To:

Joseph A. Lenhard, Assistant Manager
for Energy Research and Development
ORO, DOE, Federal Building

FROM:

Herman Postma, Director
Oak Ridge National Laboratory
4500N, Room I-210, X-10

SUBJECT: WORK FOR CHILDREN'S HOSPITAL NATIONAL MEDICAL CENTER (ERD-86-574) (deleted version)

DATE: July 24, 1986

Reply Message

FOLD ▼

Reference Letters: Richmond to Lenhard, 4/16/86
Approved by ORO, 4/21/86

MESSAGE

Document Transmitted:

Agreement with the Children's Hospital National Medical Center (Center) covering the Center's support of an ORNL Health & Safety Research Division project on "Organ Dose in Pediatric Diagnostic Radiology" (K. F. Eckerman, M. Cristy, M. G. Yalcintas; $194,953).

Three executed originals of the above document are transmitted for your approval. If satisfactory, please return four copies (at least two originals) to me for distribution.

HP:ERB:bdp
Attachments - as stated

cc: G. W. Horde - RC
C. B. Landguth
C. R. Richmond

SIGNED: Herman Postma 7/23/86

REPLY

DATE OF REPLY: AUG 26 1986

REPLY TO: Herman Postma

Approved.

Attachment:
Agreement (4)

cc w/atchmt:
W. P. Snyder, CC-10, ORO

Original Signed By
Susan S. Waddle

SIGNED: William R. Bibb, Director
Research and Waste Management Div.

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CONCURRENCES											
RTG SYMBOL	SPRADLEN		DUNAWAY		POSTEAN						
DATE	7/31/86		7/31/86		7/31/86						
RTG SYMBOL											
DATE	8/26/86										
RTG SYMBOL											
DATE											
RTG SYMBOL											
DATE											

REPOSITORY: Oak Ridge Operations Records Holding Area
COLLECTION: Documents 1944-94
BOX No. B-69-17 Bldg. 2714-H
ERD-86-574

ER-122:WNLingle:cmd:6-5580:7/28/86

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RESEARCH SERVICES AGREEMENT

BETWEEN

MARTIN MARIETTA ENERGY SYSTEMS, INC.

AND THE

CHILDREN'S HOSPITAL NATIONAL MEDICAL CENTER

Pertaining to
"Organ Dose in Pediatric Diagnostic Radiology"
(DOE Project No. ERD-86-574)

THIS AGREEMENT, entered into effective June 1, 1986, by and between MARTIN MARIETTA ENERGY SYSTEMS, INC. (Energy Systems), a corporation duly organized and existing under the laws of the State of Delaware and having an office in Oak Ridge, Tennessee 37831, acting under its Contract No. DE-AC05-84OR21400 with the UNITED STATES OF AMERICA (Government), as represented by the UNITED STATES DEPARTMENT OF ENERGY (DOE), and the CHILDREN'S HOSPITAL NATIONAL MEDICAL CENTER (Sponsor), a not-for-profit corporation organized and existing under the laws of the District of Columbia, and having its principal office at 111 Michigan Avenue, N.W., Washington, D.C. 20019.

WITNESSETH THAT:

WHEREAS, pursuant to its aforesaid Contract No. DE-AC05-84OR21400 with the Government, Energy Systems operates several facilities of the DOE, including the OAK RIDGE NATIONAL LABORATORY (ORNL) at Oak Ridge, Tennessee; and

WHEREAS, the Sponsor is conducting a research project involving "Organ Dose in Pediatric Diagnostic Radiology", and the Health and Safety Research Division of ORNL has unique capability to assist the Sponsor in the research activity aforesaid; and

WHEREAS, the Sponsor has accordingly requested that DOE, through ORNL, provide certain services more particularly described hereinbelow; and

WHEREAS, DOE has agreed that its contractor, Energy Systems, may provide such services pursuant to the terms and conditions hereinafter set forth;

NOW, THEREFORE, Energy Systems and the Sponsor agree as follows:

1. SCOPE OF WORK

Energy Systems pursuant to its aforesaid Contract No. DE-AC05-84OR21400 shall perform for the Sponsor the services described in Appendix "A", Statement of Services, which is attached hereto and hereby made a part of this Agreement. Such services will be performed through the use of facilities, equipment, and personnel in the ORNL Health and Safety Research Division.

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2. COSTS AND PAYMENT

A. Energy Systems will retain its employees assigned to this work on its payroll and will be reimbursed by the Sponsor, for the account of DOE, in accordance with DOE's pricing policy which provides for full cost recovery (except ORNL depreciation and DOE added factor, which are waived) and includes, but is not limited to:

(1) Cost of materials, labor, utilities, travel, and other direct costs; plus

(2) A proportionate percentage of Energy Systems' current overhead of item (1), above, which is recomputed monthly.

B. The Sponsor has authorized the sum of $194,953 for the services to be provided under this Agreement, which sum is the maximum amount that Energy Systems is authorized to expend or have committed for such services. When and if the amount paid and payable to Energy Systems for the services under this Agreement shall equal such authorized sum, as set forth in Section 4 of Appendix "A" to this Agreement, Energy Systems shall incur no further costs for the services hereunder unless and until the Sponsor shall increase such authorization, but Energy Systems may consider the Sponsor's failure to increase such authorization as a termination pursuant to Article 12 of this Agreement. It is expressly understood and agreed that in no event shall Energy Systems be required to incur costs or expenses in excess of any applicable limitation upon Sponsor's reimbursement obligations under this Agreement.

C. Energy Systems will invoice the Sponsor at the end of each month in which work was performed hereunder for all services and expenses as stated in Subarticle A, hereinabove, in accordance with DOE's accounting policies, and such invoice shall be paid promptly by Sponsor upon receipt of invoice in accordance with instructions furnished therewith.

D. Payments received by Energy Systems more than 30 days following the date of any invoice described in Subarticle C, next above, shall be subject to interest at the applicable rate established and published by the United States Secretary of the Treasury and to an administrative charge established by DOE, both pursuant to United States Code, Title 31, Section 3717 (the Debt Collection Act of 1982), or other applicable law. In addition, a penalty charge of not more than six percent (6%) per year, or other rate established by law, will be assessed on any portion of said invoiced debt which is more than 90 days past due, also as provided in the statute cited above. In the event of partial payments of any delinquent amounts described above, the amount received by Energy Systems will first be applied to accrued interest, then accrued penalties, then accrued administrative charges, and finally to payment of the principal debt outstanding.

E. The provisions of Subarticle D, next above, shall not apply to this Agreement if Sponsor is an agency of the United States Government, of a State government of the United States, or of a unit of general local government in the United States.

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F. Energy Systems shall maintain such records as are normally maintained for DOE-supported work. The records of Energy Systems shall not be subject to audit by the Sponsor; however, Energy Systems shall make available upon request by Sponsor, where reasonably necessary for the Sponsor to evaluate its expenditures or where otherwise considered appropriate, cost data and audit reports concerning the services performed under this Agreement, together with any related findings and all reasonably necessary explanations or discussions.

G. The rights and responsibilities of each party pertaining to costs and payment shall be subject to any additional terms and conditions set forth in Section 4 of Appendix "A" of this Agreement.

3. LIABILITY

A. Neither the Government, the DOE, Energy Systems, nor persons acting on their behalf will be responsible for any injury to or death of persons or other living things or damage to or destruction of property or for any other loss, damage or injury of any kind whatsoever resulting from the performance of services or furnishing of materials hereunder.

B. NEITHER THE GOVERNMENT, THE DOE, ENERGY SYSTEMS, NOR PERSONS ACTING ON THEIR BEHALF MAKES ANY WARRANTY, EXPRESS OR IMPLIED, (1) WITH RESPECT TO THE MERCHANTABILITY, ACCURACY, COMPLETENESS, OR USEFULNESS OF ANY SERVICES, MATERIALS, OR INFORMATION FURNISHED HEREUNDER, (2) THAT THE USE OF ANY SUCH SERVICES, MATERIALS, OR INFORMATION MAY NOT INFRINGE PRIVATELY OWNED RIGHTS, (3) THAT THE SERVICES, MATERIALS, OR INFORMATION FURNISHED HEREUNDER WILL NOT RESULT IN INJURY OR DAMAGE WHEN USED FOR ANY PURPOSE, (4) THAT THE SERVICES, MATERIALS, OR INFORMATION FURNISHED HEREUNDER WILL ACCOMPLISH THE INTENDED RESULTS OR ARE SAFE FOR ANY PURPOSE, INCLUDING ANY INTENDED OR SPECIAL PURPOSE, OR (5) THAT MATERIALS, IF ANY, ACCEPTED FOR ANALYSIS OR OTHER SERVICE WILL NOT BE CONSUMED, DESTROYED, DAMAGED, LOST, OR OTHERWISE ALTERED IN PHYSICAL OR CHEMICAL PROPERTIES.

C. Energy Systems will use reasonable efforts to provide the services under this Agreement in the manner indicated in Appendix "A", Statement of Services, but neither the Government, the DOE, Energy Systems, nor persons acting on their behalf will be responsible, irrespective of causes, for failure to perform the services or furnish the materials or information hereunder at any particular time or in any specific manner.

D. The Sponsor agrees to indemnify and hold harmless the Government, DOE, Energy Systems, and persons acting on their behalf from all liability, including costs and expenses incurred, resulting from the Sponsor's use or disclosure of the materials or information, in whatever form, furnished, supplied, or provided the Sponsor by Energy Systems under this Agreement.

