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OFFICE OF SECRETARY
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February 7, 1986

Secretary of the Commission
U. S. Nuclear Regulatory Commission
Washington, DC 20555

Attention: Docketing and Service Branch

Re: Proposed Rule Relating to Revision of
10 CFR Parts 19,20,30,31,32,34,40,50,61,70
"Standards for Protection Against Radiation"
(51 F.R. 1092-1216, January 9, 1986)

Dear Sir:

On January 9, 1986, the Commission republished a proposed revision to the rules in 10 CFR Parts 19, 20, 30, 31, 32, 34, 40, 50, 61, and 70 relating to a complete revision of the "Standards for Protection Against Radiation." The proposal requested public comment on the revision by notice in the **Federal Register** dated January 9, 1986. (51 F.R. 1092-1216)

As a professional health physicist specializing in applied power reactor health physics for over twenty-five (25) years, with particular interest and responsibilities in radiological protection programs, dosimetry and dose equivalent evaluations for occupational workers and members of the public, I have reviewed the proposed revision outlined in the notice with great interest and have the following comments concerning the proposed rules. As all the 10 CFR Part revisions, other than that of Part 20, involve changes in reference to 10 CFR Part 20, comments will be restricted to only Part 20 and to specific comments requested in the Supplementary Information, Section XXVIII, of the preamble to the proposed rule.

Background Comments

Before providing specific comments and recommended changes to the proposed rule, I would like to offer some general comments on the entire proposal. As I work for a utility nuclear power plant as a staff health physicist, I am aware that utility health physicists, desiring to maintain their radiation protection program consistent with current recommendations of authoritive scientific bodies, have frequently encountered great difficulties due to restrictions contained in the current rule that prohibited

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full implementation of these recommendations. It had long been recognized that there is a need for the NRC to revise the "Standards for Protection Against Radiation" rule as it is not consistent with current scientific organizations' recommendations on radiation protection. Although it is agreed that the current rule is considered to be safe and has provided adequate protection of the worker and members of the population throughout the rules existance. the move by NRC to incorporate the recommendations of the International Commission on Radiological Protection (ICRP) is whole-heartedly welcomed and supported for the reasons stated by the NRC in the proposal and as further discussed in the below comments. Our radiological protection program has previously incorporated all of the International Commission on Radiological Protection's Publication No. 26 and Publication No. 30 (ICRP 26 and 30) recommendations. when published. that are not contrary to the current rule: and the finalization of the proposed revision. with certain modifications. will allow our radiation protection programs to be completely in accord with these ICRP recommendations and the more recent advances and recommendations made by authoritive scientific bodies. It is believed that a final rule that is consistant with the ICRP and other authoritive scientific bodies will allow a licensee to develope and operate a more scientifically correct radiological protection program for the protection of the occupational worker and members of the public from unwarranted risk from radiation exposures. I am very much in favor of this rulemaking which attemots to finally update the NRC radiation standards to reflect the best current scientific information available.

As the following comments are of a technical nature and are based on authoritive scientific information. I have taken the liberty of emphasizing (bold print) those salient points that form the basis of the comments and recommended improvements to the proposed rule as an aid in locating references. Except as noted in the comments herein. all sections of the proposed rule are endorsed for the reasons stated by NRC in the preamble to the proposed rule.

As stated in the Summary and the Supplementary Information. Sections I. of the preamble to the Federal Register's published proposed rule. "The intent of the revision is to improve NRC radiation protection standards by reflecting developments in the principles that underline radiation protection and advances in related sciences....". and "[t]he expected results of promulgating and implementing the proposed revised rule is an improved rule that provides better assurance of protection; **establishes a clear health protection for limits...;** and **reflects current information on health risk....**" NRC acknowledges that past revisions to Part 20 "have not kept the regulations in accord with more recent recommendations of scientific organizations (namely. those having expertise in radiation

protection...) **to improve overall protection and establish a clear health risk rationale."** (added emphasis). NRC's efforts in the preparation of this proposed rule to relate these radiation protection standards **more directly to any associated health risk** is technically and scientifically appropriate, and this intent of the NRC is favorably supported and endorsed. The NRC Staff responsible for drafting this proposed rule revision are commended for their efforts in the preparation of this document.

The summation of dose equivalents received by the body's organs/tissues from external exposures and from radioactive materials taken into the body as the effective (whole body) dose equivalent is highly endorsed. The intent to perform this summation has been recommended by authoritive scientific bodies for many years. The basis for the summation of internal and external dose equivalents is that the dose received by the organs/tissues of the body produces a risk of some effect to the individual exposed. By definition, dose equivalent is dose equivalent, irrespective to the means of delivery of the dose equivalent to the organs/ tissues. The ICRP 26 concept of the effective dose equivalent which has been incorporated into the proposed Part 20 rule more clearly represents the risk to the individual exposed. This methodology is more scientifically correct for quantifying the risk to an individual and reduces misinterpretation of the risk associated with exposures under the Part 20 rule. This quantification of risk is especially important today, where the nuclear industry, and expectantly other radiation users, large or small, are facing a new formidable litigious society that is more difficult to deal with than radiation itself. Suits under tort law exists today either in threat or in court literally by the thousands. Over "11 billion" dollars in outstanding claims for radiation damages against the federal government exist at the present time. It is expected that this trend of litigation will spill over into the private sector causing countless burdens to licensees. Insurance may become too costly to bear by some licensees resulting in potential reduction or discontinuance of some beneficial uses of radioactive materials or other radiation producing sources. In personal injury suits, radiation exposure quantification and dosimetry involved is of paramount importance. Regulations that are based on the current recommendations of authoritive scientific bodies for the determining the dose equivalent delivered to individuals is of particular importance. The proposed rule is also endorsed for this reason.

Some of the noteworthy requirements incorporated in the proposed rule are:

o the summation of dose equivalents delivered from sources external and internal to the body;

o ICRP 26 dose equivalent limits based on the risk of stochastic and non-stochastic effects;

o the protection of the unborn child by setting specific limits in accordance with the scientific communities' recommendations;

o the requirement for the licensee to use personal dosimeters processed by a processor accredited by the National Voluntary Laboratory Accreditation Program (under separate rulemaking);

o the option to use more suitable means (upon availability) to determine internal doses to the embyro/fetus due to maternal intake of radioactive materials;

o the adjustment of DAC or ALI fractions to reflect actual parametric values (when suitably justified); and

o the optional use of energy spectral distribution as a means of determining dose equivalent from neutron radiation exposures.

