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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of	)	
	)	**Docket No. 30-31373-CivP**
CONAM INSPECTION, INC.	)	
	)	
(Order Imposing Civil Monetary Penalty)	)	**ASLBP No. 98-735-01-CivP**

CONAM'S SUBMISSION ON THE "LEGAL" WHOLE BODY DOSE DEFINITION

In its June 4, 1998 Order, the Board requested that the parties provide submissions which address the distinction drawn by Monte Phillips (NRC Chief of Materials Inspection, Branch 2) between "the legal definition of whole body dose and the whole body dose" (Phillips' Dep., May 14, 1998, p. 134), and the relation of those two concepts to the dose determination recommendations in ICRP Publication 26.

I. INTRODUCTION

This concerns a paradox and a footnote. Mr. Phillips' statement suggests a paradox -- that the NRC's required dose assessment procedures are different from, and lead to results contrary to, procedures dictated by good science and ICRP Publication 26. That paradox is possible, but not required, by virtue of a footnote to the definition of "weighting factor" in 10 CFR §20.1003. This panel must choose whether to permit the paradox to apply in this case.

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The definition of "weighting factor" in 10 CFR §20.1003 provides weighting factors by which exposures to discrete organs can be converted and cumulated to a "whole body effective dose equivalent." When the 10 CFR Part 20 regulations were issued, there did not exist an industry consensus on specific weighting factors that would be applicable to non-uniform external exposures that irradiate only portions of organs, like the exposure to Mr. Chastain's thigh in this case. As a result, a footnote to the "weighting factor" definition provides that,

> For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, W_T=1.0 has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

Thus, the regulations provide a "default" weighting factor of 1.0 for any external exposure to a part of the whole body.

This "weighting factor of 1.0" system may have been a conservative statement of the best available methodology at the time the regulations were adopted. But it has all the scientific subtlety of trying to perform microsurgery with a butter knife. The 1.0 weighting factor assumes that, for risk purposes, an exposure to a particular body part is the equivalent of a uniform exposure to the whole body. Such an assumption is directly contrary to the fundamental principles of ICRP Publication 26, and can lead to absurd results. For example, in this case, NRC Enforcement says that its "best estimate" of the exposure to a small part of Mr. Chastain's thigh, and therefore "legally" to his whole

body, is 34 rems, when the NRC knows from Chastain's blood tests that his actual whole body exposure could not have exceeded 20 rems. For this reason, NRC Enforcement candidly acknowledges that assessing a whole body dose equivalent based on a dose to the "radiographer's thigh may not be an appropriate indicator of biological effects."[1]

But the "default" 1.0 weighting factor applies only where other appropriate weighting factors are not available. Appropriate factors are now available in the form of the ANSI N13.41 standards, though NRC Enforcement will ask this panel to ignore them. Those weighting factors avoid the paradox of having regulations that require dose assessments for which there is no scientific basis. This panel must decide whether Mr. Phillips' paradox will apply in this case by choosing whether to apply the unscientific 1.0 default weighting factor (thereby giving Mr. Chastain the false impression that he is at risk from the exposure), or the ANSI N13.41 factors as permitted by the regulations.

Section II of this submission describes the historical basis of ICRP Publication 26 and its place in the federal regulatory structure under the 1987 Radiation Protection Guidelines to Federal Agencies For Occupational Exposure. Section III discusses how the ICRP Publication 26 standards were translated into the regulations in 10 CFR Part 20, and how Mr. Phillips' paradox is possible. Finally, Section IV describes the ANSI N13.41 standards that moot Mr. Phillips' distinction between a "legal" and an "actual" whole body dose in the instant case.

[1] NRC Order Imposing Civil Penalty, p. 4.

II. HISTORICAL ANTECEDENTS OF 10 CFR PART 20: ICRP PUBLICATION 26 AND THE GUIDANCE FOR FEDERAL AGENCIES

A. ICRP 26 Predicts Risk Based On Assumed Whole Body Exposure

In 1977, the International Commission on Radiological Protection issued its Publication 26[2] ("ICRP 26"), containing a system of dose limitation designed to protect occupational workers from the deleterious effects of radiation exposure, while at the same time allowing to proceed appropriate and beneficial activities involving irradiation. The "baseline" for this system was a set of risks of stochastic effects resulting from an assumed uniform exposure of a person's "whole body." Of course, many radiation exposures are not uniform. Thus, ICRP 26 specified the use of a weighting system, by which non-uniform exposures could be "converted" to "whole body dose equivalents." Once so converted, the risk of stochastic effects could be predicted based on the available data for uniform whole body exposures.

