

April 25, 1972

John R. Totter, Director  
Division of Biology and Medicine

THRU: W. W. Burr, Jr.

MISADMINISTRATION OF <sup>32</sup>P IN A PATIENT

A meeting on the subject matter was attended by me, as a DEM representative, at the request of the Division of Compliance (Enclosure 1). In addition to those noted in this enclosure, Dr. J. Workman of Duke and James Quinn of Wesley Memorial Hospital, Chicago, came as representatives of Mr. Cunningham's Medical Advisory Committee.

Agendas were distributed at that time to the attendees (Enclosure 2). Questions to DEM from Division of Compliance, and initial clinical information reported by Dr. Thoma plus verbal clinical additions given at the meeting are noted (Enclosure 3). Two sets of specific questions compiled by the Division of Compliance were distributed (Enclosures 4 and 5). A set of dose calculations by Grove were also made available but were withdrawn for editing at the close of the meeting.

Briefly DEM's verbal position to the three questions submitted by the Director, Division of Compliance (Enclosure 3) follows:

- Question 1. Peritoneal administration of 30 millicuries of <sup>32</sup>P in a soluble form in the given situation was very likely to be lethal.
- Question 2. Acute hematopoietic radiation syndrome.
- Question 3. Essential agreement with Dr. Thoma's conclusions except that our calculations were somewhat lower (approximately 650 rad versus 900).

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FOLDER Misadministration of <sup>32</sup>P  
Detroit Osteopathic Hosp 5/72

Impressions to the best of my understanding of the highlights of the discussions, follow:

1. Mr. Low revealed that the current AEC regulations do not provide for mandatory disclosure and reporting in this type of incident since it pertains to patient therapy. Dr. Beck, however, countered this statement with one that AEC is responsible to protect the public but did not elaborate on this matter any further. Mr. Low informed us that Regulatory procedures are now being reviewed to possibly include the situation of radionuclide drug misadministration.
2. Dr. Beck followed these introductory remarks by stating the purposes of the meeting as, first to get a technical judgment in this case and second, to obtain advice on procedures for a public information release.
3. The questions on Enclosure 4 were disposed as follows:
  - a) It was the unanimous opinion of the medical consultants present that the dose of  $^{32}\text{P}$  as administered had a high probability of being lethal.
  - b) The second question proved somewhat troublesome. After a few starts it was concluded to reword the question so as to limit it to the terminal clinical features only, i.e., a depressed hematopoietic system and infection. No comment could be made on the latter because of the lack of information. As to the effect on the hematopoiesis there was reported a marked peripheral depression of the blood elements but the inconsistency of the high lymphocyte to granulocyte count introduced an element of doubt as to the level of confidence to be given to the hemogram. No bone marrow biopsies were done and autopsy was refused at the time of death. Likewise there was no information on any platelet counts. These apparent deficiencies become somewhat understandable in that a radiation death was not suspected until about one month (March 10) after the patient expired. The Health Physicist during a routine radionuclide inventory recognized the unusually large single dose of soluble phosphorus given to a patient and reported same to appropriate members of the hospital staff. The causes of death reported on the death

certificate were cardio-renal failure and carcinomatosis. Inadequate substantiating evidence was available to us for appraisal of the diagnoses. Thoma's opinion that the cardiac failure was due to the low hemoglobin and resultant hypoxia was accepted. Without belaboring this area further, I believe the final revised statement to this question was that the patient's terminal findings were compatible with a radiation death.

c) Complete absorption was assumed.

d) Grove presented a series of various calculations which varied, as one would expect, based on the assumptions used. At one point he also introduced, based on ICRP No. 10, a RBE of 5 for the beta energy of phosphorus. This resulted in a dose calculation of greater than 2,000 rem using his lowest estimate of rads. However, on closer examination of the ICRP by a few of us it was noted that the RBE referred to bone without distinction between mineral bone and marrow. In any case, this seemed somewhat academic in our discussions in view of the fact that the consensus was that the radiation absorbed dose to the marrow was in the order of 600 rads or more. Parenthetically, the Health Physicist of the hospital involved calculated a dose of 624 rads. It will be interesting to see the final minutes of this meeting on the dose calculation in view of the estimates presented to and withdrawn from the attendees.

e) The last question in this enclosure was essentially answered earlier; complete absorption was assumed with a high probability of resultant lethality.

4. The three questions on Enclosure 5 were dealt with in a spirited manner. It seemed that the answers to these questions had parts which were inextricably involved with each other. The discussions embraced philosophy, medical ethics, legality of privileged communications, AEC's responsibility for public and family notification, possibility that it may be inferred that AEC was suppressing information, and ideas as to the level of competence and training required for a license to administer specific radiopharmaceuticals.

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Conclusions:

1. There was an erroneous administration of sodium phosphate instead of colloidal chromic phosphate due to misidentification.
2. The dose (about 650 rad to the bone marrow) probably received by the patient is sufficient to cause a lethal outcome from radiation damage.
3. Clinical information available is generally compatible with a terminal hematopoietic syndrome.
4. Director, Division of Compliance, must decide on the manner of public disclosure and should notify the hospital in advance of any release in order to allow the physician the opportunity of notifying the family.
5. There is a need to reevaluate training criteria of physicians before granting of licenses.
6. Means should be found to publicize this accident in the medical professional literature so that it might contribute to the prevention of similar incidents in the future.

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Enclosures:  
As stated

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