These proposed rule requirements will allow the licensee (when appropiate) to more accurately determine an estimate of the actual delivered dose equivalent to an individual. Inclusion of the options in the proposed rule by NRC have a scientific basis and should **not** be interpreted as encouragement for a cavalier attitude towards sound radiological protection practices; nor, should this attitude be associated with any of the specific technical comments and recommendations made herein. It would be always wise to use more conservative approaches when appropiate data is not available to use these options.

The final 10 CFR Part 20 rule should allow for professional judgement based on current acceptable scientific organizations' recommendations and scientific advances in radiological protection of individuals. The rule should not prevent this professional judgement ability from being used to provide the best state-of-the-art protection of individuals. At the same time, the rule should prevent misinterpretation or misuse of the necessary requirements for protection against radiation. It seems inappropiate, non-cost-effective, and contrary to good radiation protection practices for the NRC to be required to make necessary rule revisions before an appropiate and acceptable means are used to more accurately define the dose equivalent to individuals. A more satisfactory approach would be to allow variation from appropiate sections of the rule, without prior NRC approval, under conditions when physical parameters and methodology are available and the variation from the rule represents a reasonably accurate alternative to a specific rule requirement but retains the intent of the rule's requirement as described in the preamble to the proposed rule. The proposed rule allows suitable judgement in many areas for complying with the rule, as previously noted, but a few important routine but unique exposure conditions experienced by many licensees dictate that there should be a few additional options allowed for selection of alternative methods in complying with the

requirements of the proposed rule.

The ICRP 26 annual dose equivalent limit for the whole body is based on the risk of irradiation of the whole body: it is limited by the effective dose equivalent, H(E), as defined by ICRP. Several specific requirements stated in the proposed 10 CFR Part 20 rule are clearly inconsistant with the ICRP Publication 26's recommendations, and as they are currently stated in the proposed rule, would unduely restrict the proper determination of the dose equivalent and the H(E) by the licensee under certain specific conditions. Particularly of concern is the singular use of the secondary limits recommended by ICRP as NRC mandatory requirements with no allowance made for use of ICRP's primary means for determining the H(E). The restrictions placed on the licensee to determine the H(E) for exposures from sources external to the body, specifically for partial body exposures and for embryo/fetal exposures is of **great concern as the risk is exaggerated** by the rule's limited approach in the use of the secondary limits for determining the dose equivalent. The ICRP 26 secondary limit of the deep and the shallow dose equivalent indicies, H(I,d) and H(I,s), is defined by the NRC as the "Deep dose equivalent", H(d), and the "Shallow dose equivalent", H(s), respectfully, in the proposed 10 CFR Part 20 .20(1)(i) and (ii): 20.201(2): 20.201(3)(ii): 20.202: and 20.208(b)(1). These NRC requirements, as written, are not established on a clear risk rationale, as they are not related to an associated health risk for the mentioned situations. However, the H(d) and H(s) indicies are normally greatly useful in controlling external delivered dose equivalents by use of personal dosimeter monitoring to the prescribed limits. (Note: variables in ( ) denotes subscripts here and henceforth in these comments.)

ICRP Recommendations

The following quotations from ICRP 26 apply to the determination of the dose equivalent and are germane to the following comments.

Paragraph (32): "From the assumption about the proportionality between dose and response (see paragraphs 27-30) it would follow that for **stochastic effects it would be justifiable to consider the mean dose** (refers to the mean dose equivalent over the entire organ or tissue) **over all cells of uniform sensitivity in a particular tissue or organ.** This use of the **mean dose** has practical advantages in that the significant volume can usually be taken as that of the organ or tissue under consideration."

Paragraph (33): "...on the basis of theoretical considerations, and of available epidemiological evidence, the Commission believes that, **for late stochastic effects**, the absorption of a given quantity of radiation energy is ordinarily likely to be **less effective when due to a series of "hot spots"** than when uniformly distributed, because of the effects of high dose in

causing the loss of reproductive capacity or the death of cells. Thus, **with particulate radioactive sources within a tissue, to assess the risk by assuming a homogeneous dose distribution would probably overestimate the actual risk. Moreover, for non-stochastic effects, the limited amount of cells lost that might result at moderate dose levels would be most unlikely to cause any impairment of organ function."**

Paragraph (34): "For exposures to the skin either to external sources or as a result of skin contamination, it is not generally appropriate to average the dose equivalent over the entire skin."

Paragraph (83): "In any organ or tissue the limitation of the dose equivalent shall refer to the **sum of the annual dose equivalents** contributed by **external sources and committed dose equivalents** from radioactivity taken into the body during the year of practice."

Paragraph (85): "The basis for the limitation of individual exposures, either of workers or of members of the public, is the limit for the **weighted mean whole body dose equivalent** (see paragraph (104)...."

Paragraph (104): "For stochastic effects the Commission's recommended dose limitation is **based on the principal that the risk should be equal whether the whole body is irradiated uniformly or whether there is non-uniform irradiation.** This condition is met if

$$\sum_{T} w(T)H(T) \text{ (is less than or equal to) } H(wb.L)$$

where, w(T) is a weighting factor representing the proportion of the stochastic risk resulting from tissue (T) to the total risk **when the whole body is irradiated uniformly,**

H(T) .. the annual dose equivalent in tissue (T),

H(wb.L) is the recommended annual dose-equivalent limit for **uniform irradiation of the whole body,** namely 50 mSv (5 rem)."

Paragraph (182): "For skin contamination the irradiation is never uniform and occurs preferentially on certain parts of the body, notably the hands. However, it does not persist over many weeks and does not always occur again at exactly the same places. **For routine purposes, it is adequate to regard the contamination as being averaged over areas of about 100 square centimeter. Routine monitoring for skin contamination should therefore be interpretated on the basis and the limit applied to the average dose equivalent over 100 square centimeter."**

(Note: emphasis added in the above quotations.)

The basis for the effective dose equivalent, H(E), is found in

paragraph (104) of ICRP 26. It should be emphasized that this limit is based on **"uniform irradiation of the whole body...."** It is strongly recommended that means should be made available in the rule to allow the option of determining the external portion of the H(E) by other than by using the H(d) index. Means of determining the dose equivalent by primary methods should be not denied if it is more convenient to reasonably determine the H(E), if physical factors for the exposure are known, and if there exists sufficient information to estimate with reasonable accuracy the approximate H(E) from external sources, the H(E) from external sources to the embyro/fetus, and the dose equivalent to the skin of the whole body or portions of the skin of the whole body. Specific detailed technical justifications and comments on the proposed mandatory use of only the specific indicies to determine the H(E) are provided in the following.

