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RECOMMENDATIONS
of the
SUBCOMMITTEE ON RADIATION THERAPY
of the
LAMPF BIOMEDICAL STEERING COMMITTEE

Meeting at LASL, July 14 - 17, 1971

A. Recommendations Regarding Pion Beam and Beam Line Parameters

In response to specific questions regarding beam line, the parameters defined below were suggested from the viewpoint of their desirability for radiotherapy. It is recognized that certain of these requirements may be mutually incompatible. For this reason, it is hoped that designers of the beam line may subsequently define for us any required trade-offs in quantitative terms, so that compromises in these important parameters, if they must be made, can be decided on the basis of a maximal amount of information.

For purposes of pion radiotherapy, the following definitions are recommended and used hereafter in this report:

Tumor Volume is that volume of tissue which the radiotherapist has identified as constituting the primary volume of tumor involvement.

Target Volume is that volume of tissue which the radiotherapist wishes to treat with high dose in order to encompass all known and suspected tumor areas with an appropriate margin of safety.

Treatment Volume is that volume of tissue which the radiotherapist must treat with high dose to insure that the entire target volume has been encompassed.

For pions, the target and treatment volumes should be nearly equivalent.

1. Dose uniformity within the target volume should be such that the variation in absorbed dose within the volume shall be no greater than ± 5%. A variation no greater than ± 3% is considered highly desirable.

2. It was emphasized that further planning of beam line and beam parameters should be based on detailed considerations of the actual geometries which will be encountered in tumor therapy. A comprehensive program of [illegible] three-dimensional treatment planning based on typical target volumes in [illegible] essential.

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Only in this way can maximum flexibility and utility of the beam channel design be insured. Such a program should be undertaken as soon as possible, using cross-sectional anatomical diagrams with representative tumor volumes identified thereon.

3. In order to accomplish the above program prior to availability of experimental data on the LAMPF beam, isodose curves generated by computational techniques of the type presently being explored by Turner, Wright, Hamm, and others at Oak Ridge should be encouraged and expanded. If these techniques are successful, they will make possible an enormous reduction in the amount of experimental dosimetric data required before initiating clinical trials.

4. The Committee noted that better cross-section data for plateau and stopping regions are required for the elements found in tissue for pion energies from a few MeV to slightly over 100 MeV/c. These will be especially important in generating dose distributions reflecting the extent of perturbations from tissues of different densities and compositions (tissue heterogeneity). Distributions should be calculated in three dimensions and compared with experiments when the latter are possible. Ultimately, it will be desirable to generate dose distributions in (a) absorbed dose, (b) LET distribution, and (c) (RBE x dose) distribution.

5. A minimum pion peak dose rate of 40 rads/min for a 15 x 15 cm field was considered highly important and nearly essential.

6. The maximum short-term and long-term variation in dose rate due to fluctuations beyond the control of the therapist should be as recommended by the Physical and Biological Dosimetry Subcommittee, i.e. less than ± 20% for any given field.

7. As a major priority item, a second pion beam line should be constructed before 1975.

8. Requirements for beam boundary sharpness.

The following definitions are to be used:

<u>Distal</u> - those portions of the target volume, or high-dose region, which are oriented roughly parallel to the beam direction.

<u>Proximal Surface</u> - that surface of the target volume or high-dose region which lies roughly normal to the incoming beam direction and is closest to the entrance port.

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Distal Surface - that surface of the target volume or high-dose region which lies roughly normal to the incoming beam direction and is most distant from the entrance port.

a) The absorbed dose at the edges of the target volume should decrease from 90 to 10% of maximal dose in less than 1.0 cm for a mean stopping depth of 20 cm.

b) The absorbed dose at the proximal surface of the target volume should decrease from 90 to 60% of maximal dose in less than 1.0 cm.

c) The absorbed dose at the distal surface should decrease from 90 to 60% of maximal dose in less than 1.0 cm and from 90 to 30% in less than 1.5 cm.

9. The muon contamination in the pion beam should be less than 4%. The electron contamination in the pion beam should be less than 10%.