The weighting system is a way of comparing "apples and apples" rather than "apples and oranges" when assessing the risk of stochastic effects from a non-uniform exposure to radiation. To do this, the weighting factors serve a translation function, converting data on a non-uniform radiation exposure to a uniform whole body dose equivalent. This relationship may be expressed as:

$$\sum_{T} W_T H_T = H_{wb}$$

[2] International Commission on Radiological Protection, Publication 26, "Recommendations of the ICRP," January 17, 1977.

where W_T = a weighting factor representing the proportion of the total stochastic risk *when the whole body is irradiated uniformly* to the stochastic risk resulting from the irradiation of tissue (T), H_T = the committed dose equivalent in tissue (T), and H_{wb} = the dose equivalent from a uniform irradiation of the whole body. ICRP 26 recommends an annual limit of five (5) rems for uniform irradiation of the whole body ("$H_{wb, L}$"), which may be expressed as requiring that

$$\sum_{T} W_T H_T \leq 5 \text{ rems}^3$$

In this fundamental principle of dose limitation, the ICRP makes a clear distinction between the concept of *whole body* and the concept of *portions of the body*. However, ICRP 26 does not distinguish between internal (*i.e.,* source is inside the body) and external (source is outside the body) radiation *exposures*. In fact, the only occasion in which the maximum measured dose equivalent in a portion of the body may be considered representative of the dose equivalent to the whole body is when the radiations of interest are penetrating, and "when information is lacking concerning the actual distribution of dose equivalent in the body."[4]

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[3] ICRP Publication 26, paragraph 104 (1987 reprint).

[4] ICRP Publication 26, paragraph 108 (1987 reprint).

B. The Federal Radiation Protection Guidance[5]

In 1987, President Reagan issued the Federal Radiation Protection Guidance for Occupational Exposure (the "FRPG"), expressly incorporating as the basis for federal policy and regulation, the ICRP 26 system of risk measurement and assessment. That document reflected the state of current research and standards development then available: it specified weighting factors for internal organs (*e.g.*, the liver), but none for non-organ parts of the "whole body."

The FRPG system of dose limitation incorporates the dose weighting system introduced in ICRP Publication 26. The FRPG says that ICRP 26

> . . . assigns weighting factors to the various parts of the body for the risks of lethal cancer and serious prompt genetic effects; these factors are chosen so that the sum of weighted dose equivalents represents a risk the same as that from a numerically equal dose equivalent to the whole body.[6]

Because ICRP 26 recommended that the *weighted* dose equivalent incurred during any year by an individual be limited to five (5) rems, and because the federal regulatory agencies concurred with this recommendations, the FRPG adopted the ICRP 26 standard:

$$\sum_{T} W_T H_T \leq 5 \text{ rem}$$

where W_T and H_T are defined as above. Like the ICRP, the FRPG recommendations do

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[5] Federal Register, Vol. 52, No. 17, Presidential Documents, "Radiation Protection Guidance to Federal Agencies for Occupational Exposure," January 27, 1987.

[6] FRPG, page 2827, paragraph 3, January 27, 1987.

not distinguish between internal and external exposures, and they state that the dose equivalent to a portion of the body is equal to the dose equivalent to the whole body *only when there is uniform irradiation of the whole body* (*i.e.*, when H_T is assumed to be the same for *each* organ and tissue).[7] The FRPG specifies the use of weighting factors in all cases of non-uniform radiation exposure.

III. THE STRUCTURE OF 10 CFR PART 20 IS BASED ON ICRP 26

In 1991, the radiation protection standards created in 1977 ICRP 26 and the 1987 FRPG were incorporated into new regulations found in Title 10, Code of Federal Regulations, Part 20 ("10 CFR Part 20"). In a 1992 Statement of Consideration regarding its Standards for Protection Against Radiation,[8] the NRC said that 10 CFR Part 20 was being modified to ensure consistency with the changes in scientific knowledge and philosophy regarding radiation protection that appeared in ICRP 26. It was this version of 10 CFR Part 20 which was in effect at the time of Mr. Chastain's alleged exposure.