I. SPECIFIC COMMENTS ON PROPOSED 10 CFR PART 20

A. EFFECTIVE DOSE EQUIVALENT, H(E):

ICRP 26 recommended the effective dose equivalent, H(E) , as the primary dose limitation which is based on the principle **that risk should be equal whether the whole body is irradiated uniformly or whether there is non-uniform irradiation** (Paragraph (104)). This primary dose limit makes no exception for doses received from sources external to the body. ICRP recognized the need for a simpler technique to determine the H(E) from external sources and developed **secondary limits**, which, in practical situations, will **usually suffice;** namely, these are the deep dose equivalent index, H(I.d), and the shallow dose equivalent index, H(I.s) (Paragraph (107)). The indices were recommended **"on those occasions when information is lacking** concerning actual distribution of dose equivalent in the body...." (Paragraph (108)). (emphasis added)

ICRP 26 defines in Paragraph (108) these indicies (secondary limits) as:

o Deep dose equivalent index - the maximum value of dose equivalent that would occur at a depth of 1 cm **or more** in a 30 cm diameter sphere.

o Shallow dose equivalent index - the maximum value of dose equivalent in the shell from **0.07 mm to 10 mm depth** in the 30 cm sphere.

It should be noted here that the International Commission on Radiation Units and Measurements (ICRU) in their Report ICRU 33, "Radiation Quantities and Units," defines these indicies identically to that of ICRP 26.

The proposed 10 CFR 20.3, Definitions states: "'Deep dose equivalent' H(d) applies to the external whole-body exposure and is taken as the dose equivalent at a tissue depth of 1 cm." and the "'Shallow dose equivalent' H(s) applies to external exposure of the skin or an extremity and is taken as the dose equivalent at a tissue depth of 0.007 cm." Although these NRC terms are used in a similar manner as the ICRP 26 **secondary limits** (indicies), **they are not identical** in meaning and **may be grossly over-conservative or under-conservative** in unique but recurring personnel exposure irradiations. The occupational dose limits of 10 CFR Part 20.201 are based only on these "indicies" for exposures from external sources: allowances for determining the H(E) (as defined by ICRP) by primary means is not mentioned. It is recognized that the use of secondary limits is practical and acceptable as it simplifies dose determinations for NRC licensees: but, in some instances, the ICRP 26 primary H(E) is more appropiate and scientifically correct for determining the dose equivalent for whole body exposures from external sources. The indicies can significantly underestimate the dose equivalent to the skin of the body and grossly overestimate the external H(E) to the whole body, and the H(E) to the embyro/fetus when exposed to sources external to the maternal body. It is recommended that the proposed rule be modified to allow the licenses to determine the external H(E), the dose equivalent to skin, and the H(E) to the embryo/fetus by means other than the use of the indicies when physical factors are known, and if there exists sufficient information to estimate with reasonable accuracy the approximate external H(E), the dose equivalent to skin of whole body (or extremities), and the H(E) to the embyro/fetus from sources external to the maternal body.

Precedent for similar allowances can be found: for examole, in the current and proposed Part 20.4(c)(4) for determining the dose in rem from absorbed dose in rads when externally exposed to neutrons and physical and other parameters are know to reasonably determine the dose: and in the proposed Part 20.204(c) for internal exposures and Part 20.208(b)(2) for H(E) to an embryo/fetus from radioactive material taken into the maternal body.

The following detailed discussion provides the basis and the need for the addition of the above recommendation.

The occupational annual dose limit for the whole body for adults in the proposed Part 20.201 is stated as being equal to "The sum of the (external) deep dose equivalent to the whole body and the (internal) committed effective dose equivalent being equal to 5 rem." In most routine occupational exposures of workers, this method for determining the H(E) is practical and justified as the total dose to the individual's organs/tissues is generally uniformly distributed and is relative to the risk involved. Therefore, the summation of the external whole body dose

equivalent and committed H(E) method is endorsed under these condition.

1. Partial Body Exposures:

Notwithstanding the aforementioned, in some important and warranted routine occupational exposures of workers only portions of the whole body are exposed and receive a larger dose equivalent than the remainder of the body. **The same limit on risk should apply whether the body is irradiated uniformly or the irradiation is non-uniform or limited to segments or specific tissue or organs, and therefore, is appropiate to partial body exposures.** As defined in Part 20.3 "Definitions," "whole body" means, for purposes of external exposure, head, trunk, arms above the elbow, or legs above the knees. Based on the organs/tissues located in the latter body parts, the definition is considered to be generally satisfactory for uniform and near-uniform whole body irradiations. But, when this method is used to determine the H(E) from external exposures to limited portions of the whole body, the assigned whole body H(d), as defined in Part 20.3, **greatly overestimates** the actual (whole body) **risk** and the H(E) received by the individual. The appropiate H(E) can be determined with reasonable accuracy using ICRP 23, "Reference Man" data to calculate the fraction of organ/tissue in partial body irradiations. The use of these specific fractions, the appropiate ICRP 26 weighting factors, and the delivered organ-tissue dose equivalent allows easy determination of the **weighted mean whole body dose equivalent,** H(E), received under partial body exposure situations (see Paragraph (85)). To illustrate the significance of these over-estimates of the H(E), consider the following two examples of routine partial body radiation exposure scenarios. For simplicity and conservatism, the measured H(d) (index) is used in these examples and it is assumed to be equal to the uniform dose to the involved organ/tissue. If organ/tissue dose to body surface exposure ratios (rem/R) are available they should be used vice the H(d).

Example #1:

Worker performs work where his head and neck are exposed to radiation; the rest of the body is completely shielded. This scenario is found in industry and research and medical facilities, as well as at nuclear power plants. As the head and neck contains only about 20% of the whole body's red bone marrow and bone and the entire thyroid gland, it would be scientifically inappropiate to assume that his total body was uniformly irradiated as this would grossly over-estimating the risk to the individual. In this example, it is assumed that the head and neck alone were exposed to a 5 rem H(d) from a external gamma radiation source. The following estimates the H(E)s.