4. SPONSOR'S MATERIAL

In the event any material is to be supplied by the Sponsor pursuant to this Agreement, it is recognized that such material may be damaged, consumed, altered or lost as a necessary result of the work to be performed or services to be provided under this Agreement. Any such material (including residues and/or other

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contaminated material) remaining after performance of the work or analysis will, upon Sponsor's request, be returned in its then condition to the Sponsor at the Sponsor's expense.

5. PERMITS AND LICENSES

Except as otherwise directed by Energy Systems, the Sponsor shall procure all applicable permits or licenses necessary for the performance of the services under this Agreement, and shall abide by and comply with all applicable laws, regulations, and ordinances of the United States and of the State, territory, and political subdivision in which the work under this Agreement is performed.

6. RIGHTS IN TECHNICAL DATA (NON-PROPRIETARY)

A. Definitions

1. "Technical Data" means recorded information, regardless of form or characteristic, of a scientific or technical nature. It may, for example, document research, experimental, developmental, demonstration, or engineering work to be usable or used to define a design or process or to procure, produce, support, maintain, or operate material. The data may be graphic or pictorial delineations in media such as drawings or photographs, text in specifications or related performance or design type documents, or computer software (including computer programs, computer software data bases, and computer software documentation). Examples of technical data include research and engineering data, engineering drawings and associated lists, specifications, standards, process sheets, manuals, technical reports, catalog item identification and related information. Technical data as used in this subpart does not include financial reports, cost analyses, and other information incidental to contract administration.

2. "Proprietary Data" means technical data which embody trade secrets developed at private expense, such as design procedures or techniques, chemical composition of materials, or manufacturing methods, processes, or treatments, including minor modifications thereof, provided that such data:

   a. Are not generally known or available from other sources without obligation concerning their confidentiality,

   b. Have not been made available by the owner to others without obligation concerning their confidentiality, and

   c. Are not already available to the Government without obligation concerning their confidentiality.

3. "Unlimited Rights" means rights to use, duplicate or disclose technical data, in whole or in part, in any manner and for any purpose whatsoever, and to permit others to do so.

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B. The Sponsor agrees to furnish to DOE or Energy Systems those data, if any, which are (1) essential to the performance of work by DOE or Energy Systems personnel or (2) necessary for the health and safety of such personnel in the performance of the work. Any data furnished to DOE or Energy Systems shall be deemed to have been delivered with unlimited rights.

C. It is understood and agreed that no "proprietary data" of the Sponsor is to be disclosed, transferred, furnished, or delivered under this Agreement.

D. Except as otherwise provided in this Agreement, Energy Systems, DOE, the Government, and the Sponsor shall have the right to use for any purpose, without payment of any compensation to any party, any Technical Data generated, developed or acquired by Energy Systems in the course of or under this Agreement, including the right to separately and independently publish or disclose any such Technical Data. However, in order that public disclosure of such information will not adversely affect the patent interests of the Sponsor and the Government, as set forth in Article 7, hereinbelow, patent approval for release or publication shall be secured from Energy Systems prior to any such release or publication.

E. The Government retains a nonexclusive, royalty-free license in and to any copyright obtained by any person or party covering any Technical Data generated or developed by Energy Systems or its employees, solely or in conjunction with others, in the course of or under this Agreement, to publish or reproduce the published form of such Technical Data, or to allow others to do so, for government purposes only and not for resale.

7. PATENT RIGHTS - USE OF FACILITIES (CLASS WAIVER)

A. Definitions

1. "Sponsor" means the person or entity with which this Agreement is made.

2. "Subject Invention" means any invention or discovery of Energy Systems or, to the extent the Sponsor is performing any work under this Agreement, of the Sponsor, conceived in the course of or under this Agreement, or, in the case of an invention previously conceived by the Sponsor, first actually reduced to practice in the course of or under this Agreement. An invention conceived by Energy Systems outside this Agreement, but first actually reduced to practice in the course of or under this Agreement, may also be considered a "Subject Invention" if specifically identified as such in this Agreement. "Subject Invention" includes any art, method, process, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plants, whether patented or unpatented under the Patent Laws of the United States of America or any foreign country.

3. "States and domestic municipal governments" means the States of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, the Trust Territory of the Pacific Islands, and any political subdivision and agencies thereof.

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4. "Government agency" includes an executive department, independent commission, board, office, agency, administration, authority, Government corporation, or other Government establishment of the Executive Branch of the Government of the United States of America.

5. "Energy Systems" means the operating contractor which manages and operates the Government-owned, contractor-operated facility where the work under this Agreement is to be performed.

6. "Patent Counsel" means the DOE Patent Counsel assisting the procuring activity.

B. Rights of the Sponsor.

1. Election to retain rights - Subject to the provisions of paragraph C.(2) of this clause with respect to any Subject Invention reported and elected in accordance with paragraph D. of this clause, the Sponsor may elect to obtain the entire right, title and interest in any patent application filed in any country on a Subject Invention and in any resulting patent secured by the Sponsor. Where appropriate, the filing of patent applications by the Sponsor is subject to DOE security regulations and requirements.

2. Minimum license - The Sponsor reserves an irrevocable, nonexclusive, paid-up license in each patent application filed in any country on a Subject Invention and any resulting patent in which the Sponsor does not elect to retain title or in which the Government acquires title. The license shall extend to the Sponsor's domestic subsidiaries and affiliates, if any, within the corporate structure of which the Sponsor is a part and shall include the right to grant sublicenses of the same scope to the extent the Sponsor was legally obligated to do so at the time this Agreement was entered into. The license shall be transferable only with approval of DOE except when transferred to the successor of that part of the Sponsor's business to which the invention pertains.

C. Rights to Government.

1. Assignment to the Government - The Sponsor agrees to assign to the Government, upon request, the entire right, title, and interest in any country to each Subject Invention of the Sponsor and to each Subject Invention of Energy Systems to which the Sponsor has acquired title, except to the extent that rights are retained by the Sponsor under paragraph B.(2) of this clause, where the Sponsor:

   a. Does not elect pursuant to this clause to retain such rights; or

   b. Fails to have a patent application filed in that country on the Subject Invention or decides not to continue prosecution or not to pay any maintenance fees covering the invention; or

   c. At any time, the Sponsor no longer desires to retain title.

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2. Terms and Conditions of Waived Rights.

a. To preserve the Government's residual rights to Subject Inventions, the Sponsor shall take all actions in reporting, electing, filing on, prosecuting and maintaining invention rights promptly, but in any event, in sufficient time to satisfy domestic and foreign statutory and regulatory time requirement, or, if the Sponsor decides not to take appropriate steps to protect the invention rights, it shall notify DOE in sufficient time to permit the Government to file, prosecute and maintain patent applications and any resulting patents prior to the end of such domestic or foreign statutory or regulatory time requirements.

b. The Sponsor shall convey or assure the conveyance of any executed instruments necessary to vest in the Government the rights set forth in this clause.

c. The Sponsor hereby grants to the Government a nonexclusive, nontransferable paid-up license to make, use, and sell each Subject Invention throughout the world by or on behalf of the Government of the United States (including any Government agency) and States and domestic municipal governments.

d. The Sponsor shall provide the Government a copy of any application files on a Subject Invention promptly after such application is filed, including its serial number and filing date.

e. The Sponsor agrees to grant to responsible applicants, upon request of the Government, a license to waived inventions on terms that are reasonable under the circumstances:

(1) Unless the Sponsor, its licensee, or its assignee demonstrates to the Government that effective steps have been taken within three years after a patent issues on such invention to bring the invention to the point of practical application, or that the invention has been made available for licensing royalty-free or on terms that are reasonable in the circumstances, or can show cause why the principal or exclusive rights should be retained for a further period of time; or

(2) To the extent that the invention is required for public use by governmental regulations or as may be necessary to fulfill public health, safety or welfare needs, or for other public purposes stipulated in this Agreement.

f. The Sponsor shall submit written reports at reasonable intervals upon request of the Government during the term of the patent on the Subject Invention regarding:

(1) The commercial use that is being made or is intended to be made of the invention; and

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(2) The steps taken by the Sponsor or its transferee to bring the invention to the point of practical application or to make the invention available for license.

g. The Sponsor agrees to refund any amounts received as royalty charges on any Subject Invention in procurements for or on behalf of the Government and to provide for that refund in any instrument transferring rights to any party in the invention.

D. Invention identification, disclosures, and reports.

1. The Sponsor shall furnish the Patent Counsel a written report containing full and complete technical information concerning each Subject Invention of the Sponsor within 6 months after conception or first actual reduction to practice, whichever occurs first, in the course of or under this Agreement, but in any event prior to any on sale, public use or public disclosure of such invention known to the Sponsor. The report shall identify the agreement and inventor and shall be sufficiently complete in technical detail and appropriately illustrated by sketch or diagram to convey to one skilled in the art to which the invention pertains a clear understanding of the nature, purpose, operation, and to the extent known, the physical, chemical, biological, or electrical characteristics of the invention. The report should also include any election of patent rights under this clause. When an invention is reported under this paragraph D., it shall be presumed to have been made in the manner specified in Section (a)(1) and (2) of 42 USC 5908.

2. Energy Systems' contract with DOE requires that Subject Inventions of Energy Systems will be reported to DOE. In addition DOE shall direct Energy Systems to disclose to the Sponsor any such inventions promptly upon conception or first actual reduction to practice, and the Sponsor shall notify DOE promptly thereafter of any election of patent rights under this clause.

E. Limitation of rights.

Nothing contained in this patent rights clause shall be deemed to give the Government any rights with respect to any invention other than a Subject Invention except as set forth in the Facilities License of paragraph F.