10. The Committee agreed that scanning in depth in order to utilize the maximum number of incident pions to cover a target volume should be employed if it can be determined that this method results in satisfactory dose uniformity throughout the target volume at each treatment session. We understand that this will result in an increase in dose rate by a factor of approximately two compared with selecting a broad momentum distribution in order to spread the peak dose over the target volume. The effect of this approach on the RBE variation across the target volume should be investigated, especially at the proximal surface and proximal portions of the target volume where high LET effects may be present for only a fraction of the treatment time.

11. Other beam parameters were discussed and are virtually unchanged from those given in LA-4490-P:

Design Features	Maximum Value	Minimum Value
Field size*	15 x 15 cm**	4 x 4 cm
Maximum depth of distal surface of high-dose region	30 cm	
Minimum depth of proximal surface of high-dose zone without using bolus		0.0 cm
Peak width	12 cm	1.5 cm

*For fields up to 10 x 10 cm a nearly parallel beam is desired. For therapeutic purposes, this means a beam divergence at the treatment volume no greater than that from a point source of radiation viewed

at a distance ≥ 5 meters for a 10 x 10 cm field. For a field size of 15 x 15 cm, the beam divergence at the treatment volume shall be no greater than that from a point source of radiation viewed at a distance ≥ 3 meters. For fields larger than 15 x 15 cm, the divergence should be capable of being increased to that equivalent to a point source viewed at a distance of 50 cm.

**Without employing appreciable beam divergence and consequent reduction in dose rate. Geometric sharpness of the target volume should be preserved for field sizes larger than 15 x 15 cm, however, by use of the method of scanning in depth with essentially monoenergetic pions.

B. Recommendations Regarding the Biomedical Facility

The following recommended facility criteria are those necessary to carry on a clinical investigation program utilizing negative pi mesons. It is recommended that LASL personnel consider the design of the radiation therapy and radiobiology support areas based upon these criteria and to interact with the Radiation Therapy Subcommittee if trade-offs or compromises need to be made.

1. The Biomedical Facility should be oriented out of the congestion developing at and near the beam stop.

2. A staging room should be provided adjacent to the treatment rooms to handle the prestaging of four patients. There should be straight-line access from the staging area to each treatment room.

3. A 16 x 18 ft simulator room should be adjacent to the staging room.

4. A 20 x 18 ft mold room should be adjacent to the simulator room.

5. The control room should be close to the exposure rooms.

6. Design should be such as to ensure maximum separation of patient areas from those devoted to animal experiments, medical physics, and cellular radiobiology.

7. Five examining rooms of approximate size 10 x 12 ft should be available. One should be set up as a photographic facility and examining room.

8. Six offices should be provided:
   - Physicians, 2 each, 8 x 10 ft
   - Chief technician, 1, 8 x 10 ft
   - Head nurse, 1, 8 x 10 ft
   - Social service, 1, 8 x 10 ft
   - Receptionist, 1, 8 x 10 ft
   - Transportation, 1, 8 x 10 ft

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9. One 15 x 10 ft records office is required.

10. One 15 x 20 ft conference room is required within or at a short distance from the facility.

11. The facility should be pleasant looking, perhaps with decorations by local artists.

12. Stored equipment should not be readily visable to the patients.

13. Planned expansion of the above facility should be considered initially. For example, facilities for conventional x-ray and electron radiotherapy for treatment of control patients in a meson trial will be necessary. The latter facility will need to be designed to accommodate a high-energy accelerator of the type recommended by the Committee on Radiation Therapy Studies (NCI) survey on the new generation of medical accelerators.

C. Recommendations Regarding Cellular and Animal Radiobiology

Cellular and tissue radiobiology form the basic knowledge to which therapeutic strategies must be related. Knowledge of these effects which can be obtained before availability of the beam at LAMPF would be beneficial.

1. It is strongly recommended that support be given to preclinical biological studies including the effects on normal tissues which can be carried out using the π^- meson beam at Nevis because of the tremendous importance to the studies to be undertaken at LAMPF. Even though the dose rate is lower, these studies will provide useful information and give valuable experience in techniques and methods of study for those who will later undertake these investigations using the more intense beam at LAMPF.