Organ/Tissue	w(T) H(T)*	H(E)
Thyroid (100%)	0.03 x 5000 mrem x 1.0 =	150 mrem
R.B. Marrow (20%)	0.12 x 5000 mrem x 0.2 =	120 mrem
Bone (20%)	0.03 x 5000 mrem x 0.2 =	30 mrem
Total Head/Neck		300 mrem

If the head and neck alone were irradiated, the annual H(E) limit of 5 rem would not be reached, but if the proposed Part 20 "Deep dose equivalent" criteria is used, the exposure to the head and neck of 5 rem H(d) (index) would equal the annual H(E) limit and **would grossly exaggerated the risk of this exposure by a factor of 16.7.**

Example #2:

Workers frequently perform work at a nuclear power plant by using hand-holes in vessels that have high internal radiation exposure rates. Exposure rates external to the vessel are always significantly lower. Typically, these workers wear multiple dosimeters of which the mean H(d) for these workers are:

Head/Neck	700 mrem
Upper Arm (Incl. Shoulder)	1500 mrem
Chest/Back (Trunk)	700 mrem
Lower Extremities and Unexposed upper arm	700 mrem

By definition of Part 20.3, the assigned H(d) (or H(E)) for whole body would be 1500 mrem. If one calculates the H(E) based on the non-uniform (considered as separate partial exposures) exposures indicated, the approximate H(E) would be:

Organ/Tissue	w(T) H(T) (mrem)*	Comments**
Head/Neck	42	R.B. Marrow 20%, Bone 20%, Thyroid 100%
Upper Arm (Incl. Shoulder)	19	R.B. Marrow 4.1%, Bone 5.7%
Trunk and lower Extremities and and other Arm	574	All organs 100%, except for: R.B. Marrow 75.9%, Bone 74.3%
Sum	635	

* Values conservatively estimated assuming that the H(d) represents the uniform dose to all organ/tissue involved.
** ICRP 23, Table 14 and 31 values.

The actual H(E) due to this partial body exposure is about 42% of the H(d) that would be required to be assigned to the individual

as the H(E) by the proposed Part 20 definition. In this case the deep dose equivalent would **grossly overestimate the risk by a factor of about 2.4.**

Health physicist tend to be conservative in their radiation protection practices, but **excessive over-conservatism** in dose estimations is considered contraindicated as it **over-estimates the risk** of exposure to the individual and the inherent implications that are associated with the level of risk.

It should be noted that the National Council on Radiation Protection and Measurements (NCRP) is presently in the process of drafting their latest Recommendations on Radiation Exposure Limits which is to supercede NCRP Report No. 39, Basic Radiation Protection Criteria," issued in January of 1971. It is expected that their new report will address the methodology similar to that used above to calculate the H(E) for partial body exposures. When NCRP recommenations are finalized and published, determination of the H(E) for partial body exposures should be allowed by the proposed rule without subsequent rule revision. A specific recommended change to the proposed rule is included in Attachment 1.

2. External Exposure of the Unborn

Part 20.208(a) "Dose to an embyro/fetus" specifies an H(E) limit of 0.5 rem during the entire pregnancy period. As this requirement is based on supportive scientific data and recommendations, the 0.5 rem H(E) limit on the embryo/fetus is fully endorsed. It may be of interest to note that our radiological protection program has administrated this specific limit in 1974; and in administrating the limit, difficulties as noted in the Supplementary Information, Section XII, "Minors and Pregnant Women", preamble to the proposed revision to Part 20, have not been experienced.

Part 20.208(b)(1) specifies that the H(E) to an embryo/fetus is the sum, in part, of "the deep dose equivalent to the declared pregnant woman: and...." As discussed in the general and specific technical comments mentioned previously regarding H(E) from sources external to the body, the **H(d)** would **overestimate the H(E) to the embryo/fetus** from external exposures. In Section XII, NRC referenced ICRP statements on exposure to the embryo/fetus: "[b]ecause of the shielding provided to the fetus by fluids and the mother's overlying tissue and the duration of pregnancy, it is likely that the fetus would receive less than 0.5 rem under such working conditions [women working so that she would be unlikely to receive more than 1.5 rem per year]." This equates to 1.125 rem maternal dose and 0.5 rem fetal dose delivered at uniform monthly exposure rates during the entire

average (nine months) gestation period, and it implies a fetal to maternal dose equivalent ratio of 0.44 for exposures from external sources. In other words, the fetus is expected to receive a dose equivalent equal to about 44% of the maternal dose equivalent received from external sources. The NCRP in Report No. 54, provides methods for estimating the fetal dose from external exposures of the mother to various low energy photon spectra. Appropiate tissue-air-ratios are provided for a referenced size woman where the fetus is assumed to be located 8 cm below the anterior surface of the abdomen. Ratios or factors for relating a fetal dose (tissue depth dose) from maternal dose are photon energy dependent and must be selected for use on this basis. This method works reasonably well for averaged-sized women in early pregnancy (during the first half of pregnancy). For women considerably larger or smaller than average, or if the women is in the latter stages of pregnancy, more specifically appropiate tissue-air-ratios as described by R. J. Schulz and C. Gignac in 1976, as referenced in NCRP Report 54, are available. Other published authoritive scientific recommended depth-dose distribution factors for low and high energy photons and computer generated Monte Carlo calculated organ/skin dose factors are available for use in calculating the fetal dose from the maternal dose due to external exposures. Using this type of calculation, it can be shown that the fetal dose varies from approximately 40% to 61% of the maternal doses received from photons normally available at nuclear power plants. The use of these factors allows the licensee to more accurately estimate the dose equivalent to the fetus and the inferred risk to the fetus associated with such exposures.

Note numbered "2" pretaining to Part 20.208(b)(2) requires prior approval of specific factors used by the licensee, other than a factor of 2. This requiremet is considered unnecessary, non-cost effective and contrary to precedence for other options are given in the current and proposed rule that does not required this type of pre-approval. Comments were mentioned previously in the "Background Comments" as to the need of options without prior NRC approvals in estimations of dose equivalents. Therefore, it is recommended that the phrase "and are approved by regulatory authorities for use by licensees." be deleted from note number "2" to allow professional judgement to prevail in this case. It should be sufficient to state that "'... when such factors become available from scientific authorities....' they may be used by th licencees."

Whenever overestimations in the dose to the fetus are made, the mother's allowed exposures may be unduly restricted and may unjustifiably affect her work capabilities. A more reasonable and accurate estimation of the fetal dose would cause less interference with the mother's work abilities . If physical and biological factors and methodology are available, the licensee should have the option of using this data to more accurately

define the H(E) to the fetus due to sources external to the maternal body. It is recommended that NRC provide the means in the revised Part 20 rule to allow the licensee this option. A specific recommended change to the proposed rule is included in Attachment 1.