F. Facilities License.

In addition to the rights of the parties with respect to inventions or discoveries conceived or first actually reduced to practice in the course of or under this Agreement, the Sponsor agrees to and does hereby grant to the Government an irrevocable, nonexclusive paid-up license in and to any inventions or discoveries regardless of when conceived or actually reduced to practice or acquired by the Sponsor, which at any time through completion of this Agreement are owned or controlled by the Sponsor and are incorporated in the facility as a result of this Agreement to such an extent that the facility is not restored to the condition existing prior to the Agreement

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(1) to practice or to have practiced by or for the Government at the facility, and (2) to transfer such license with the transfer of that facility. The acceptance or exercise by the Government of the aforesaid rights and license shall not prevent the Government at anytime from contesting the enforceability, validity or scope of, or title to, any rights or patents herein licensed.

8. LIMITED PATENT INDEMNITY

The Sponsor shall indemnify the Government and Energy Systems and their officers, agents, and employees against liability, including costs, for infringement of any United States patent arising out of any acts required or directed by the Sponsor to be performed under the Agreement to the extent such acts are not normally performed at ORNL. Further, the foregoing indemnity shall not apply unless the Sponsor shall have been informed in a reasonable time by Energy Systems or the Government of the suit or action alleging such infringement, and such indemnity shall not apply to a claimed infringement which is settled without the consent of the Sponsor unless required by a court of competent jurisdiction.

9. LEGAL NOTICE

The following legal notice shall be affixed to each report furnished to the Sponsor under this Agreement and to any report resulting from this Agreement which may be distributed by the Sponsor:

"DISCLAIMER NOTICE

"This report was prepared by the Oak Ridge National Laboratory, operated by Martin Marietta Energy Systems, Inc. (Energy Systems) on behalf of the U.S. Department of Energy (DOE), as an account of work sponsored by _____ (Sponsor's Name) _____. Neither Energy Systems, DOE, the U.S. Government, or any person acting on their behalf: (a) makes any warranty or representation, express or implied, with respect to the information contained in this report; or (b) assumes any liabilities with respect to the use of, or damages resulting from the use of any information contained in the report."

10. PUBLICITY

No advertising or publicity mentioning the Sponsor with regard to the services provided under this Agreement shall be used by Energy Systems without written approval by the Sponsor.

11. EMPLOYMENT PRACTICES

Energy Systems represents that, pursuant to its aforesaid Principal Contract with the Government, as represented by DOE, it is subject to the provisions of Executive Order No. 11246 of September 24, 1965, pertaining to Equal Employment Opportunity, and Section 503 of the Rehabilitation Act of 1973, relating to Employment of the Handicapped.

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12. TERM AND TERMINATION

A. Unless otherwise provided in this Agreement, the term of this Agreement shall be concurrent with the period of performance set forth in Section 3 of Appendix "A", Statement of Services, unless extended by written agreement of the parties or sooner terminated pursuant to other provisions of this Article 12.

B. Either party hereto may terminate this Agreement for any reason at any time by giving not less than thirty (30) days prior written notice to the other party.

C. Energy Systems reserves the right to immediately cancel, without regard to the aforesaid written notice, this Agreement (1) in the event the Sponsor's license (where applicable) is suspended, cancelled, or revoked pursuant to the Atomic Energy Act of 1954, as amended, or (2) when cancellation of this Agreement is determined to be necessary to the national defense and security of the United States.

D. Any such termination under any provision of this Agreement shall only affect the term of this Agreement, and shall otherwise be without prejudice to the rights of the parties hereunder which may have accrued prior to the time of termination. Upon any such termination by either party, Energy Systems shall be compensated, for the account of DOE, in accordance with Article 2, hereinabove, for work performed or services rendered for which Energy Systems has not previously been compensated.

13. COVENANT AGAINST CONTINGENT FEES

The Sponsor warrants that no person or selling agency has been employed or retained to solicit or secure this Agreement upon an agreement or understanding for a commission, percentage, brokerage, or contingent fee, excepting bona fide employees or bona fide established commercial or selling agencies maintained by the Sponsor for the purpose of securing business. For breach or violation of this warranty the Government shall have the right to annul this Agreement without liability or in its discretion to deduct from the Agreement price or consideration, or otherwise recover, the full amount of such commission, percentage brokerage or contingent fee.

14. OFFICIALS NOT TO BENEFIT

No member of or delegate to Congress, or resident commissioner, shall be admitted to any share or part of this Agreement, or to any benefit that may arise therefrom; but this provision shall not be construed to extend to this Agreement if made with a corporation for its general benefit.

15. CERTIFICATION

The Sponsor certifies that the capability to perform the work, provide the services, or furnish the materials covered by this Agreement is not available in domestic private facilities and laboratories, or state facilities and laboratories if Sponsor is a state instrumentality, on an independent, convenient and timely basis, and at a reasonable charge.

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16. ENTIRE AGREEMENT

It is expressly agreed by the parties hereto that this Agreement constitutes the entire and only contract between the parties hereto; that there are no agreements, understandings, or covenants between the parties hereto of any kind, nature or description, express or implied, oral or otherwise, which have not been set forth herein; and that this Agreement cannot be modified, altered, amended, or changed, nor any provision thereof waived or abrogated, except by an instrument in writing and duly executed on behalf of each of the parties hereto by the duly authorized representatives or officers of each party who have been expressly authorized in writing to execute such an instrument.

17. STATUS OF ENERGY SYSTEMS

It is understood and agreed that this Agreement is entered into by Energy Systems for and on behalf of the Government; that Energy Systems is authorized to and will administer this Agreement in other respects for the DOE, unless otherwise specifically provided for herein; that administration of this Agreement may be transferred from Energy Systems to the DOE or its designee, and in case of such transfer and notice thereof to the Sponsor, Energy Systems shall have no further responsibilities hereunder.

18. APPROVAL BY DOE

This Agreement and any extension, revision or modification thereof shall be subject to the written approval of DOE, and shall not be binding until so approved.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement effective as of the date first above indicated.

MARTIN MARIETTA ENERGY SYSTEMS, INC.

BY: _____
Herman Postma, Vice President and
Director, Oak Ridge National Laboratory

CHILDREN'S HOSPITAL
NATIONAL MEDICAL CENTER

BY: _____

NAME (typed): Donald P. Schmigel

TITLE: Director, Office of Sponsored Programs

APPROVED ON BEHALF OF THE
UNITED STATES DEPARTMENT OF ENERGY

BY: _____

NAME (typed): for William R. Bibb, Director

TITLE: Research & Waste Management Division

DATE: 8/26/86

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APPENDIX "A" TO
RESEARCH SERVICES AGREEMENT
BETWEEN
MARTIN MARIETTA ENERGY SYSTEMS, INC.
AND THE
CHILDREN'S HOSPITAL NATIONAL MEDICAL CENTER

Pertaining to
"Organ Dose in Pediatric Diagnostic Radiology"
(DOE Project No. ERD-86-574)

STATEMENT OF SERVICES

Pursuant to the attached Agreement between Martin Marietta Energy Systems, Inc. (Energy Systems), acting under its Contract No. DE-AC05-84OR21400 with the United States Government (Government), and the Children's Hospital National Medical Center (Sponsor), Energy Systems, utilizing the facilities and personnel of the Oak Ridge National Laboratory (ORNL), shall perform the following services for the Sponsor:

1. SCOPE OF WORK

Energy Systems (ORNL) will develop an anatomical/mathematical model of the "standard" child based on CAT scan data supplied by Sponsor. Models representing newborn, 1-, 5-, 10-, and 15-year olds will be implemented in a computer code using Monte Carlo methods to perform calculations of the absorbed dose for common pediatric X-ray diagnostic procedures. Energy Systems (ORNL) will supply to Sponsor a data base of organ tissue-air ratios as a function of incident photon energy for each radiation projection and each phantom.

2. KEY PERSONNEL AND COORDINATION

A. Coordination between Energy Systems designated representatives and the Sponsor's Project Manager will be maintained during the period of performance. Briefings on the progress of the work, in addition to the reporting schedule listed elsewhere in the Agreement or Appendix "A", will be provided as required.

B. Dr. Thomas C. Fearon is the Sponsor's designated Project Manager for the services to be provided under this Agreement. Reports and other communications of a technical nature shall be directed to the Project Manager at the following address:

Dr. Thomas C. Fearon, Professor
Department of Radiology
Children's Hospital National Medical Center
111 Michigan Avenue, N.W.
Washington, D.C. 20019

C. Dr. K. F. Eckerman is the designated Energy Systems Principal Investigator and Drs. M. Cristy and M. G. Yalcintas are the designated Co-Principal Investigators for the services to be furnished under this Agreement.

D. Either party shall promptly notify the other of any change in designation of Sponsor's Project Manager or Energy Systems' Person in Charge or Co-Principal Investigators under this Agreement.

3. PERIOD OF PERFORMANCE

The period of performance for the work to be performed or services to be provided under this Agreement shall commence on June 1, 1986, and end on March 31, 1989, unless extended by written agreement of the parties.

4. COSTS AND PAYMENT - ADDITIONAL PROVISIONS

A. As set forth in Subarticle 2.B of the Agreement, the maximum cost to the Sponsor for the work to be performed or services to be provided under this Agreement shall not exceed $194,953 with estimated breakdown by category as follows:

ESTIMATED BUDGET

	First Project Period (6/1/86-3/31/87)	Second Project Period (4/1/87-3/31/88)	Third Project Period (4/1/88-3/31/89)
Salaries (including fringe benefits) -	$25,000	25,266	26,430
Technical Services -	19,000	22,200	16,250
Travel -	2,000	2,000	2,000
Other -	2,400	3,090	3,183
Subtotal:	48,400	52,556	47,863
ORNL G&A/GPS -	15,004	16,293	14,837
TOTAL:	$63,404	$68,849	$62,700

B. Any deviation between actual charges to the Sponsor under each category and the estimates set forth above shall not affect the basis on which Energy Systems shall be paid, as set forth in Article 2 of the Agreement.