A. The Regulations Provide For Use Of Weighting Factors

The 10 CFR Part 20 regulations adopt the structure of ICRP 26, in that they create a risk measurement system based on assumed "whole body" uniform exposures. The

[7] FRPG, page 2831, paragraph 2, January 27, 1987.

[8] U.S. Nuclear Regulatory Commission, "Standards for Protection Against Radiation," 56 FR 23360, May 21, 1991.

regulations require that data regarding any non-uniform exposure be "converted," by the use of weighting factors, to the equivalent of a uniform whole body dose[9]. So converted, the data can then be assessed for risk or compliance with radiation dose limits. The use of weighting factors for all types of non-uniform exposures, both internal and external, is required by these regulations. In this respect, the 10 CFR Part 20 regulations are consistent with ICRP 26 and the FRPG.

B. Weighting Factors For Internal vs. External Exposures

The regulations specify, in the definition of "weighting factor,[10]" weighting factors direcctly applicable to non-uniform internal exposures, but do not specify weighting factors directly applicable to non-uniform external exposures. The reasons for the absence of such weighting factors are simple: (1) neither ICRP 26 or the FRPG drew a distinction between internal and external exposures, and (2) there were not, as of 1991, consensus industry standards for weighting factors to be employed for non-uniform external exposures.[11]

In the absence of such industry consensus standards, the drafters of the regulations were forced to do something simple and crude, to remain in place only until consensus

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[9] The use of weighting factors is required by the definition of "Effective Dose Equivalent" in 10 CFR §20.1003, as "(H_E)the sum of the products of the dose equivalents to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma\ W_T\ H_T$)." That the use of weighting factors is intended to "convert" data on non-uniform exposures into the equivalent of uniform whole body exposures is made clear in the definition of "weighting factor." "*Weighting Factor* (W_T) for an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly."

[10] 10 CFR §20.1003.

[11] "However, none of the principal standard-setting organizations has included specific recommendations for the use of weighting factors for external dose." 56 Fed. Reg. 23360 (May 21, 1991).

industry standards became available. For non-uniform external exposures, the regulations provisionally required that (1) the deep-dose equivalent (the measure of an external exposure) be "for the part of the body receiving the highest exposure[12], and (2) the "weighting factor" applied to that exposure be 1.0, unless other weighting factors were available and approved. This weighting factor, and its provisional (to be used only if nothing better was available) nature, are specified in a footnote to the definition of "weighting factor:"

> For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, W_T=1.0 has been specified. *The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.*

10 CFR §20.1003 (emphasis added).

The drafters of this important footnote recognized two important points: (1) appropriate weighting factors could be developed either on a case-by-case basis or for general application, and (2) when generally applicable weighting standards for parts of the "whole body" were so developed, the regulations should incorporate them. The implication of this provision is that NRC approval would be forthcoming on a case-by-case basis as long as the specific weighting factors that a licensee proposed to use were technically sound and consistent with the underlying bases for 10 CFR Part 20 (*i.e.*, ICRP 26 and the FRPG).

[12] 10 CFR §20.1201(c).

C. Mr. Phillips' Paradox

The provisional 1.0 weighting factor for non-uniform external exposures (stated in the footnote to the "weighting factor" definition) makes possible Mr. Phillips' paradox. The paradox is that the regulations could, even provisionally, permit the use of outrageously bad science that is also entirely inconsistent with ICRP 26 and the FRPG.

The central premise of the 1.0 weighting factor is to treat a limited exposure to a small part of the whole body as if it presented a risk equal to that of a uniform exposure to the whole body. That equation is directly contrary to the central principle of ICRP 26 and the FRPG, which holds that the risk from an "x" rems limited exposure to a small part of the body is *not* equal to the risk from a uniform "x" rems exposure to the whole body. That non-equality is why ICRP 26 requires the use of weighting factors. The 1.0 provisional weighting factor is no weighting factor at all.