3. Summation of external and internal doses

Part 20.202 requires the summation of the external and internal doses at levels exceeding both 10% of the (external) H(E) [defined as the (external) deep dose equivalent] and 30% of the (internal) annual limit of intake (ALI) of radioactive material. Below these levels, summation need not be performed. Part 20.502 states that monitoring is not required when 10% of the annual H(E) (equal to 0.5 rem) or when 30% of the ALI (equal to a committed H(E) of 1.5 rem) would not be received by individuals (except for minors, who have lower limits). Theoretically, an adult could then receive an H(E) in a year equal to 40% of the annual H(E) (2.000 rem) and not be required to be monitored nor to have his dose summed for the internal and external exposures. ICRP 26 recommends a 30% criteria for monitoring based on the annual H(E). In comparison, NRC's criteria is less conservative. NRC makes no mention in the preamble to the proposed revised rule as to the basis for the 30% for monitoring and summation of internal exposures. A concern is expressed that these requirements for internal exposures are not the same as those for external exposures. The nuclear industry has no problem in determining fractional intakes much less than 10% of the ALIs by bioassay techniques. With the NRC's allowance for use of DAC x Time calculations to estimate intakes of radioactive material for demonstrating compliance with the annual H(E), licensees should not experience problems in monitoring of internal exposures at a 10% criteria and subsequent summations at a 10% criteria for these estimated internal exposures with the external exposures.

A more in-depth examination of the 30% criteria for monitoring and summation of external and internal dose equivalents, revealed an addition problem which may lead to significant overexposure of the embryo/fetus. By-product radioactive material available at nuclear power plants include radionuclides that have relatively short physical and biological half-lives and deliver the majority of the internal organ/tissue dose, and hence the committed H(E), within a relative short period of time. At the 30% level, these radionuclides would cause an overexposure of the embryo/fetus 0.5 rem gestation period limit. Using iodine-131 as an example, an intake of up to 30% of the ALI would produce a committed H(E) to the mother of 1.5 rem, which when using NRC's factor of 2, would deliver a committed H(E) of 3.0 rem to the embryo/fetus. If the 10% external exposure without monitoring criteria was also received by the mother, under the proposed rule, the child would receive an additional 0.5 rem H(E) from external sources, giving a potential exposure to the embryo/fetus of 3.5 rem H(E) without

any monitoring of the exposures nor summation of the external and internal components of the H(E) received. Even if a 10% monitoring rule, vice a 30% rule was required, a committed H(E) received could still over-exposure the embyro fetus.

As the above exposures to the embryo/fetus is expected to be infrequent, a major change to the rule to include protection of the embryo/fetus may not be justified. A note in the rule should suffice and would be helpful in reminding licensee of this possibility. It is further recommended that the 30% criteria be reviewed as to the need for retention in the rule, vice reducing this criteria to 10%. Licensees should have the capabilities of monitoring at or below this 10% level for intakes of radioactive material. A recommended change to the proposed revised rule is provided in Attachment 1.

B. SKIN DOSE EQUIVALENT

Part 20.201(a)(3)(ii) prescribes annual dose equivalent limits to the skin and to each of the extremities. These limits are consistent with the ICRP 26 recommendations and are therefore endorsed. The rule does not however specifically prescribe how to determine the dose equivalent to the skin and to the extremities. Part 20.3 definition in paragraph (4)(iii) under "Dose" terms defines the "shallow dose equivalent," but no reference in the rule implies or requires its use to determine the dose equivalent to the skin and to the extremities. It should be noted that this definition varies significantly from the recommendations of both ICRP and ICRU as previously mentioned. If the intent of the NRC is to require the H(s) to be used in this manner, the following comments are considered technically appropiate for consideration in modifying this requirement.

Before preceeding in commenting on the rule's treatment of skin dose equivalent measurement, a brief review on specific skin tissue-at-risk from irradiation may to be appropiate.

1. Tissue At Risk Considerations:

Radiation dose limits should be set which do not result in detrimental effects. For skin doses equivalent, the ICRP 26 in Paragraph (64) states that "**The basal cell layer** of the epidermis is taken to be the skin tissue most at risk. Because of undulations in the basal cell laver and because of the finite thickness of its cells, a range of 50-100 um (or 5-10 mg/square centimeter) is appropiate for specifying the depth of the sensitive layer of **most** parts of the skin that in practice are not protected by clothing and are therefore exposed directly to radiation. **For practical dose assessment** the Commission

recommends the use of a depth of 70 um as a reasonable **mean** value." (emphasis added). It is noted that **these recommendations are limited by the paucity of biological data** and are based on radiobiological studies that included the **irradiation of the skin of rodents.**

The National Radiological Protection Board published Bulletin No. 62, "Effects of radiation on the skin" (January 1985), that reported results of studies of skin effects caused by irradiations with photons and beta particles. These studies demonstrated that, anatomically, pig skin is the best animal tissue for studies on human skin, as radiation-induced early and late reactions in pig and human skin are similar. Figure 1 provides a comparative summary of the anatomical parameters of skin for the human, pig, and the rodent.

Table 1

COMPARATIVE ANATOMICAL PARAMETERS OF THE SKIN

PARAMETER	HUMAN	PIG	RODENT
Basal Cell Density (cells/mm)	~165	~165	~130
Epidermis thickness (μm)	60-90	60-90	~10
TOTAL skin thickness (Epidermis and dermis) (μm)	~1400	~1400	~400
Hair follicle density (mm^{-2})	25	25	1000
Vasculative organization			
fixed-skinned	Yes	Yes	No
loose-skinned	No	No	Yes
vessel density		same as man	>man

Definitions:

1. **Fixed skinned** - the skin is firmly attached to the deep fascia and there are segmental vessels perforating the fascia muscle into the dermis.

2. **Loose skinned** - no segmental vascular supply

These differences in thickness and distribution of cells in the skin have important connotations with respect to dosimetry, particularly from low energy particle radiations, and are important implications for radiation effects on dermal tissue. Irradiation on pig skin and human skin revealed a 'second wave' (late) effect in the dermis even in the absence of significant

'first wave' (early) epidermis effects. These 'second wave' effects were not detected in irradiated rodents. Therefore, as significant dermal effects and subsequently risks can occur, and as effects on the dermal tissue could be more significant than that of epidermal tissue, **the dosimetry of the dermis is considered necessary** and **dose limits for skin should include the dermis** as well as the basal layer of the epidermis to provide a better assurance for protection of the skin, and establishes a clear health protection basis for skin dose equivalents limits.