C. If Energy Systems has expended or committed less than the cumulative amount authorized for these services by the Sponsor as of the last day of the particular Project Period involved, as set forth in the Estimated Budget in Subsection 4.A, above, then the difference between the amount so expended or committed by Energy Systems and the cumulative amount so authorized to such date by Sponsor may be carried over and added to any further amount authorized for these services by Sponsor for any subsequent Project Period(s), provided the total authorized sum of $194,953. is not exceeded.

D. All travel under this Agreement will be reimbursed by Sponsor only on the basis of travel policies approved by Energy Systems for travel by ORNL staff members in the performance of DOE-supported work, which includes coach/second class air transportation.

5. SCHEDULE

Energy Systems shall use its reasonable best efforts to complete all services described in Section 1 of this Appendix "A" and to furnish all required reports or models to Sponsor on or before March 31, 1989.

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MARTIN MARIETTA

Internal Correspondence

May 19, 1986

MARTIN MARIETTA ENERGY SYSTEMS, INC.

E. R. Bowers

Information requested by E. R. Bower's in May 8, 1986 memo to R. M. Poteat regarding WFO Agreement with Children's Hospital (DOE No. ERD-86-574)

In your memo to Poteat, DOE-ORO OPC, you identified some specific information needs which are addressed below. If I can be of any further assistance in meeting your information needs on this matter and thus facilitating the implementation of the WFO agreement please give me a call (4-6251). The prompt attention you have given this matter is greatly appreciated.

1. Abbreviated work statement appropriate for the agreement.

ORNL will develop an anatomical/mathematical model of the "standard" child based on CAT scan data supplied by Children's Hospital. Models representing newborn, 1-, 5-, 10-, and 15-year olds will be implemented in a computer code using Monte Carlo methods to perform calculations of the absorbed dose for common pediatric X-ray diagnostic procedures. ORNL will supply to Children's Hospital a data base of organ tissue-air ratios as a function of incident photon energy for each radiation projection and each phantom.

2. Estimated budget breakdown.

A detailed budget was presented within the WFO request (see attachment). The ORNL subcontract is for 64, 70, and 63 K in each of the three years.

3. Anticipated performance period.

The proposed period of performance is 4/86 through 3/89. The ending date is reasonably fixed; ORNL will start work when approval is obtained.

4. Titles of ORNL Personnel.

The proposal, as written for DHHS, lists all ORNL personnel under contract to Children's Hospital as consultants. The principal investigator is Dr. Thomas Fearon of Children's Hospital with Mr. James Vucich of Children's Hospital as co-investigator. Within the ORNL contract list Dr. Eckerman as principal investigator with Drs. Cristy and Yalcintas as co-principal investigators.

1078110

ERD 86-574

5. Children's Hospital Technical Representative.

Dr. Thomas Fearon, Professor
Department of Radiology
Children's Hosptial National Medical Center
111 Michigan Avenue, N.W.
Washington, D.C. 20019

Phone No. (202) 745-5079

6. Children's Hospital Contract Contact.

Mr. Donald P. Schmigel
Asst. Controller for Sponsored Programs
Children's Hosptial National Medical Center
111 Michigan Avenue, N.W.
Washington, D.C. 20019

Phone No. (202) 745-4021

7. Legal status of Children's Hospital.

Children's Hospital National Medical Center is a not-for-profit corporation incorporated in the District of Columbia.

Keith Eckerman

K. F. Eckerman, Bldg. 7509, ORNL (4-6251)

KFE:bpw

Enclosure

cc:wo/enc: M. J. Bolinger, Bldg. 4500N, K-246, ORNL (4-4191)
R. O. Chester, Bldg. 7509, ORNL (6-2100)
M. Cristy, Bldg. 7509, ORNL (4-6253)
S. V. Kaye, 4500S, S-108, ORNL (4-5845)
R. M. Poteat, DOE-ORO OPC (6-1070)
✓S. S. Waddle, DOE-ORO RMB (6-0729)
M. G. Yalcintas, Bldg. 7503, ORNL (6-2078)

1078111

MEMORANDUM

TO: R. M. Poteat, DOE-ORO OPC

FROM: E. R. Bowers, Energy Systems OGC ERB

DATE: May 8, 1986

RE: WFO Agreement with Children's Hospital National Medical Center covering "Organ Dose in Pediatric Diagnostic Radiology" (DOE No. ERD-86-574)

Please refer to the enclosed ORNL request to perform the captioned work, with ORO approval noted thereon, and advise whether you will approve use of the DOE Class Waiver patent provisions in our implementing agreement.

Since ORNL expenses in performing this work will be reimbursed under a DHHS grant to the Medical Center, I expect to encounter the usual difficulties in negotiating an agreement with the sponsoring organization. I therefore hope you will continue your efforts - despite the recent demise of our intended project for the University of Pittsburgh under an NIH grant to Pitt - to obtain guidance from DOE-HQ regarding the impasse between DOE and DHHS policies and regulations, which imperils all proposed ORNL work for DHHS-affiliated agencies.

Your early attention to this matter will be appreciated.

ERB:bdp

Enclosure - as stated

cc w/o enc: S. S. Waddle, DOE-ORO RMB

1078112

OAK RIDGE NATIONAL LABORATORY

OPERATED BY MARTIN MARIETTA ENERGY SYSTEMS, INC.

POST OFFICE BOX X
OAK RIDGE, TENNESSEE 37831

CONCURRENCES

ORG. SYMBOL	ER-122
	SPRADLEN
INITIALS/SIG.	RDS
DATE	4-4-86
ORG. SYMBOL	ER-122
	DUNAWAY
INITIALS/SIG.	PBD
DATE	4/21/86
ORG. SYMBOL	ER-122
	WADDLE
INITIALS/SIG.	SSW
DATE	4/21/86

April 16, 1986

Mr. Joseph A. Lenhard, Assistant Manager
Energy Research and Development
Department of Energy, Oak Ridge Operations
Post Office Box E
Oak Ridge, Tennessee 37831

Dear Mr. Lenhard:

Grant Application by Children's Hospital National Medical Center to the Department of Health and Human Services, Public Health "Organ Dose in Pediatric Diagnostic Radiology" (DOE No. ERD-86-574)

Enclosed for your review and approval is a grant application prepared by Children's Hospital National Medical Center, Department of Radiobiology, based upon discussions between Dr. T. C. Fearon of Children's Hospital and Dr. K. F. Eckerman of Oak Ridge National Laboratory. The application requests a total funding level of $351,241 over a period of three years, $197,684 of that amount to be subcontracted to Oak Ridge National Laboratory.

The following information is provided to assist you in your review and approval of this proposal:

(1) This type research is described in the approved ORNL Institutional Plan for FY 1986-1991 on pages 32-34 and 67 under "Department of Health and Human Services." The personnel required for this research are available.

(2) The principal investigators for this research subcontract will be Dr. K. F. Eckerman, Dr. M. Cristy, and Dr. M. G. Yalcintas of Oak Ridge National Laboratory.

(3) Existing space and resources are available to support this research without interfering with DOE activities.

(4) The proposed subcontracted research to ORNL would result in the development of an anatomical model for "standard" child phantoms from X-ray CT images for the following classes of patient: newborn, 1 year, 5 year, 10 year, and 15 year. The results will be input to detailed Monte Carlo calculations of radiation transport in the body to be undertaken with Children's Hospital. The calculations will be used to estimate organ absorbed doses for common pediatric X-ray diagnostic projections.

1078113

ERD-86-574

The Metabolism and Dosimetry Research Group of ORNL has developed the computational models for the anatomy of man presently used world-wide in radiation protection dosimetry. ORNL's past experience and leadership role represents a unique resource and capabilities that do not exist elsewhere.

Specific programs that will benefit include DOE HA 02 01 01 0 (FTP/A 004582), HA 02 04 03 0 (FTP/A 000717), NRC 41 35 55 06 7 (FIN No. B0834), and EPA 42 01 54 90 1 (IAG No. 40-1549-851). Based on these above programmatic relationships, approval is requested to perform this work at actual cost with depreciation and DOE added factor waived.

If you approve this request, please complete the approval block and return one copy to me.

Technical questions concerning this proposal should be addressed to Dr. K. F. Eckerman, extension 4-6251; administrative questions should be addressed to J. E. Carr, Work for Others Coordinator, extension 4-6062.

