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Sent: Tuesday, December 04, 2001 3:54 PM
To: NIOCINDOCKET@CDC.GOV
Subject: Comments on 42CFR81

Attached file.

Frank Roddy

12/6/2001

Comments on 42CFR81:

The Probability of Causation calculations using the NIOSH computer code (NIOSH-IREP) are too conservative for use in determining whether or not workers should be paid benefits.

In performing the calculations with NIOSH-IREP, the dose to achieve the criteria for paying the claim for lung cancer for heavy smokers is a factor of 2 times the dose needed for a person who never smoked. This factor for taking smoking into account does not seem reasonable. In reality, data shows that heavy smokers are 30 times as likely to contract lung cancer as people who have never smoked. Therefore, it appears that the probability of causation calculation program used by NIOSH is a factor of 15 conservative in this aspect for lung cancer. The program calculates as much as a 27% adjustment in the probability of causation for smoking for persons who have never smoked.

The NIOSH-IREP code uses the radiation weighting factors from a paper prepared for NIOSH under contract. The radiation weighting factor for alphas in that paper is as high as 40. At a recent ICRP meeting on Nov. 12, the ICRP indicated that they are intending to reduce the weighting factor for alphas to 10 from 20 which is the current factor. NIOSH is acting contrary to ICRP by raising the alpha weighting factor while ICRP is lowering it. This results in the introduction of a factor of conservatism of 4 in the NIOSH-IREP code for isotopes such as plutonium 239.

NIOSH uses the 99% confidence interval for claim determination. This means that there is only a 1% chance that the person's dose is greater than this. This adds considerable conservatism to the calculation. In some calculations using NIOSH-IREP (e.g., lung cancer), a 1% increase in dose causes a factor of 14 increase in the probability of causation. This does not appear to be reasonable. This feature of the program can cause as much as a factor of 14 in conservatism.

Combining all 3 factors: $15 \times 4 \times 14 = 840$. This level of conservatism is not justified for use in determination of the validity of claims for causation of cancer. The program needs thorough scientific peer review before it becomes part of the final rule or is used for disbursement of funds.

The paper from which the radiation weighting factors are taken and the NIOSH-IREP program have not been peer reviewed or approved by scientific consensus bodies. The existing 10CFR835 and 10CFR20 are based on reports by scientific consensus bodies. By attempting to establish new standards for radiation protection in direct conflict with the existing ones, the NIOSH-IREP program severely undermines the aforementioned regulations. A thorough peer review and scientific consensus body approval of this program and its underlying assumptions is mandatory before it can be finalized and used for payment of claims to individuals. The proposed rule cannot be finalized prior to this thorough scientific review and approval of the documents which form the bases for the rule.