younger people who have yet to take part in conceiving children. The problem might (in theory, according to the linear dose-effect relationship) be more serious for women who may be pregnant since the foetus has a greater radiosensitivity. There will be the question of deciding whether that kind of risk is greater or less than the risk of losing a plane full of passengers in flight or even on the ground.

Application of the principle of "lowest practicable" radiation exposure is certain to cause increasing problems if the concept is expanded to applications other than the water-cooled nuclear reactor. It is, indeed, sound to require design factors that will assure maintenance of exposure levels as far as practicable below the prescribed population dose limits for a particular application, but a rigid enforcement of these on a broad scale could, if carried to extremes, lead to unreasonable situations and chaotic conditions. At the same time, we can find no technical justification for lowering the basic permissible standards below those established and in current use.

The "lowest practicable" concept was intended to be used with judgment, common sense and reason. It is, in essence, a first step in dose apportionment. Perhaps we were naive enough 20 years ago to think that such factors could be applied easily in a practical way. But, recent attempts to legislate judgment, common sense and reason into monolithic laws and regulations seem to have undermined the basic concept itself.

The implications arising from the attempted use of the "least practicable" concept in regulations are of concern to the NCRP. It is generaly accepted that laws or regulations should be uniform in their application to all within their jurisdiction. Indeed this is one of the prime virtues of laws or regulations. The "low as practicable" concept, however, has merit precisely because it allows deviation from the radiation protection standards which are, indeed, designed to be applicable to all. The attempt to specify by regulation what is "least practicable" appears to be an unfortunate melding of concepts which vitiates the merits on each side. It undoes the assured uniformity of regulations because deviation on a case-by-case basis would appear essential, and yet removes from those subject to the regulation, the responsibility for ascertaining what need be done to meet the "least practicable" criteria.

The general question of the extension of regulatory procedures in the radiation field is not without its difficulties. For a while it appeared, in addition to the Atomic Energy Commission's

standards for radiation under their control, that states might adopt their own standards at various levels below those set by the Commission. This could lead to only chaotic results and unnecessary and wasteful bickering and arguing between states and between industry and workers. While this situation appears to have been settled for the moment by the courts, I feel that it will be facing us again from time to time.

It has already been noted that among primary concerns of the protection bodies in the past has been fear of exploitation of workers by industry. Fortunately, this has not proved to be the problem that it was once thought it might be, but it does not mean that it could not be a problem in the future. It is something against which industry must carefully police itself and it is something about which labor must be reasonable and rational.

There is no question that in the future this country will be increasingly dependent upon power generated by nuclear means and it behooves industry not only to be constantly alert to the problem but also constantly open about how it is dealing with it, so that public does not lose confidence in industry's willingness and ability to "do what is right".

Essential components of such things as aircraft, reactor components, pipelines, and hundreds of other devices will be subject to inspection by radiographic means and each of these involves some risk of exposure to the people making the

11-73

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Fears rigid interpretation of "as low as practicable"

We take note of the statement on page 40 of your September 1973 issue entitled "Issue final statement on 'as low as practicable,'" and find it distressing to realize what a rigid point of view our regulatory agencies appear to take with regard to radiation dose limits to the population resulting from the normal operation of nuclear power reactors. The hearings held last year in reference to proposed changes in 10CFR50 centered about what may become a rigid interpretation of "low as practicable," a concept introduced by the NCRP in its 1949 report (published in 1954).

If, indeed, experience in the operation of light-water-cooled nuclear power plants has shown that it is feasible to maintain conditions which will assure levels of annual exposure as low as 5 percent of that attributable to the natural background, it is in the public interest that light-water-cooled nuclear power plants be operated in a manner that such low levels be generally maintained. Such a program coincides with the completely defensible recommendation that nuclear programs should be conducted in a way which keeps exposure to radiation as low as practicable.

We may point out, however, that the proposed limit of 5 mrem per year has not been proven practicable under all circumstances, and occasional small over-runs, while of no biomedical significance, are certain to cause unnecessary controversy. Since, at best, the concept of "low as practicable" is subjective in its interpretation, we feel that some reasonable and controllable latitude in the use of a special dose limitation is desirable.

We are concerned that those members of the public who are unreasonably worried about radiation dose levels resulting from proper utilization of radiation sources will interpret the new rule as an acknowledgment that dose rates any higher than the very low dose rates which are considered "practicable" in connection with the operation of light-water-cooled nuclear power plants are cause for alarm. The current, excessive apprehension about the validity of presently recommended protection standards will more than likely be intensified unless it is made abundantly clear that the reason for the proposed reduction *is not a change in the basic radiation protection standards*, but only because experience has shown that it is cheap and feasible to operate light-water-cooled nuclear power plants at very low levels.

It must, thus, be clear that *the reasoning underlying the constant pressure to reduce dose limits is more of a political than a scientific nature.* Continued agitation by the press and a few of the less careful scientific writers seems to keep the radiation exposure problem constantly before the public to the point of causing over-reaction. We can see no other reason for the repeated efforts to further reduce the permissible dose of the population to levels that are now lower than the normal "background noise" of radiation exposure.

The NCRP and the ICRP, mindful of the public concern for radiation protection standards, have held our permissible dose and dose-limit standards under almost continual review for the past decade and a half since they were last changed. The ICRP has issued a statement indicating that on the basis of their recent and exhaustive examination of the question, they have decided that the standards not only do not need to be lowered but could in fact be raised if there was any special reason to do so. (*Health Physics*, Vol. 24, p. 360, 1973). The NCRP in its evaluation has not issued such a statement but in its latest report (No. 39, 1971) on the subject reiterated its belief that the occupational and population dose standards which we have used for some years are reasonable and adequate for protection purposes.

The implications arising from the attempted use of the "least practicable" concept in regulations are of concern to the NCRP. It is generally accepted that laws or regulations should be uniform in their application to all within their jurisdiction. Indeed, this is one of the prime virtues of laws or regulations. The "lowest practicable" concept, however, has merit precisely because it allows deviation from radiation protection standards which are indeed designed to apply to all. The attempt to specify by regulation what is "lowest practicable" appears to be an unfortunate melding of concepts which vitiates the merits on each side. It undoes the assured uniformity of regulations because deviation on a case-by-case basis would appear essential and yet removes from those subject to the regulation the responsibility for ascertaining what need to be done to meet the "lowest practicable" criteria.

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