Sincerely,

Chester R. Richmond

Chester R. Richmond
Associate Laboratory Director for
Biomedical and Environmental Sciences

CRR:bpw

Enclosure

cc: E. R. Bowers
J. E. Carr
R. O. Chester
K. F. Eckerman
G. W. Horde
S. V. Kaye
H. Postma - RC
C. S. Travaglini

APPROVED:

Original Signed By
Susan C. Waddle

J. A. Lenhard, Assistant Manager
Energy Research and Development

APR 2 2 1986

Date

1078114

Research Proposal:

Organ Dose in Pediatric Diagnostic Radiology

Thomas Fearon, Ph.D. Principal Investigator
James Vucich, M.S. NIH; Co-Investigator

Consultants:

Keith Eckerman, Ph.D.; ORNL
Mark Cristy Ph.D.; ORNL
M. Guven Yalcintas, Ph.D.; ORNL

DO NOT TYPE IN THIS SPACE—BINDING MARGIN

Form approved
OMB No. 0925-0001

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

GRANT APPLICATION

FOLLOW INSTRUCTIONS CAREFULLY

LEAVE BLANK		
TYPE	ACTIVITY	NUMBER
REVIEW GROUP		FORMERLY
COUNCIL/BOARD *(Month, year)*		DATE RECEIVED

1. TITLE OF APPLICATION *(Do not exceed 56 typewriter spaces)*
Organ Dose in Pediatric Diagnostic Radiology

2. RESPONSE TO SPECIFIC PROGRAM ANNOUNCEMENT ☒ NO ☐ YES *(If "YES," state RFA number and/or announcement title)*

3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR

3a. NAME *(Last, first, middle)*
Fearon, Thomas, Charles

3c. POSITION TITLE
Assistant Professor of Radiology

3d. MAILING ADDRESS *(Street, city, state, zip code)*
Children's Hosp. Natl. Med. Center
Department of Radiology
111 Michigan Avenue, N.W.
Washington, D.C. 20010

3e. DEPARTMENT, SERVICE, LABORATORY OR EQUIVALENT
Department of Radiology

3f. MAJOR SUBDIVISION
None

3g. TELEPHONE *(Area code, number and extension)*
(202)745-5079

4. HUMAN SUBJECTS
☐ NO ☒ YES { ☒ Exemption # 5 * OR ☐ Form HHS 596 enclosed

5. RECOMBINANT DNA
☒ NO ☐ YES

6. DATES OF ENTIRE PROPOSED PROJECT PERIOD
From: 4/1/86 Through: 3/31/89

7. DIRECT COSTS REQUESTED FOR FIRST 12-MONTH BUDGET PERIOD *(from page 4)*
$147,773

8. DIRECT COSTS REQUESTED FOR ENTIRE PROPOSED PROJECT PERIOD *(from page 5)*
$ 351,241

9. PERFORMANCE SITES *(Organizations and addresses)*
Children's Hospital National Medical Center
111 Michigan Avenue, N.W.
Washington, D.C. 20019

Oak Ridge National Laboratory
Health and Safety Research Division
P.O. Box X
Oak Ridge, Tennessee 37830

10. INVENTIONS *(Competing continuation application only)*
☒ NO ☐ YES { ☐ Previously reported OR ☐ Not previously reported

11. APPLICANT ORGANIZATION *(Name, address, and congressional district)*
Children's Hospital National Med. Ctr.
111 Michigan Avenue, N.W.
Washington, D.C. 20010

Congr. Dist. 099

12. TYPE OF ORGANIZATION
☐ Public. Specify ☐ Federal ☐ State ☐ Local
☒ Private Nonprofit
☐ For Profit *(General)*
☐ For Profit *(Small Business)*

13. ENTITY IDENTIFICATION NUMBER
53-0196580A1

14. ORGANIZATIONAL COMPONENT TO RECEIVE CREDIT FOR BIOMEDICAL RESEARCH SUPPORT GRANT
Code 3 0 Description

15. OFFICIAL IN BUSINESS OFFICE TO BE NOTIFIED IF AN AWARD IS MADE *(Name, title, address and telephone number.)*
* Donald P. Schmigel
Assistant Controller for Sponsored Programs
Children's Hospital National Medical Center
111 Michigan Avenue, N.W.
Washington, D.C. 20010 (202)745-4021

16. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Name, title, address and telephone number)*
* Donald P. Schmigel
Assistant Controller for Sponsored Programs
(Address - See #15)

17. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application. Willful provision of false information is a criminal offense *(U.S. Code, Title 18, Section 1001).*

SIGNATURE OF PERSON NAMED IN 3a *(In ink. "Per" signature not acceptable)*: Thomas Fearon
DATE: 6/28/85

18. CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true and complete to the best of my knowledge, and accept the obligation to comply with Public Health Service terms and conditions if a grant is awarded as the result of this application. A willfully false certification is a criminal offense *(U.S. Code, Title 18, Section 1001).*

SIGNATURE OF PERSON NAMED IN 16 *(In ink. "Per" signature not acceptable)*: D.P. Schmigel
DATE: 6/28/85

PHS 398 (Rev. 5/82)

10 7 8 1 1 6

Thomas Fearon, Ph.D.	Principal Investigator	Department of Radiology Children's Hospital National Medical Center
Joseph Hoe, R.T.	Research Assistant	"
James Vucich, M.S.	Co-Investigator	Department of Radiology National Institutes of Healt
Pamela Getson	Statistician	Research Department Children's Hospital National Medical Center
Keith Eckerman, Ph.D. Mark Cristy, Ph.D. M. Guven Yalcintas, Ph.D.	Consultant " "	Metabolism & Dosimetry Group Health & Safety Research Div Oak Ridge Natl. Laboratory

Radiation exposure as a consequence of diagnostic and therapeutic radiological procedures to the child involves a significant proportion of the pediatric population. The potential risk associated with radiation exposure is significantly greater in children than adults (i.e.; leukemogenesis and carcinogenesis of the breast). Accurate knowledge of the absorbed dose in an organ sensitive to radiation damage is critical in the evaluation of the risk-benefit ratio. Oak Ridge National Laboratory has pioneered efforts to quantitate organ-absorbed dose based on calculational models that use Monte Carlo radiation transport codes and mathematical models of the human body. While computational and experimental methodologies have been developed and performed in order to estimate organ dose in adults, relatively little effort has been devoted to similar estimates for children based upon actual physical measurements. Pediatric organ doses have been estimated using transformed adult phantoms. These phantoms suffer from geometrical limitations in their portrayal of the human child. These limitations are critical in the estimation of active bone marrow dose.

This proposal is a collaborative effort between Children's Hospital National Medical Center and Oak Ridge National Laboratory. The objective is the development of anatomical child phantoms from computerized axial tomography scans of pediatric patients and cadavers for the following classes of patients: newborn, 1 year, 5 year, 10 year and 15 year. These digital phantoms will be input to detailed Monte Carlo radiation transport calculations resulting in calculated organ-absorbed doses for common pediatric diagnostic examinations. Additionally, normalized organ-absorbed doses for pediatric sized patients for common diagnostic x-ray projections will be measured in anthropomorphic phantoms. These measurements will be used to verify the accuracy of the calculational model.

1078117

TABLE OF CONTENTS

Number pages consecutively at the bottom throughout the application. Do not use suffixes such as 5a, 5b. Type the name of the Principal Investigator/Program Director at the top of each printed page and each continuation page.

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Budgets Pertaining to Consortium/Contractual Arrangements	8-10
Biographical Sketch-Principal Investigator/Program Director *(Not to exceed two pages)*	11-12
Other Biographical Sketches *(Not to exceed two pages for each)*	13-20
Other Support	21
Resources and Environment	22

SECTION 2. Research Plan

Introduction *(Excess pages; revised applications; supplemental applications)*	
A. Specific Aims *(Not to exceed one page)*	23
B. Significance *(Not to exceed three pages)*	24-26
C. Progress Report/Preliminary Studies *(Not to exceed eight pages)*	27
D. Experimental Design and Methods	23-31
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G. Consultants	
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SECTION 3. Appendix *(Six sets) (No page numbering necessary for Appendix)*

Number of publications: 1 Number of manuscripts: _____

Other items *(list)*:

Two letters from Humanoid Systems, Carson, California

☒ Application Receipt Record, Form PHS 3830

☐ Form HHS 596 if Item 4, page 1, is checked "YES" and no exemptions are designated.

108118

PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR: Thomas Fearon, Ph.D.

DETAILED BUDGET FOR FIRST 12 MONTH BUDGET PERIOD DIRECT COSTS ONLY

FROM 04/01/86 THROUGH 03/31/87

DOLLAR AMOUNT REQUESTED (Omit cents)

PERSONNEL (Applicant organization only)		TIME/EFFORT				
NAME	POSITION TITLE	%	Hours per Week	SALARY	FRINGE BENEFITS @16.2%	TOTALS
Thomas Fearon, Ph.D.	Principal Investigator	25	10	9,807	1589	11,396
Joseph Hoe, R.T.	Radiological Tech	25	10	6,386	1035	7,421
Pamela Getson, Ph.D.	Statistician	5	2	2,501	405	2,906
James Vucich, M.S.	Co-Investigator	10	4	0	0	0
			SUBTOTALS →	18,694	3,029	21,723

CONSULTANT COSTS 0

EQUIPMENT (Itemize)

Humanoid anthropomorphic phantoms: newborn ($7,000),1yr ($6,000),3yr ($6,000)
Harshaw Atlas Automated TL Analyzer System with printer,($23,500)
line spike suppressor and temperature control unit
High temperature annealing oven ($1,000)
Low temperature annealing oven ($500)

44,000

SUPPLIES (Itemize by category)

Thermoluminescent dosimeter chips ($2,400)
Expendables (Nitrogen gas, solvents) ($300)
Magnetic tapes ($780)
Index discs 2 ea @ $200/ea
TLD Holders - 16 ea @ $35 = $560

4,440

TRAVEL	DOMESTIC one meeting/yr PI, 2 trips yr to Oak Ridge P.I.	3,000
	FOREIGN	0
PATIENT CARE COSTS	INPATIENT Cadaver scans $200 ea x 20 cadavers = $4,000	4,000
	OUTPATIENT	

ALTERATIONS AND RENOVATIONS (Itemize by category) 0

CONSORTIUM/CONTRACTUAL COSTS

Oak Ridge National Laboratory Contract

69,160

OTHER EXPENSES (Itemize by category)

Telecommunications ($250.00) Publications - reprints ($300), Computer use fee ($2,000), data entry ($600). Duplication, media, mail ($300)

3,450

TOTAL DIRECT COSTS (Also enter on page 1, item 7) → $ 147,773

1078119

PRINCIPAL INVESTIGATOR PROGRAM DIRECTOR: Thomas C. Fearon, Ph.D.