Naturally, the 1.0 weighting factor can lead to absurd results. The most obvious example is the one Mr. Phillips was talking about when he made the distinction here at issue between an "actual" whole body dose and a "legal" whole body dose. NRC Enforcement here calculates that Mr. Chastain's thigh received somewhere between 6.6 and 86 rems of radiation exposure[13], with its "best estimate" being 34 rems. Using that "best estimate," and the 1.0 weighting factor, the NRC comes up with an effective dose equivalent for Mr. Chastain -- the assumed equivalent of a uniform whole-body exposure

[13] This is not unlike a weather forecaster predicting that the temperature tomorrow will be between 6 and 86 degrees. It may or not be right, but the very breadth of the range causes one to question the underlying scientific basis for the prediction.

-- of 34 rems. But the blood test performed on Mr. Chastain immediately following the incident in question shows that his actual whole body dose was less than 20 rems[14]. What the NRC Enforcement calls its "best estimate" thus leads to a "legal whole body dose" (in Mr. Phillips' parlance), that is, from a scientific standpoint impossible -- an absurd result.

The mischief of the 1.0 weighting factor is perhaps even more serious when one considers its effect on Mr. Chastain. If the teachings of ICRP 26 are carried out by using the appropriate weighting factors now available, it is clear that Mr. Chastain received a total effective dose equivalent of less than 3 rems, presenting no known risk of stochastic effects. But NRC Enforcement, using a methodology for which there is little scientific basis (the 1.0 weighting factor), wants to tell Mr. Chastain that he may have received a total effective dose equivalent of up to 86 rems, a figure that carries with it a genuine risk of stochastic effects. NRC Enforcement can tell this to Mr. Chastain only by ignoring the central premise of ICRP 26: that an exposure of "x" rems to only part of the whole body (*i.e.*, a non-uniform exposure) creates less of a risk of stochastic effects than a uniform exposure of "x" rems to the whole body. NRC Enforcement's uncritical insistence on using what it acknowledges to be a scientifically blunt tool, when far more precise tools are available, represents merely bad policy for the country and an unfair result for Conam. More importantly, it is highly unethical in its effect on Mr. Chastain.

[14] As Mr. Phillips explained in his deposition, the blood test does not admit to any greater level of certainty than to say that the whole body effective dose, if any, was between 0 and 19 rems.

NRC Enforcement seeks to have this panel adopt that blunt tool, that bad policy, that unfairness, and that unethical effect, by deciding this case based on what Mr. Phillips calls a "legal" whole body dose rather than the "actual" whole body dose that would be calculated with appropriate weighting factors.

Fortunately, appropriate weighting factors are available, in the form of consensus industry standards adopted by the American National Standards Institute, Inc. ("ANSI"). This panel has the power to approve using those weighting factors.

IV. ANSI N13.41 SPECIFIES TECHNICALLY SOUND, INDUSTRY CONSENSUS, WEIGHTING FACTORS CONSISTENT WITH ICRP 26 AND THE FRPG

A. The Creation of ANSI N13.41 Weighting Factor Standards

In 1994, the Health Physics Society (HPS) Standards Committee appointed a subcommittee to, among other things, recommend a methodology for determining the effective dose equivalent in cases of non-uniform irradiation of the whole body. The subcommittee compiled a series of external dose weighting factors that use the same organ weighting factors that appear in 10 CFR Part 20.[15] The approach used by the subcommittee for deriving and applying the new external dose weighting factors was consistent with both ICRP 26 and the FRPG.[16]

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[15] 10 CFR §20.1003, definition for "weighting factor".

[16] ANSI N13.41, Appendix A.