2. Significant Beta-emitting Radionuclie Considerations:

Although a variety of beta-emitting radionuclides are utilized by licensees in general, these comments are limited to those beta-emmitters available at nuclear power plants. The energy spectrum of these beta-emitters which produce a skin dose has a distribution between 68 keV and 2.3 MeV, therefore, the tissue depth-dose varies considerably in skin with the beta energy. For routine personnel monitoring of skin dose for beta-emitters at a distance from the skin by use of dosimeters, the use of the H(s) is considered satisfactory when appropiate beta-energy correction factors are use to modify the dosimeters response and the dosimeter is processed in accordance with the NVLAP dosimeter accrediation program (Part 20.501(c)). For skin dose equivalents delivered from contamination with radioactive materials on the skin, the H(s) is considered to be inadequate to quantify the dose equivalent and **associated risk** to the skin. Normally, such contamination exists as a mixture of radionuclides having varing beta-energy spectra, which normally can be identified by nuclear power plants. Determination of the dose equivalent to the skin in these cases necessitates performance of standardized calculative methods. Calculations using the H(s)'s 7 mg/square centimeters depth (a value selected by ICRP to represent the mean depth of the basal cell layer of the epidermis) does not represent the dose equivalent of interest if one is to include the dermis equally at risk as described above. An alternative method is necessary to determine the dose to the skin. The integrated tissue depth-dose distribution from skin contamination for selected beta-emitters are shown in Table 2. The percent of the total integrated dose delivered in skin tissue and underlining tissue were obtained from ICRP 21, Figure 7, data. For nickel-63 all of the beta energy is absorbed in the cornium (dead layer of the epidermis), a **mean** thickeness of 10% of the epidermal thicknes or 5 um, as stated by ICRP 23, Section II.1.b for skin of whole body except for the lower portions of the upper and lower extremities, notably the palms of the hand and the soles of the feet which have a minimum cornium thickness of 600 um. For the remainder of the radionuclides shown in Table 2, it can be seen that the dermis receives a larger integrated dose than the epidermis of the skin, especially for high energy beta particles. If only the epidermis is considered, then the dose equivalant to the skin would be underestimated by a factor from approximately 2 to 10, depending upon the particular beta energy

distribution.

Table 2

APPROXIMATE PERCENT DEPTH DOSE DISTRIBUTION*

NUCLIDE (Mev)	EPIDERMIS 0 to 50 um	DERMIS 50 to 1300 um	HYPODERMIS 1300 to 5050 um	DEEPER TISSUE >5050 um
^{63}Ni (0.067)	100	-	-	-
^{147}Pm (0.23)	38	62	-	-
^{204}Tl (0.7[illegible])	10	86	4	-
^{90}Sr-^{90}Y (0.54,2.27)	5	52	39	4

ICRP 21, Figure 7 data used.

* Integrated dose

3. Significant Skin Volume and Area Considerations:

ICRP 26 specifies the use of the **mean dose** over all cells of uniformly sensitivity in a particular tissue to limit both stochastic and non-stochastic effects in that tissue (Paragraph(32)). Based on the previous discussion on tissue-at-risk for skin and the integrated tissue depth-dose distribution for significant beta-emitting radionuclides for skin contamination dose determinations, it is recommended that this determination should include the epidermis and dermis. ICRP 26 recommends for routine monitoring that the dose to the skin from skin contamination should be based on the **average dose equivalent** of an area of 100 square centimeters for interpretating the annual skin dose limit (Paragraph (182)). Derived tissue depths and masses for contaminated skin dose equivalent determinations are shown in Table 3. As shown in this table, for most of the body skin, the tissue-thickness depth of concern would be from 5 to 1300 um or about 0.6 to 149 mg/square centimeters. For this case, using the ICRP recommended significant area of 100 square centimeters for monitoring of the skin a volume (in mass units) of about 148 mg may be used. Integrating the beta dose in this volume and over this area would directly relate to the risks of stochastic and non-stochastic effects in skin. Derived parameters for monitoring dose equivalents for extremity parts are also in Table 3 to show the effects on monitoring due to the thickness of the cornium in these areas.

Table 3

DERIVED TISSUE DEPTH FOR CONTAMINATED
SKIN DOSE EQUIVALENT DETERMINATION

ANATOMICAL REGION	EPIDERMIS & DERMIS ONLY um	mg/cm^2	MASS (g)
PALMS OF HANDS	600 to 1660	68.7 to 190.1 (121.4)	12.14
SOLES OF FEET	600 to 2710	68.7 to 310.3 (241.6)	24.16
REMAINDER OF BODY	5 to 1300	0.57 to 148.9 (148.3)	14.83

(1) ICRP 23 Table 6 mean thicknesses.
(2) Specif.. gravity of 1.145 used.
(3) ICRP 23: II.1.b.

No basis is found in the Supplementary Information, Section XI, "Standards for Occupational Exposures of Individuals," for the 10 square centimeters area specified in Part 20.201(a)(3)(ii) for averaging the dose equivalent for skin. It may be a possibility that the 10 square centimeters area relates to the effective area of a commonly used hand-held personal contamination (frisking) monitoring detector. If so, there is no apparent relationship to a specific risk or to any authoritive scientific recommendations. If the basis for the proposed rule specified area was based upon risk due to "hot spots", an often misunderstood presumption, the ICRP 26, Paragraph (33) should be referred to, as averaging over an area of 100 square centimeters containing "hot spots" probably over-estimates the actual risk of both stochastic and non-stochastic effects in the skin, and it would be inappropiate to consider localized doses from these "hot spots" as exposures delivered under the dose equivalent annual limit to the skin (see ICRP 26, Paragraph (183)). Often misinterpretations of the dosimetry of "hot spots", its risk and relationship to dose equivalent limits for skin and other organs/tissues have caused unnecessary concern about the risk and grossly overestimations of the assigned doses, and in a few instances, misinterpretated as regulatory overexposures. An appropiate rule that would specifically clarify this situation by incorporation of the ICRP methodology should aid in elimination of the exaggerated concerns.

4. Recommendations:

Based on the aforementioned considerations, licensee should be given the option to more accurately determine an estimation of the actual dose equivalent to the sensitive tissue of the skin when physical and biological parameters and methodology are available from authoritive scientific bodies, vice being

restricted to the H(s) requirement implied in the proposed rule. In addition, the NRC should adopt ICRP recommendation on the significant area of 100 square centimeters for averaging the skin dose which are based on a reasonable scientific basis to prevent undue risk from exposure of individuals. A specific recommended change to the proposed rule is included in Attachment 1.