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY

BUDGET CATEGORY TOTALS		1st BUDGET PERIOD (from page 4)	ADDITIONAL YEARS SUPPORT REQUESTED			
			2nd	3rd	4th	5th
PERSONNEL (Salary and fringe benefits.) (Applicant organization only)		21,723	22,592	23,496		
CONSULTANT COSTS		0	0	0		
EQUIPMENT		42,000	0	0		
SUPPLIES		4,440	300	300		
TRAVEL	DOMESTIC	3,000	3,000	3,000		
	FOREIGN	0	0	0		
PATIENT CARE COSTS	INPATIENT	4,000	1,000	0		
	OUTPATIENT	0	0	0		
ALTERATIONS AND RENOVATIONS		0	0	0		
CONSORTIUM/ CONTRACTUAL COSTS		17,160 52,000	18,503 56,070	26,818 50,965	indirect direct	
OTHER EXPENSES		3,450	3,620	3,804		
TOTAL DIRECT COSTS		147,773	105,085	98,383		

TOTAL FOR ENTIRE PROPOSED PROJECT PERIOD *(Also enter on page 1, item 8)* → $ 351,241.

JUSTIFICATION (Use continuation pages if necessary): Describe the specific functions of the personnel and consultants. If a recurring annual increase in personnel costs is anticipated, give the percentage. For *all* years, justify any costs for which the need may not be obvious, such as equipment, foreign travel, alterations and renovations, and consortium/contractual costs. For any additional years of support requested, justify any significant increases in any category over the first 12 month budget period. In addition, for COMPETING CONTINUATION applications, justify any significant increases over the current level of support.

Personnel:

Dr. Fearon, a board certified diagnostic physicist, will organize and conduct all anthropomorphic dosimetry experiments as detailed in this proposal. He will be assisted by Joseph Hoe, R. T. who is a highly trained and very competent special procedures and quality assurance technologist. In addition, James Vucich, M.S., a board certified diagnostic physicist, from NIH will also assist in these measurements. Mr. Hoe will run the thermoluminescent analyzer system and perform all annealing operations.

Cadaver CT scans will be performed by Dr. Fearon and Mr. Hoe including data transfer from disk to tape. Mr. Hoe will transfer clinical CT data to tape for delivery to Oak Ridge.

The final phase of the calculations of organ absorbed dose for pediatric diagnostic projections for various sized pediatric patients will be conducted by Dr. Fearon with assistance from Mr. Hoe and Mr. Vucich on Children's Hospital's VAX 11-750 system.

0078120

Dr. Pamela Getson, a statistician, will provide statistical analysis for each of the major segments of this project. It is anticipated that this will require about 5% of Dr. Getson's time.

Equipment:

The major equipment cost is that for three anthropomorphic pediatric phantoms. These phantoms will be specifically manufactured for this project by Humanoid Systems, Carson California. The estimated cost of these three phantoms is $19,000.00 based on the current cost of $5,950.00 for the six year old phantom currently available from Humanoid Systems (Appendix B).
The second major equipment purchase is an automated thermoluminescent analyzer system with printer. The current total price for this system is $23,500.00 available from Harshaw Chemical Company, Salon Ohio. This equipment is not available within the hospital and the volume of work required (i.e., TLD batching, calibrations, phantom measurements) for these experiments makes it impossible to use the system at the Center for Devices and Radiological Health since that system is used primarily for Bureau work.

Supplies:

Required supplies and expenses are as follows:

- CaF_2 and Li F TLD dosimeter chips (800 of each type each $1.50=$2400.00)
- expendables (e.g.; nitrogen gas, x-ray film, solvents for cleaning TLD's) ($300.00)
- magnetic tapes (30 BASF high quality tapes, $26.00 each for a total of $780.00). The tapes will be used for CT scan data transfer and storage to Oak Ridge and for data base transfer to Children's Hospital.
- lucite TLD holders are required to sort and identify chips, each holder will be capable of storing 100 chips.

Travel:

Travel expenses include one trip to a scientific meeting per year for the principal investigator for the purpose of presentation of the results of this project. The estimated expense for this trip is $1,000.00 (including $550.00 for airfare, 5 days of perdiem at $22.00 per day, hotel for 4 nights at $70/night $280 and ground transportation $60.)

In addition, the principal investigator will make two trips per year to Oak Ridge (each for one week) for personal contact and consultation with personnel involved in the project at Oak Ridge. The principal investigator will be better able to oversee the project's progress as a result of these trips and to discuss problems, alternatives and future directions for the project. These trips are expected to cost $1,000.00 each as estimated above.
Patient Care Cost:

CAT scans for research purposes are charged at 66% of normal clinical scans to cover depreciation, machine maintenance and operating expenses. The normal charge for a body scan is $314.00. At 66% this results in $200/scan. Approximately 20 whole body cadaver scans will be performed in the first year of the proposal and the remaining 5 in the second year. The first year charge is therefore $4,000.00. This charge is considered reasonable in that we will be doing a complete body scan (head to toe) on each cadaver with repeated scans at thinner slice thickness for areas of particular interest (i.e., trabecular bone).

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10781121

Contractual Cost:
A major portion of the proposed research will be performed at the Health and Safety Research Division of Oak Ridge National Laboratory under the direction of Dr. Keith Eckerman. Dr. Eckerman will be assisted by Dr. Mark Cristy and Dr. Guven Yalcintas as well as a computer programmer. The Oak Ridge group has been the primary source in the development (since the late 1960's) of internal and external dosimetry based on mathematical descriptions of the human body and Monte Carlo radiation transport calculations. The work performed by the Oak Ridge group will be performed under a contractual agreement and will include the following:

-develop and test software necessary to implement slab-geometry phantoms based on CT scans of pediatric cadavers and clinical patients provided by Children's Hospital.

-develop slab-geometry phantoms for age classes of newborn, one year, five year, ten year and fifteen year old pediatric patients.

-perform Monte Carlo radiation transport calculations for three views of each phantom (AP, PA and lateral) based on a grid network (approximately 160 grids per view) with monoenergetic normally incident photons for up to seven energies in each grid. Approximately 60,000 phanton histories will be reqired for each grid calculation resulting in a data base of tissue-air ratios as a function of energy and location for a given view for each phantom.

-develop and test software compatible with the VAX 11-750 located at Children's Hospital that will enable the transformation of the tissue-air ratio data base into organ doses for input paremeters relevant to common pediatric diagnostic radiographic examinations. Input data will include the following: projection and view, patient weight and height, x-ray field size at the image planes, x-ray field location relative to anatomical landmarks, entrance exposure free-in-air at the skin surface, beam quality i.e., HVL or peak kilovoltage and filtration, or incident x-ray spectrum, source-to-image receptor distance.

The contractual cost are detailed separately.

Other:

-Telecommunications expenses are estimated on the basis of one telephone call per week to Oak Ridge at a rate of $5.00 per call (15 minutes) for a total yearly expense of $250.00.

-Publications and reprint costs are estimated as $300.00.

Data entry fees are based on a rate of $7.50 per hour for a research assistant for a total of 80 hours in the first year for a total of $600.00. The data will be the resulting anthropomorphic phantom dosimetry raw data.

-Computer use fees are based on a fixed fee of $2,000.00 per year for unlimited use of the VAX 11-750 system. Computer time will be used to analyze the anthropomorphic dosimetry data and to implement organ dose calculations using the Monte Carlo transport code results for pediatric phantoms.

-Duplication, printing, media work and postage are estimated as $300.00 per year.

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1078122

Detailed Oak Ridge Laboratory Contract

PRINCIPAL INVESTIGATOR/PROGRAM DIREC Thomas C. Fearon, Ph.D.

DETAILED BUDGET FOR FIRST 12 MONTH BUDGET PERIOD DIRECT COSTS ONLY

FROM 04/01/86 THROUGH 03/31/87

DOLLAR AMOUNT REQUESTED (Omit cents)

PERSONNEL (Applicant organization only)

NAME	POSITION TITLE	TIME/EFFORT %	TIME/EFFORT Hours per Week	SALARY	FRINGE BENEFITS	TOTALS
	Principal Investigator					
Keith Eckerman, Ph.D.	Group Leader	20	8	$10,000	3,300	13,300
Mark Cristy, Ph.D.	Research Associate	20	8	$10,000	3,300	13,300
SUBTOTALS →				$20,000	$6,600	$26,600

CONSULTANT COSTS

EQUIPMENT (Itemize)

SUPPLIES (Itemize by category)

TRAVEL	DOMESTIC 2 trips to Washington/yr, one scientific mtg/yr	3,000
	FOREIGN	
PATIENT CARE COSTS	INPATIENT	
	OUTPATIENT	

ALTERATIONS AND RENOVATIONS (Itemize by category)

CONSORTIUM/CONTRACTUAL COSTS

OTHER EXPENSES (Itemize by category)

Indirect costs (@33% = $17,160) CPU time ($1,000)
Laboratory Administration (12% of salaries $2400)
Graphic arts and library services ($1,000) Computer Programmer ($18,000) 39,560

TOTAL DIRECT COSTS (Also enter on page 1, item 7) → $ 69,160

1078123

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY

BUDGET CATEGORY TOTALS		1st BUDGET PERIOD (from page 4)	ADDITIONAL YEARS SUPPORT REQUESTED			
			2nd	3rd	4th	5th
PERSONNEL (Salary and fringe benefits.) (Applicant organization only)		26,600	27,398	28,219		
CONSULTANT COSTS						
EQUIPMENT						
SUPPLIES						
TRAVEL	DOMESTIC	3,000	3,000	3,000		
	FOREIGN					
PATIENT CARE COSTS	INPATIENT					
	OUTPATIENT					
ALTERATIONS AND RENOVATIONS						
CONSORTIUM/ CONTRACTUAL COSTS						
OTHER EXPENSES		39,560	44,175	36,564		
TOTAL DIRECT COSTS		69,160	74,573	67,783		

TOTAL FOR ENTIRE PROPOSED PROJECT PERIOD *(Also enter on page 1, item 8)* → $ 211,516

JUSTIFICATION (Use continuation pages if necessary): Describe the specific functions of the personnel and consultants. If a recurring annual increase in personnel costs is anticipated, give the percentage. For *all* years, justify any costs for which the need may not be obvious, such as equipment, foreign travel, alterations and renovations, and consortium/contractual costs. For any additional years of support requested, justify any significant increases in any category over the first 12 month budget period. In addition, for COMPETING CONTINUATION applications, justify any significant increases over the current level of support.

