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Dr. Stewart Schneider
U.S. Nuclear Regulatory Commission
Division of Regulatory Applications
Office of Nuclear Regulatory Research
5650 Nicholson Lane, N-007
Rockville, Maryland 20852

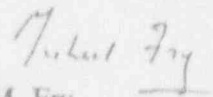
Dear Dr. Schneider:

I enclose my review of the work carried out under contract with NRC on "Beta Ho-Particle Confirmation Research" and proposed new studies.

I enjoyed the meeting and I thought the exchange of information was not only interesting, but allowed an informed assessment of the proposal.

Please call me if you have any questions.

Yours sincerely,



R. J. M. Fry

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Enclosure: 1

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Review of Proposal for Hot Particle Studies
to be carried out by Drs. J. W. Baum, A. L. Carsten,
and D. G. Kaurin, at Brookhaven National Laboratory

Background

Despite the studies on the effects of hot particles on the skin of a human volunteer, monkeys and pigs, there remain questions about the dose-response relationships and threshold doses in relation to the characteristics of the particles, for example, the energy of the emission. The current recommended limits by ICRP and the policy of the Nuclear Regulatory Agency apparently result in considerable expenditure and some disruption of the work patterns in nuclear power stations.

There is a significant difference in the recommended exposure and dose limits between that of ICRP 60 and 10 CFR 20, 0.5 Gy/cm², and NCRP 10¹⁰ particles or βq sec. or about 3-6 Gy/cm². The estimates of the threshold doses for hot particles left a number of critical questions unanswered. For example, was the dosimetry in the studies accurate and appropriate, and was the lesion, especially the severity of the lesion, the same in studies from which results were being compared?

Brookhaven National Laboratory (BNL) Studies

Having analyzed the studies, and particularly the dosimetry, carried out in the U.S. and U.K., the BNL group has studied the dosimetry and effects of radiation from three sources; UC₂, TM-170 and Yb-175, giving a range of energy from ~2 MeV down to ~0.5 MeV.

These studies have highlighted some of the complexities and the uncertainties in the study of the effects of hot particles and in the determination of threshold doses. For example, the problems of using ulcer diameter as a function of beta particles or dose averaged over 1 cm² at 70 μm depth, the influence of the age of the pig, and the period over which the assessment of ulcer or scab formation is assessed. The finding that the apparent threshold dose varied from 2.2 Gy to 0.5 Gy, depending on the length of the period of observation suggests that there are some very fundamental aspects of radiation-induced ulceration that are not known or, as yet, taken into account. The experiments with Yb-175 were a good idea but the results are equivocal but suggest a finding of considerable importance.

Recommendations based on the Work Proposed

In general, the proposal is modest in size and scope, perhaps too modest considering the problem.

1. It is clear that a sufficient number of exposures to determine the threshold for radiations from the various proposed sources, including UC₂, should be carried out so that thresholds, with acceptable estimates of error, can be determined. The thresholds for radiations of relevant energies are required and the influence of the particle being on the surface of the skin or not directly on the skin should be determined. Both the number of areas exposed and the number of pigs should be sufficient to reduce the errors, including interanimal variation. Control areas must be included in the assessment. The assessments should be carried out over a sufficiently long period of time to ensure that lesions appearing later than one month are not missed.

2. There appears to be a critical need for histopathological studies of the lesions in relation to dose, age and time of appearance. There needs to be a correlation between the macroscopic appearance and the histology in relation to the variables mentioned above. For analyses data should be stratified based on the type of scab and related to the variables.

One wonders whether the thickness of the keratin layer accounts for the age-dependent differences in responses. The application of the data for pigs to humans depends on understanding the factors, including age, involved in the induction of ulcers by radiation. The histopathology and a critical classification of the macroscopic lesions seem necessary prerequisites for pooling data from the different studies, which, of course, should be done.

3. The comparison of dosimetry data from the various studies is also a prerequisite for pooling data.

4. The intercomparison of the methods of dosimetry is strongly recommended.

5. Investigation of methods of analysis is recommended. Has the expertise amongst biostatisticians been fully exploited?

6. It was a very sensible and productive idea to hold the previous workshop, and another one at the most appropriate stage of the proposed studies should be held.

In summary, the BNL group has demonstrated its capability to carry out the required studies and it has approached the problem of "hot particles" in a systematic and logical manner. I think that it is essential that in the next series of experiments that a sufficient number of pigs and exposures are made. Now is the time to obtain the data required to settle the question of hot particles once and for all.