2. It is very strongly recommended that statistically significant studies with concurrent RBE adjusted photon irradiated controls be performed at Nevis.

3. No studies should be undertaken at Nevis using combined modalities.

4. Fractionation of biological experiments at Nevis should utilize as many fractions as practical for the specific experimental system; then a smaller number of fractions for comparison. A suggestion was made that fractions be given every [illegible] hours, which may be close to clinical projections.

5. RBE's for fractionated meson doses may be reasonably close to those encountered for fast neutrons as reported by Stanley B. Field (Radiology [illegible], 915-920, October [illegible]).

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Recommendations Specifically for Cellular Work

6. It is suggested that the consideration of normal tissue systems, which can be assayed by skin or gut cell cloning or spleen colony forming units, is appropriate for the Cellular Radiation Biology Subcommittee.

7. No OER vs Depth studies should be undertaken at Nevis.

8. Recommendations for priority of cellular studies at Nevis:
   a. Mammallian cells (human, hamster, mouse)
      1. survival vs depth
      2. split dose studies
   b. Skin or gut colonies
   c. Slow growing mouse tumor system with fractionation

Recommendations Specifically for Animal Radiobiology:

9. It is recommended for the program at Nevis that long-term normal tissue effects be studied in systems in which there is a considerable past experience and which can be quantitated.

10. The most important tissue systems to be studied at Nevis are:
   a. Skin
   b. Spinal cord
   c. Cartilidge
   d. Heart

11. The study of LD_{50} following whole body irradiation in mice was felt to have low priority at Nevis.

D. Recommendations Regarding Isotopes and Diagnostic Applications

The LAMPF facility will have the unique capability of producing large amounts of isotopes which have not been previously available or available in only very limited quantities. Implementation of these new resources for nuclear medical applications should proceed without delay. It is strongly recommended on the basis of general medical considerations and those related to the use of isotopic methods of tumor localization, that the production and use of the new isotopes to be available from spallation reactions be given strong support at LASL.

Areas of immediate importance for development are:

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a. Visualization of the pion stopping region

b. Tumor localization

c. Isotope production and development of new radio pharmaceuticals

The diagnostic uses of mesons is recognized as being extremely important to the entire sphere of diagnostic medicine, however, it is felt that such techniques are not within the scope of the Radiation Therapy Subcommittee even though they are of a personal interest to individual members of the Committee.

Routine x-ray and nuclear medical services to support the clinical trials might best be purchased under contract from the local hospital. New development techniques should be done elsewhere at institutions willing to undertake studies of new and improved methods of tumor localization.

E. Recommendations Regarding Physical and Biological Dosimetry

The fields of radiologic physics and dosimetry are extremely important in radiation therapy because they provide the knowledge of quantity, quality, and distribution of the deposited dose. Besides the obvious efforts in dosimetry and beam diagnostics, there are several other areas in clinical physics that should be stressed:

a. absolute dosimetry-calorimetry

b. 3-D distributions of absorbed dose, LET and (RBE x dose)

c. external visualization of pion stopping region or tumor-seeking isotope distribution

d. dosimetry in body cavities and regions of tissue heterogeneity

e. new basic physical information such as improved cross sections for tissue elements, interface effects, investigation of a possible build-up region for pion ionization and/or protons at the skin surface, etc.

Visualization of the pion stopping region should have effort devoted to it by the Physical and Biological Dosimetry Subcommittee in order to coordinate studies of tissue heterogeneity, dose-depth distributions and other dosimetry areas.

F. General Recommendations

The Committee felt that since the overall goal for this effort is the utilization of negative pi mesons for radiation therapy, it is incumbent to

develop plans for the ultimate clinical trials as soon as possible. This will enable the other efforts in dosimetry, radiobiology, etc. to coordinate closely with the radiation therapy effort. The following set of recomendations related to clinical trials are by no means complete but represent a substantial start towards defining the ultimate program.

1. The Committee felt very strongly that, in addition to the preclinical studies, an organized clinical evaluation of pi mesons is required. It is important that when these clinical trials are undertaken, they be accomplished by staff and investigators who have spent considerable time in other more conventional clinical investigation or cooperative clinical trials, and that there be adequate patient control populations available. Thus, an institution with a history of excellence in clinical trials should undertake the coordination of the clinical investigations, and organize mobilization of the population of patients required for the clinical trials.