Personnel:

Doctor Keith Eckerman will direct the work to be performed by the Oak Ridge Group under a contractual agreement between Children's Hospital and Oak Ridge National Laboratory as delineated in the budget justification. Doctor Mark Cristy, a research associate will work with Doctor Eckerman on this project each devoting 20% effort for each of the three years proposed for this project. Doctor Guven Yalcintas will work as a consultant to the project. The Oak Ridge Metabolism and Dosimetry Group is a unique resource and Doctors Eckerman and Cristy have extensive experience in dose estimation based on Monte Carlo radiation transport calculations.

Travel:

The travel budget includes two trips to Washington, D.C. each year for consultation and one trip to a scientific meeting to be attended by either Doctor Eckerman or Doctor Cristy. The estimated expense is $1,000/trip.

1018124

Other:

- Indirect costs are calculated as 33% of directs costs.

- Laboratory administration expenses are charged at the rate of 12% of total salary per year.

- Graphic arts and library services are estimated to cost $1,000 per year.

- CPU time is estimated to cost $1,000 for the first year of the project since this phase of the project will involve mainly programming development and only initial Monte Carlo calculation time.

  In the second and third year production runs of the Monte Carlo radiation transport codes will be undertaken. Based on our experience with the present Monte Carlo Code we anticipate approximately 14 hours of CPU time on an IBM 3033 will be required during each of the second and third years. This estimate assumes in a year the completion of calculations for two age groups, three views, 160 grid points per view, and seven photon energies. We presently have no experience with digital phantoms in Monte Carlo transport codes and thus our estimate of CPU time might be in error. At the end of the first year of the contract it should be possible to develop a reliable estimate of CPU time. At a rate of $300/CPU hour it is estimated that CPU time will cost $4,200 per year in the second and third years of the contract. Some savings will be anticipated by using off hours for production runs.

- A major cost of the contract is that associated with necessary computer programming. For example, codes will be required to manipulate the CT data, produce graphic views of cross sections and to superimpose these cross sectional images. In addition, it will be necessary to develop the software such that the investigator can interact with the system to define regions of interest that may not be distinguished by the CT numbers (e.g., ovaries). Commercial software will be examined for its utlity in this application. Following satisfactory definition of the digital anatomic phantoms ALAMP (FORTAN IV code) will be modified to use the digital phantoms. Considerable testing of the code will be necessary to ensure that it is error free. It is anticipated that testing of the code will be completed in the second year. In the second and third years, production runs will be initiated as well as finalization of phantoms for the older age classes.

  Oak Ridge will develop and implement software compatible with the VAX-11-750 at Children's Hospital that will enable transformation of the tissue-air ratio data base into absorbed-organ dose for common x-ray projections in pediatric diagnostic radiology. It is anticipated that this phase of the project will be initiated near the end of the second year.

  A full time computer programmer is required for the first and second years ($18,000/yr) and 66% effort is required in the third year of the proposed contract ($12,000).

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BIOGRAPHICAL SKETCH

Give the following information for key professional personnel listed on page 2, beginning with the Principal Investigator/Program Director. Photocopy this page for each person.

NAME	TITLE	BIRTHDATE (Mo., Day, Yr.)
Thomas C. Fearon	Medical Physicist	4/29/47

EDUCATION (Begin with baccalaureate or other initial professional education and include postdoctoral training)

INSTITUTION AND LOCATION	DEGREE (circle highest degree)	YEAR CONFERRED	FIELD OF STUDY
The Catholic University of America Washington, D.C.	A.B.	1969	Physics
Univ. of Rochester, Rochester, New York	Ph.D.	1975	Radiation Biology

RESEARCH AND/OR PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order previous employment, experience, and honors. Include present membership on any Federal Government Public Advisory Committee. List, in chronological order, the titles and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. **DO NOT EXCEED TWO PAGES.**

Employment

1970-1972: Laboratory Assitant - Radiation Physics Laboratory, Univ. of Rochester

1975-1980: Scientific Staff Assistant - National Council on Radiation Protection and Measurements

1980-present: Medical Physicist, Assistant Professor of Radiology, Dept. of Radiology, Children's Hospital National Medical Center and Depts. of Radiology and Child Health and Development, George Washington University School of Medicine.

Publications

Fearon, T., Maillie, H. D. and Kremer, W. A. (1974). "Calibration of LiF dosimeters for in vivo 14 MeV neutron dosimetry." (abstract) Health Physics 27, 656.

Fearon, T., Maillie, H. D. and Kremer, W. A. (1975). "Energy spectra and fractional absorbed dose distributions in LET for 14 MeV neutrons: Health Physics 28, 443.

Published reports of the National Council on Radiation Protection and Measurement for which I provided full scientific staff support:

Report No. 45: Natural Background Radiation in the United States

Report No. 48: Radiation Protection for Medical and Allied Health Personnel (1976)

Report No. 49: Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies Up to 10 MeV (1976)

Report No. 54: Medical Radiation Exposure fo Pregnant and Potentially Pregnant Women (1977)

Report No. 56: Radiation Exposure from Consumer Products and Miscellaneous Sources (1977)

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Report No. 61: Radiation Safety Training Criteria for Industrial Radiography (1978)

Report No. 62: Tritium in the Enviroment (1979)

Report No. 64: Influence of Dose and Its Distribution in Time on Dose Response Relationships for Low LET Radiations (1980)

Report No. 66: Mammography (1980)

Report No. 68: Radiation Protection in Pediatric Radiology (1981)

Report No. 73: Protection in Nuclear Medicine and Ultrasonoc Diagnostic Procedures in Children (1983)

Report No. 74: Biological Effects of Ultrasound: Mechanisms and Clinical Implications (1983)

Report No. 75: Iodine-129: Evaluation of Releases from Power Generation (1983)

Fearon, T., Vucich, J. Hoe, J.; McSweeney, W. J. and Potter, B. M. (1985). "A comparative evaluation of rare earth screen film systems. Part I. System speed, contrast, sensitometry, RMS noise and square-wave response function." (Submitted Investigative Radiology).

Fearon, T.; Vucich, J.; Hoe, J.; McSweeney, W. J. and Potter, B. M. (1985). "A comparative evaluation of rare earth screen film systems. Part II. Contrast-detail-dose analysis." (Submitted Investigative Radiology).

Fearon, T.; Vucich, J.; Hoe, J.; McSweeney, W. J. and Potter, B. M. (1985). "A comparative evaluation of rare earth film screen systems. Part III Free response operating characteristic analysis." (Submitted Investigative Radiology).

Fearon, T.; Vucich, J.; McSweeney, W. J.; McIlhenny, J.; Markle, B. and Tepper, J. (1985). "A comparative evaluation of rare earth screen film systems. Part IV. Anatomic Criteria. (Submitted Investigative Radiology).

Fearon, T. and Vucich, J. (1985). "Pediatric patient exposures from computed tomography examinations from a General Electric CT/T 9800 scanner." American Journal of Roentgenology. 144:805-809.

Fearon T. and Luban N. (1985). "Practical dosimetric aspects of blood and blood product irradiations", (Submitted Transfusion).

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BIOGRAPHICAL SKETCH

Give the following information for key professional personnel listed on page 2, beginning with the Principal Investigator/Program Director. Photocopy this page for each person.

NAME	TITLE	BIRTHDATE (Mo., Day, Yr.)
James Vucich	Medical Physicist	11/22/49

EDUCATION (Begin with baccalaureate or other initial professional education and include postdoctoral training)

INSTITUTION AND LOCATION	DEGREE (circle highest degree)	YEAR CONFERRED	FIELD OF STUDY
Duquesne University, Pittsburgh, Penn.	B.S.	1972	Physics
University of Pittsburgh, Pittsburgh, Pa.	M.S.	1974	Radiation Health Physics

RESEARCH AND/OR PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order previous employment, experience, and honors. Include present membership on any Federal Government Public Advisory Committee. List, in chronological order, the titles and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. **DO NOT EXCEED TWO PAGES.**

Experience:

3/20/74-11/23/81 — Special Projects Officer, Division of Training and Medical Applications. Bureau of Radiological Health, Rockville, Maryland.

11/23/81-present — Medical Physicist, Diagnostic Radiology Department, National Institutes of Health, Bethesda, Maryland.

Publications:

Vucich, J. J.; Quality Assurance--A Fundamental Whose Time Has Come; Proceedings of SPIE/SESE Symposium--Application of Optical Instrumentation in Medicine IV; September 1975.