C. DE MINIMUS FOR DOSES TO MEMBERS OR THE PUBLIC

1. De Minimus for Doses to Individual Members

The proposed revision contains a section, Part 20.304, "Collective dose evaluations.", and a discussion in Section XVIII of the preamble to the rule, pretaining to a de minimus levels for doses to individual members of the public. This concept is a helpful addition to the NRC regulations and is strongly supported. Although the de minimus level chosen by NRC of 0.001 mrem per year is on the low side and could certainly be considered trivial, the adoption of the concept is a very important consideration at the present time. A level of about 0.010 rem per year whould provide a better opportunity for real use of the de minimus in practice while still maintaining the risk to population groups at a negligible level. As the average natural background dose rate throughout the United States is 0.100 rem per year, it would be reasonable to define a negligible risk limit of 10% of background or 0.010 rem per year without discernibly increasing the biological risk of stochastic or non-stochastic effects of radiation exposure. As the difference in natural background radiation levels appear unlikely to influence the general public in residential selection, a fatality risk of 1/100,000 per year is close to the level below which an activity is considered safe. A risk of 1/100,000 per year are given in the scientific literature as the risk resulting from 50 years of exposure to 0.100 rem per year. Background radiation levels also varies by about 0.020 rem per year.

In Section XVIII of the preamble to the proposed rule, NRC uses stated calculation to derive its de minimus level for exposures of individual members of the population. There is an obvious order of magnitude difference between the risk derived by NRC and that derived from natural background irradiation. NRC's calculation is incorrectly based on a correlated risk on a unduly conservative basis, since the de facto risk is much less at older ages: age-adjusted incidence rates similar to those used in SEER Data Reports produced with actual incidence data are more appropiate.

NRC bases their calculation on one (1) death occurring in a million persons from exposures received continuously over lifetime of 70 years. The relationship of 0.0001 rem per year exposure proposes to have the risk of 1 death in a million for a

lifetime. Using this relationship, then: 0.100 rem/y (Nat. Background) x 1 Cancer Death/0.0001 rem/year = 1000 deaths per million individuals due to natural background are to be assumed. This risk assumption is not consistent with the stated estimated risks from natural background radiation and grossly overestimates the risk at low doses, and gives cause for unnecessary concern by members of the public. A 10% of background de minimus limit is well within the average variation in the natural background and any risk associated with a de minimus of 0.010 rem/year is considered acceptable and below any regulatory concern.

It appears that the argument in the preamble discussion could just as easily have been used for establishing a de minimus dose level at least an order of magnitude higher than selected, and based on the above considerations, it is recommended that the de minimus level for individual members of the public be changed to 0.010 rem per year.

2. De Minimus for Collective Dose to Members of the Public

In addition to a de minimus cutoff for individual members of the public, it is recommended that the NRC include a discerning de minimus value for the collective H(E) of the public to eliminate the cost of detailed assessment of the collective H(E), or of considering the need for further measures to reduce the detriment to the health of the public which are greater than the cost of the radiation detriment. A collective H(E) of 100 man rem is recommended for discounting those public exposures less than those having regulatory concern. Cost of assessment of the collective H(E) at levels less than a de minimus of 100 man rem by many licensees would represent an unwarranted allocation of resources when both the individual and collective H(E) are small. As collective H(E) are representative of the detriment of large numbers of people exposed, the assessment of small collective H(E) would not discernibly represent the associated potential risk of the public. As indicated in paragraph I.C.1 above, the natural background radiation level varies by about 0.020 rem per year, and this variance represents a collective H(E) of 2000 man rem from natural background for a population of 100,000 persons. Collective H(E) attributible from licensee sources below the de minimus of 100 man rem would be undecernible from that caused by natural background.

It is noted that the United Kingdom recently accepted and regulated the advice given by the National Radiological Protection Board (NPRB) in their January 1985 publication ASP 7 on a collective H(E) de minimus of 100 man rem (1 man Sv) as being of no longer of concern to regulatory bodies.

3. Recommendations:

Based on the aforementioned considerations, it is recommended that the rule should be modified to include a individual H(E) de minimus of 0.010 rem per year and a collective H(E) de minimus of 100 man rem/year to allow exclusion of performing costly assessments of the collective H(E) for very small doses. A specific recommended change to the proposed rule is included in Attachment 1.

II. COMMENTS ON RULE'S SUPPLEMENTARY INFORMATION

A. SECTION XXVIII. IMPLEMENTATION

NRC's discussion in Section XXVIII relates to potential difficulties which may be experienced by licensees with the exchange of information or exposure data caused by use of both the present and the revised Part 20 over a period of years, and that these difficulties would not occur if all licensees were required to fully implement the revised rule all on one prescribed date, five full years after publishing the final rule.

For the reasons stated in the Background Comments section, it is recommended that the revised rule provide an option to implement the rule prior to the full implementation date of the rule. Licensees should be allowed to choose to implement the revised rule earlier than the effective date based on their site-specific capabilities. As previously mentioned, some licensees have already implemented portions of the ICRP 26 and 30 recommendations, not contrary to the current Part 20, have incorporated these recommendations into their written procedures, and are anxious to be in complete agreement with these ICRP recommendations. For these licensees, an additional delay time of approximately seven (7) more years would be considered to be unwarranted. This time lapse equates to seventeen (17) years post-publication of the ICRP recommendations. Therefore, the NRC is discouraged in considering mandatory requirements of all licensees to implement the revised rule as of January 1st -- five full years after the final rule has been published. Licenses should be allowed to implement the revised rule, either in whole or in part, prior to the final implementation date. Partial implementation capabilities allows for an appropriate time to perform orientation and training for those individuals responsible for complying with the rule, and to perform procedure revisions, etcetra, while systematically incorporating the revised rule's criteria. These tasks are site specific. It is anticipated that an approximate six months to one year period would be required for the radiological protection program that I am involved in to be fully implemented to meet the revised rule criteria. Certainly, other licensees will have variable estimated implementation schedules.

NRC's discussion in Section XXVIII describes potential difficulties for licensees with the exchange of information or exposure data which may be caused by the use of both the present and the revised Part 20 over a period of years. It should be noted that, in preparation as a separate rulemaking, a requirement for licencees to use dosimeters that are processed by processors who are accrediated under the NVLAP DOSLAP accrediation program. At the present time, thirty-four (34) utility licensees are accrediated by NVLAP for processing dosimeters, eleven (11) utilities are in the process of becoming accrediated by NVLAP, and some utilities are using dosimetry that is provided by a NVLAP accrediated processor. In this regard most of the current information and exposure data for external irradiation exposures of occupational workers are being reported both to the NRC, under the current rule's requirements, and to other licensees on the same basis as required on the proposed revised rule. Difficulties in the exchange of external exposure information or data, therefore, is not expected to occur with the early implementation of the revised rule by some licencees.

The internal exposure criteria in the revised rule, also, is not considered to cause any problem in information and exposure data exchange, as internal exposures historically have not been a problem at nuclear power plants. No significant intakes of radioactive materials have ever occurred at any of these plants. Exceeding 10% of the ALI or annualy DAC quantities as specified in the revised rule is not expected to occur under normal operating conditions. Therefore, for this reason, reporting and exchange of internal exposure information and exposure data is not expected to cause any difficulties in the early implementation of the revised rule.