These clinical trials should be national in scope and should be organized through the Radiation Therapy Oncology Group, which has established mechanisms for setting priorities among the different national trials. In this way, effective cooperation between multiple institutions should be facilitated and ensured. It is, of course, necessary that the principal investigator conducting the clinical trials be fully aware of the preclinical biological and physics implications of pi meson therapy, and that a specific team under his direction be charged with direct responsibility for care of the patients and proper conduct of the clinical trials, with advice provided by this Committee (Radiation Therapy Subcommittee)or other duly constituted advisory group.

2. Effective communication with other groups interested in pion radiotherapy should be maintained with coordination in both preclinical stages and later clinical trials. Such groups include those associated with TRIUMF in Vancouver, British Columbia, SIN in Zurich, Switzerland, Stanford University in California, Brookhaven National Laboratory, New York, and others interested in newer radiations such as fast neutrons, heavy ions, etc.

3. It was unanimously agreed that eventual clinical trials must include the availability of a modern mega-voltage unit located on site in the Los Alamos area with the same team working on conventional and pion radiotherapy, thereby

ensuring homogeneity of staging, care, observation and follow-ups.

4. Patient treatment will start at LAMPF when the radiotherapists have sufficient information. This may occur in 19 . Human radiobiology will start earlier.

5. The Users Group concept does not appear to be an appropriate mechanism under which clinical trials can take place. It was designed for physics investigators who come for a time to perform specific experiments.

6. During the clinical trial phases, support should be sought for medical and other costs, including living expenses and transportation, over and above third party coverage.

7. During Phase I trials, patients rejected from other clinical trials should be sought as well as other referrals.

8. Phase II trials should receive support from the Radiological Physics Center, as do other national clinical trials coordinated by the Committee on Radiation Therapy Studies and/or the Radiation Therapy Oncology Group.

9. Fractionation schedule for clinical treatment may be 3-5 fractions per week over a 6-week period. The exact schedule will be determined after examination of data from experimental animal tumor systems, spontaneous tumors in animals and normal tissue responses in patients. The fractionation schedule need not be the same as for conventional radiations during the randomized prospective clinical trials phase.

10. Further recommendations for types of cases to be included in clinical trials will be forthcoming at later Committee meetings. Meanwhile, reference should be made to LA-4490-P, "A Proposal for a Biomedical Addition to the Los Alamos Scientific Laboratory's High-Flux Meson Physics Facility," pp. 132-134

11. Recommendations for clinical staffing are given below:

	FY 73	1974	1975
Radiotherapists	1*	2	3-4
Radiologic Physicists (MS and PhD)	1	2	3-4
Social Workers	0.5**	1	2
Secretories	2	4	6

	FY 73	1974	1975
Treatment Planning Technicians	0.5	1.5	2
Nurses	0.5	1.5	2
Treatment Technicians (including mold room)	0.5	1.5	4
Transportation Arranger	0.5	1	1
Orderlies	0.5	2	4
Clinical Photographer	0.5	1	1

*Two beginning January 1973.

**One beginning January 1973

G. Other Recommendations

1. Program plans and recommendations in all areas related to prethera-peutic and therapeutic work with negative pi mesons be published in order to elicit comments or criticism by other investigators.

2. It is recommended that Peter Fowler be invited to the next meeting.

LOS ALAMO: ENTIFIC LABORATORY
UNIV OF CALIFORNIA
LOS ALA: NEW MEXICO 87544

OFFICE MEMORANDUM

TO : R. E. Schreiber, Dir-Off. DATE: 20 May 1971

FROM : Louis Rosen

SUBJECT: SCHEDULED MEETING - SUBCOMMITTEE ON RADIATION THERAPY

SYMBOL : MP-DO

We are scheduling here a four day meeting of the Subcommittee on Radiation Therapy (see attached) for purposes of developing a plan which will guide us in design of beam-channel-related instrumentation and other equipment.