Once the draft standard was prepared, it was reviewed, balloted, and approved by the ANSI-accredited HPS N13 Committee on June 20, 1996. At the time of balloting, members of the following organizations were represented on HPS N13: The American Chemical Society, the American Industrial Hygiene Association, the American Iron and Steel Institute, the American Mining Congress, the American Nuclear Insurers, the American Nuclear Society, the American College of Occupational and Environmental Medicine, the Conference of Radiation Control Program Directors, the Edison Electric Institute, the Health Physics Society, the Institute of Electrical and Electronic Engineers, the Institute of Nuclear Materials Management, the National Council on Radiation Protection and Measurements, the Nuclear Management and Resources Council, the U.S. Department of Commerce, the U.S. Department of Energy, the U. S. Department of Defense, the U.S. Environmental Protection Agency, **the U.S. Nuclear Regulatory Commission**, the U.S. Public Health Service, the U. S. Navy, the Oil Chemical and Atomic Workers International Union, and a variety of individuals.[17]

The standard was subsequently approved for publication by ANSI on December 3, 1996, and it became available for distribution in January, 1997 as "Criteria For Performing Multiple Dosimetry," HPS N13.41 ("ANSI N13.41").[18]

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[17] ANSI N13.41, page 6.

[18] American National Standards Institute, Inc., "Criteria for Performing Multiple Dosimetry," HPS N13.41, 1997.

B. The New Weighting Factors For Non-Uniform Radiation Dose Assessment

The ANSI N13.41 factors take the original ICRP 26 weighting factors, and redistribute them among portions of the "whole body" referred to as "compartments." Each compartment, of course, contains parts of what are otherwise classified as "organs," *i.e.*, the thigh contains fractional portions of the body's bone surface and red bone marrow. Thus, the ANSI N13.41 factors redistribute the ICRP 26 weighting factors to the "compartments," based both on the type and amount of "organ" tissue within the "compartment."

The ANSI N13.41 weighting factors are nothing new, but simply a restatement of the organ weighting factors stated in 10 CFR §20.1003, apportioned among the various compartments of the body. The assumptions of organ size, shape and placement are identical to the assumptions used in the ICRP 26 and 10 CFR §20.1003 weighting factors. The ANSI N13.41 weighting factors represent a practical system for applying the existing weighting factors, using current scientific knowledge about the relationship between radiation dose and risk of stochastic effect.

C. The ANSI N13.41 Standards Should Apply In Mr. Chastain's Case

This panel has the power to approve the use of the ANSI N13.41 weighting factors in its assessment of the radiation dose that may have been incurred by Mr. Chastain. It should exercise its discretion to do so because:

- the intended use of the external dose weighting factors in the ANSI N13.41 is to permit the comparison of partial body irradiations to regulatory dose limits applicable to irradiation of the whole body.
- the factors have received broad-based industry and government approval,
- they meet the letter and intent of the ICRP 26 and the FRPG,
- they are equivalent to the weighting factors that appear in 10 CFR Part 20, and
- they are precisely the type of reliable standards anticipated by the footnote to the "weighting factors" definition in 10 CFR §20.1003.

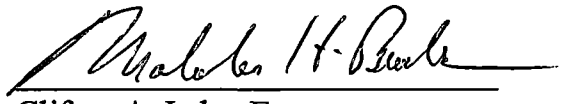
Failing to use the ANSI N13.41 weighting factors permits an enforcement process likely to lead to an scientifically absurd, and humanly unethical, results. There is no reason for NRC Enforcement to tell Mr. Chastain that he bears a significant risk of stochastic effects when this is simply untrue. Where scientifically precise weighting factors consistent with the years of careful study that went into the establishment of the ICRP 26 recommendations are available, this panel should approve the use of those factors.

CONCLUSION

Mr. Phillips identified a *potential* paradox: that the method legally required to determine compliance with radiation safety standards has nothing to do with the actual risk to the exposed worker. This panel should not permit that paradox to apply in this case, but rather should apply the ANSI N13.41 weighting factors to reach a scientifically defensible decision.

Respectfully submitted,

CONAM INSPECTION, INC.



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BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

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CONAM INSPECTION, INC.	)	
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CERTIFICATE OF SERVICE

I hereby certify that copies of **CONAM'S SUBMISSION ON THE "LEGAL" WHOLE BODY DOSE DEFINITION** in the above-captioned proceeding have been served on the following by deposit in the United States Mail, First-Class, (also via email where indicated) this 21st day of August, 1998.

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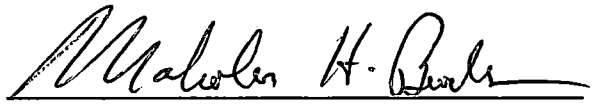

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Dated: August 21, 1998