Proceedure revisions and training are site-specific factors, and therefore, require variable lengths of time for implementation depending on the present level of incorporation of ICRP 26 and 30 recomendations into radiological protection programs.

For the above stated reasons, it is recommended that licensees be given the option as to when they may implement the revised Part 20 prior to the final implementation date, and should be allowed to implement the revised Part 20 in whole or in part prior to the final date.

Summary

The Commission has made major progress toward revising their "Standards for Protection Against Radiation" rule by incorporating current recommendations of authoritive scientific bodies, but it is believed that a few additional appropiate improvements to allow licensees to more accurately define the

dose equivalent and its associated risk to an individual are warranted under conditions when dose equivalents are significant and appropiate in accordance with available scientific methodology, parameters and data. While I completely concur with the general approach taken in the proposed Part 20 rule and believe it is necessary to implement current scientific recommendations on the radiation protection of individuals at this time, it is believed necessary that the Commission consider inclusion of the recommended options herein described that allow more accurate determination of the assigned dose equivalent which is related to the stated risk to the exposed individuals. It is recommended that the Commission consider inclusions of these modifications in future rulemaking on the "Standards for Protection Against Radiation" rule. Allowance for early implementation of the revised rule would be especially welcomed.

Thank you for the opportunity to submit these comments.

Sincerely,

Eugene T. Kleiss

Attachment 1

RECOMMENDED CHANGES TO THE PROPOSED 10 CFR PART 20 RULE
(Modifications to rule are emphasized in bold print.)

10 CFR PART:

20.3 Definitions.

"Dose" terms:

(4) ***

Add the following new paragraph and renumber existing paragraphs:

(ii) External effective dose equivalent [H(E,e)] applies to external partial or whole body exposure and is taken as the sum of the products of the dose equivalent [H(T)] to the organ or tissue (T), the weighting factors [w(T)] applicable to each of the body organs or tissues irradiated, and the applicable fraction of the organ or tissue irradiated from external sources. [Σ F(T)w(T)H(T)]

(iii) Same as current (ii)

(iv) Same as current (iii)

20.201 Occupational dose limits for adults

(a) ***

(1) ***

(i) The sum of the (external) deep dose equivalent **and the external effective dose equivalent** and the (internal) committed effective dose equivalent from exposures....

(ii) The sum of the (external) deep dose equivalent **and the external effective dose equivalent** and the (internal) committed dose equivalent....

(2) The **sum of the** (external) deep dose equivalent **and the external effective dose equivalent** component....

(3) ***

(i) ***

(ii) .... This limit applies to the dose equivalent averaged over 100 square centimeters in the region of highest exposure.

February 7, 1986

20.202 Compliance with requirements for summation of external and internal doses.

If an individual is occupationally exposed at levels exceeding 10% of the **sum of the** (external) deep dose equivalent **and the external effective dose equivalent** and **10%** of the (internal) annual limit on intake (ALI) of radioactive material, the licensee shall demonstrate compliance with the annual dose limit by summing the deep dose equivalent **and the external effective dose equivalent** and the committed effective dose equivalent. If the **sum of the deep dose equivalent and the external effective dose equivalent** is less than 10% of the annual limit, or if the committed effective dose equivalent is less than **10%** of the annual limit, the dose need not be summed.

(a) Because the actual dose equivalent cannot be measured directly, the licensee may use the individual monitoring data or other radiation measurements if these data or data or measurements yield, or are adjusted to yield, a value to yield, a value that is not less than the deep dose equivalent in the region of highest exposure to the whole body of an individual. **The licensee may use dose equivalents other than the deep dose equivalents when it is more convenient to reasonably determine the effective dose equivalent from external sources to an individual if physical factors for the exposure are known, and if there exists sufficient information to estimate with reasonably accuracy the approximate external effective dose equivalent to the individual on the basis of data and factors available from scientific authorities. The licensee may adjust the dose equivalent for partial body exposures to estimate the external effective dose equivalent under the conditions in this paragraph on the basis of data and factors available from scientific authorities.**

(b) ***

(1) ***

(i) If the sum of the (external) deep dose equivalent **and the external effective dose equivalent fraction of the annual effective dose equivalent limit** and the sum of the fractions of the ALI by inhalation of each radionuclide during the year do not exceed unity (see....

(ii) If the sum of the (external) deep dose equivalent **and the external effective dose equivalent fraction of the annual effective dose equivalent limit** and the sum....

(iii) If the sum of the (external) deep dose equivalent **and the external effective dose equivalent fraction of the annual effective dose equivalent limit** and the sum....

20.203 Further provisions - external exposure.

(a) through (d) ***

Add the following new paragraph:

(e) The annual dose equivalent limit to the skin and to each of the extremities and the annual dose equivalent limit to the eye is based on the annual shallow dose equivalent and the annual eye dose equivalent respectively. If it is more convenient to reasonably determine the dose equivalent to the skin relative to the tissue at risk (such as in the case of dose equivalent of the skin caused from external contamination of the skin) and physical and biological factors and parameters for the exposure are known and if there exists sufficient information to estimate with reasonable accuracy the approximate dose equivalent to the skin the licensee may use such equivalency or methods other than the shallow dose equivalent on the basis of these physical and biological parameters.

20.208 Dose to an embryo/fetus.

(a) ***

(b) The effective dose equivalent to an embryo/fetus is the sum of -

(1) The deep dose equivalent of the pregnant woman. If it is more convenient to reasonably determine the external effective dose equivalent to an embryo/fetus relative to the delivered maternal deep dose equivalent or from air exposure rate at some reference point, if physical factors for the exposure are known, and if there exists sufficient information to estimate with reasonable accuracy the approximate external effective dose equivalent to the embryo/fetus, the licensee may use such equivalency methods other than the actual maternal deep dose equivalent to calculate the dose to the embryo/fetus on the basis of either the delivered maternal deep dose equivalent or from air exposure rate at some reference point; and"

(2) ***

Delete the following from Note "2" pretaining to this paragraph:

"... and are approved by regulatory authorities for use by licensees."

20.304 Collective dose evaluations.

Doses to individual members of the public receiving 0.010 rem (0.10 mSv) or less in a year and collective doses of 100 man rem (1 Sv) or less in a year may be omitted in collective dose evaluation to prevent unwarranted commitment of resources for

controlling or regulating exposures at levels where calculated risks are negligibly small **and undiscernible from natural background exposures.**