In accordance with our standard plans, which have been blessed by the DBM, we are proposing to pay travel and subsistence for these people. The only difference from previous meetings is that the duration will be longer, but this is well justified.

Louis Rosen

Att.

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SUBCOMMITTEE ON RADIATION THERAPY

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Alternate Chairman:

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David E. Groce
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P.O. Box 1393
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LH5 - attendees mtgs.

Out of town

RADIATION THERAPY SUBCOMMITTEE MEETING

July 14 to 17, 1971

Name	Organization
Dr. Malcom Bagshaw	Stanford Medical Center, Stanford, Cal.
Dr. Max L. M. Boone	Texas Medical Center, Houston, Texas
Dr. Joseph R. Castro,	M. D. Anderson Hospital, Houston, Texas
Dr. C. Chahbazian	Penrose Cancer Hospital, Colorado Springs, Co
Dr. Jack Dobson	Enviro-Med, Inc., La Jolla, Cal.
Dr. David E. Groce	JRB Associates, La Jolla, Cal.
Dr. R. N. Hamm	Oak Ridge National Laboratory, Oak Ridge, Ten
Dr. David Herring	Enviro-Med, Inc., La Jolla, Cal.
Dr. F. Bing Johnson	Dept. of Radiology, U. of Colo. Med. Center Denver, Colo.
Dr. Scott Jordan	School of Medicine, UNM, Albuquerque, NM
Dr. Richard E. Keesee	School of Medicine, UNM, Albuquerque, NM
Dr. Morton M. Kligerman	Yale Univ. School of Medicine
Dr. James J. Nickson	Michael Reese Hospital, Chicago, Ill.
Dr. Robert Powers	Shrine Hospital, St. Louis, Mo.
Dr. C. D. Pruett	Enviro-Med, Inc., La Jolla, Cal.
Dr. M. R. Raju	Lawrence Radiation Laboratory, Berkeley, Cal.
Dr. Robert J. Shalek	M. D. Anderson Hospital, Houston, Texas
Dr. and Mrs. Carl Shonk	School of Medicine, UNM, Albuquerque, NM
Dr. Doyle L. Simmons	St. Joseph Hospital, Albuquerque, NM
Dr. J. Robert Stewart	Univ. of Utah School of Medicine, Salt Lake City, Utah
Dr. Morris C. Taylor	Rice University, Houston, Texas
Dr. Paul Todd	Pennsylvania State University, Univ. Park, Pa
Dr. Carl Von Essen	University Hospital, San Diego County, San Diego, Cal.
Dr. Albert L. Wiley, Jr.	Univ. of Wisconsin Hospital, Madison, Wis.
Dr. Robert Wood	AEC, Washington, D.C.
Dr. H. A. Wright	Oak Ridge National Laboratory, Oak Ridge, Ten.

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Invited guest: Peter Allmon

SUBCOMMITTEE ON RADIATION THERAPY

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Ex officio Member

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INFORMAL SUMMARY

RADIATION THERAPY SUBCOMMITTEE

First Day, Wednesday, July 14, 1971

Morning Session

Louis Rosen, Director, LAMPF - Welcoming remarks

The accelerator is on schedule and budget

Biomedical facility stubout will be under construction soon

Interagency agreement between the AEC and NCI to provide $1 M for biomedical beam line -- January 1973

AEC's Division of Biology and Medicine is now providing support at LASL (MP, H-4, and H-9) for pretherapeutic pion research

The need is for a detailed plan for experimental programs leading to clinical trials

Dr. Edward Knapp is to head practical applications group at LAMPF, which will include biomedical; Dick Hutson and Arvid Lundy will form the core of an MP group

George Voletz, ~~Director~~, LASL Health Division

Group H-4, under Wright Langham, will deal in basic biology research

Group H-9, Chaim Richman, Group Leader with M. R. Raju, will be concerned with pion dosimetry and radiobiology

David Groce -

Organizational structure
(See LA-4586-MS and LA-4602-MS)

Max Boone, Chairman, Subcommittee

CRTS Report (High LET Subcommittee)

Priorities: (1) Cancer centers, (2) High LET radiation including neutrons and pi-mesons

Communication and coordinated efforts are important

Clinical trials to involve national group and experienced investigators

Possible meson biomedical facilities are:

LAMPF (800 MeV, [illegible] protons)
Low energy pion physics -- [illegible]
Biomedical -- [illegible]
Stanford ([illegible] electron) [illegible] rad/min (small vol.
[illegible]

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Berkeley: 184" cyclotron (720 MeV proton)
operational 1 rad/min
Bevatron (15 GeV proton) 3 months, 7 rad/min (20 cc)
1 year, x10 increase

Nevis (550 MeV, 25 μA proton) January 1972
10 rad/min (20 cc)

SIN, Zurich - proton - biomedical facility planned

TRIUMF, Vancouver (500 MeV, 100 μA proton) 1974

H. A. Wright (ORNL)

Pi-meson dose calculations
Joint effort with CERN
Calculations: ionization losses from tables
Monte Carlo for particle interactions
Secondary particle generation and transport
Star data from Guthrie calculation
No photon transport
Relative calculation - normalized at 10 cm
Adjust contamination parameters (e^- & μ^-).

Preprint passed out, "Some Studies in Pion Beam Dosimetry"
Data presented

Dean Robert Stone (UNM Medical School)

Cancer Center Planning

Albuquerque ought to have cancer center - geographical distribution
Relation with π^- trials not stipulated
Jack Dobson: Environ - med
Impact of therapy trials considerable on center
Problems in Southwest: Population and different incidence of cancer from national figures
Questionnaires: (1) Basic patient data
(2) Patient treatment data
Different cancer center models
Meson Questionnaire: 4600 physicians
600 ASTR
1500 'local' physicians
2500 radiologists west of the Mississippi
Greater than 400 returns on questionnaire

Afternoon Session

Chaim Richman

Possibility of biomedical research at Nevis cyclotron
Leon Lederman, Nevis Director, very encouraging
Draft proposals submitted to NSF, AEC, and NCI

CO...

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Mark Jakobson, University of Montana

LAMPF Low Energy Pion Physics Beam Channel, January 1973
Described in MP-7-10 (August 1970)
Changes to this document: $\Delta p/p = \pm 2\%$
Intensity x0.8 (perat
$5\% < (e^-/\pi^-) < 25\%$
may have separator
Ta degrader π^- x 1/4; (e^-/π^-) x 1/[illegible]
Horizontal Beam: ~8rads/min (1000 cc)

Statement from Ken Crowe (LRL)

Great interest at LRL
184" cyclotron still good for dosimetry
Bevatron - pion channel can be made available soon
10^7 π^-/sec, 10^8 π^-/sec with more work

Mal Bagshaw (Stanford)

Superconducting electron accelerator and "orange peel" spectrometer
500 MeV, ultimately, 1 mA
Niobium cavity problem
Spectrometer: 2.0 steradian acceptance
50-60 channels, each 30 rads/min
each volume: "sausage" or "mouse" size
spread out beam or scan, patient bolus(?)
Visualization Apparatus - Doug Boyd
multiwire proportional counter
12 x 12" now, whole body soon
excellent resolution

Charles Key, Chairman, Whole Animal Radiobiology and Pathology Subcommittee

Need input from Therapy Committee
Basic premise is to provide 'enough' radiobiology so that therapists can use pions with minimum hazard
How much is 'enough'?
Possibilities:
1) Early and late effects
2) Peak and plateau regions
3) Single and divided doses
4) Small and large volumes
5) Various organized tissues
6) Early acute effects in mice
7) Skin effects in swine or rabbits
8) Carcinogenesis
9) Low and high dose rates
10) Spontaneous tumors in dogs

First pathology experiment at Berkeley (with Raju):
3 mice: Peak at 4 hrs, 264 rads
Plateau at 4 hrs, 150 rads
Peak at 2 hrs, 132 rads
Spleen weight - end point RBE 2.0 - 2.5

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M. R. Raju, Chairman, Physical and Biological Dosimetry Subcommittee

Review of experiments at Berkeley
- LET, RBE, OER
- Dosimetry
- Biological 'stars' in chromosomes
- Survival curves

Subcommittee recommendations to be passed out

D. E. Groce
7/15/71

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