Bunge, R. E.; Gross, R. E.; Vucich, J. J.; and M. Barnett. The Need for Quality Assurance in Diagnostic Radiology; Proceedings of the Ninth Midyear Topical Symposium of the Health Physics Society; February 1976.

Goldman, L. W.; Vucich, J. J.; Beech, S.; and L. W. Murphy. Automatic Processor Quality Assurance: Impact on a Radiology Department; Radiology 125:591-595, (1977).

Vucich, J. J.; The Role of Anatomic Criteria in the Evaluation of Radiographic Images; In The Physics of Medical Imaging: Recording System Measurements and Techniques; Ed. A. G. Haus; American Intsitute of Physics Press, New York, New York (1979).

Vucich, J. J.; A Survey of Entrance Skin Exposure Values for Two Radiographic Projections; Proceedings of SPIE/SPSE Symposium--Application of Optical Instrumentation in Medicine VIII; April 1980.

Vucich, J. J.; Goodenough, D. J.; and Lewicki, A. M.; et al. Use of Anatomic Criteria in Screen/Film Selection for Portable Chest X-ray Procedures; Proceedings of Symposium on Optimization of Chest Radiography; DHEW Publication No. (FDA) 80-8124; June 1980.

Miller, D. L.; O'Leary, T.; Vucich, J. J.; et al. Experimental Evaluation of Five Liver-Spleen Specific CT Contrast Agents; J Comput Assist Tomogr 7(6) 1022-1028, December 1983.

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Miller, D. L.; Vucich, J. J.; Cope, C.; A Flexible Shield to Reduce Scatter During Interventional Procedures; (In press) Radiology, 1985.

Fearon, T. C. and Vucich, J. J.; Pediatric Patient Exposures from Computed Tomography Examinations: GE CT/T 9800 Scanner; 1985;144:805.

Fearon, T. C.; Vucich, J. J.; Hoe, J.; et al. A Comparative Evaluation of Rare-Earth Screen-Film Systems: I-System Speed, Contrast, Sensitometry, RMS Noise and Square Wave Response Function; (Submitted Investigative Radiology) 1985.

Fearon, T. C.; Vucich, J. J.; Hoe, J.; et al. A Comparative Evaluation of Rare-Earth Screen-Film Systems: II-Contrast-Dose-Detail Analysis; (Submitted Investigative Radiology) 1985.

Fearon, T. C.; Vucich, J. J.; Hoe, J.; A Comparative Evaluation of Rare-Earth Screen-Film Systems: III-Free-Response Operating Characteristic Analysis; (Submitted to Investigative Radiology) 1985.

Fearon, T. C.; Vucich, J. J.; Hoe, J.; A Comparative Evaluation of Rare-Earth Screen-Film Systems: IV Anatomic Criteria; (Submitted to Investigative Radiology) 1985.

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BIOGRAPHICAL SKETCH

Give the following information for key professional personnel listed on page 2, beginning with the Principal Investigator/Program Director. Photocopy this page for each person.

NAME	TITLE	BIRTHDATE (Mo., Day, Yr.)
Pamela Getson	Research Statistician	

EDUCATION (Begin with baccalaureate or other initial professional education and include postdoctoral training)

INSTITUTION AND LOCATION	DEGREE (circle highest degree)	YEAR CONFERRED	FIELD OF STUDY
Univ. of Illinois, Champaign-Urbana, Ill.	B.S.	1972	Physiology & Psycholog
Univ. of Virginia, Charlottesville, Va.	M.Ed.	1974	Special Education
Univ. of Virginia, Charlottesville, Va.	Ph.D.	1978	Research Methodology

RESEARCH AND/OR PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order previous employment, experience, and honors. Include present membership on any Federal Government Public Advisory Committee. List, in chronological order, the titles and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. **DO NOT EXCEED TWO PAGES.**

Experience:

1969 — Research Assistant - University of Illinois, Children's Research Center (Ritalin Therapy and Hyperactivity) Champaign, Illinois.

1969-1970 — Instructor - HEED School for the Emotionally Disturbed, Champaign, Illinois.

1974-1175 — Evaluation Specialist - An Analysis of Grading and Reporting, Campbell County Public Schools, Rustberg, Virginia.

1975 — Evaluation Specialist - Rural Cooperative Project, Winston-Salem University/Appalachian State University.

1975-1976 — Associate Evaluator - WVPT Utilization/Impact Analysis, Virginia State Department of Education, Division of Educational Research and Statistics, Richmond, Virginia.

1976 — Evaluator - Teacher Center Utilization and Development Campbell County School System.

1976-1977 — Research Director - Campbell County Study of Student Retention, Campbell County Public Schools, Rustberg, Virginia.

1977 — Project Associate - Campbell County Citizen Survey of Educational Issues, Campbell County Public Schools.

1974-1977 — Research Associate - University of Virginia, Bureau of Educational Research, Charlottesvill, Virginia.

1977-1979 — Research Specialist - Division of Research and Evaluation, MSSD, Gallaudet College

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1978-1979	Consultant - U.S. Office of Education, Bureau of Education for the Handicapped, research panels (program development, field initiated studies).
1979-present	Director of Testing and Evaluation - LMP Associates, Takoma Park, Maryland.
1979-1983	Research Scientist
1981-1981	Associate Professor - Gallaudet College, Graduate School, Dept. of Educational Foundations and Research
1983-present	Research Statistician - Children's Hospital National Medical Center, Washington, D.C., and Assistant Professor, The George Washington University School of Medicine and Health Sciences, Department of Child Health and Development.

Selected Publications:

Getson, P. Based item detection techniques. J. Educ. Statistics 1980:5:213

Getson, P. A Monte Carlo investigation of seven tim bias detection techniques. J. Educ. Meas. 1980;17:1

Rudner L, Getson P, Dirst R. Interpreter competence. RID J. 1981: 1:10

Leatherbury, L., Ruckman, R., Friedman, J., Deitchman, D., Soyka, L., Getson, P. Acute hemodynamic effects of bucindolol in patients (children) with acute congestive heart failure, Journal of Pediatrics, 1984.

Numerous presentations and workshops.

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BIOGRAPHICAL SKETCH

Give the following information for key professional personnel listed on page 2, beginning with the Principal Investigator/Program Director. Photocopy this page for each person.

NAME	TITLE	BIRTHDATE (Mo., Day, Yr.)
Keith F. Eckerman	Leader of Metabolism and Dosimetry Research Group	2/9/40

EDUCATION (Begin with baccalaureate or other initial professional education and include postdoctoral training)

INSTITUTION AND LOCATION	DEGREE (circle highest degree)	YEAR CONFERRED	FIELD OF STUDY
Univ. of Wisconsin, Plattville, Wisconsin	B.S.	1962	Mathematics
Marquette, Milwaukee, Wisconsin	M.S.	1967	Physics
Northwestern Univ. Evanston, Illinois	Ph.D.	1972	Health Physics

RESEARCH AND/OR PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order previous employment, experience, and honors. Include present membership on any Federal Government Public Advisory Committee. List, in chronological order, the titles and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. **DO NOT EXCEED TWO PAGES.**

Experience:

1962-1966	Instructor of mathematics, physics and chemistry, Warren High School, Warren, Illinois.
1966-1967	Research at Oak Ridge Institute of Nuclear Studies, Oak Ridge, Tennessee.
1967-1970	Graduate Student, Northwestern University, Evanston, Illinois.
1970-1972	Guest and Argonne National Laboratory Fellow, Argonne National Laboratory, Argonne, Illinois.
1972-1974	Enviromental Scientist, Argonne National Laboratory, Argonne, Illinois.
1974-1978	Senior Radiological Physicist, U.S. Nuclear Regulatory Commission, Washington, D.C.
1979-present	Leader of Metabolism and Dosimetry Research Group, Oak Ridge National Laboratory, Oak Ridge, Tennessee.

Selected Relevant Publications:

Crawford DJ, Eckerman KF. Modifications of the ICRP Task Groups lung model to reflect age dependence. Rad. Protect. Dosimetry 1983;2:209.

Coocher DC, Eckerman KF. Electron dose-rate conversion factors for external exposure of the skin. Health Phys. 1981;40:467.

Leggett RW, Eckerman KF, Williams LR. Strontium-90 in bone: A case study in age dependent dosimetric modeling. Health Phys. 1982;43:307.

Eckerman KF, Cristy M. Computational method for realistic estimates of the dose to active marrow. Proc. VI Intl. Cong. of the Intl. Rad. Prot. Assoc. May 1984.

Leggett RW, Eckerman KF. A model for the age dependent skeletal retention of Plutonium. Proc. VI Intl. Cong. of the Intl. Rad. Prot. Assoc., May 1984.

Numerous publications and presentation.

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BIOGRAPHICAL SKETCH

Give the following information for key professional personnel listed on page 2, beginning with the Principal Investigator/Program Director. Photocopy this page for each person.

NAME	TITLE	BIRTHDATE (Mo., Day, Yr.)
Mark Cristy	Research Scientist	8/27/46

EDUCATION (Begin with baccalaureate or other initial professional education and include postdoctoral training)

INSTITUTION AND LOCATION	DEGREE (circle highest degree)	YEAR CONFERRED	FIELD OF STUDY
Univ. of Tennessee, Knoxville, Tennessee	B.S.	1969	Physics
Univ. of Oregon, Eugene, Oregon	Ph.D.	1976	Biology
U.S. Natl. Eye Institute, Univ. of British Columbia, Vancouver, British Columbia, Vancouver, Canada	Post Doc.	1976-1977	

RESEARCH AND/OR PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order previous employment, experience, and honors. Include present membership on any Federal Government Public Advisory Committee. List, in chronological order, the titles and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. **DO NOT EXCEED TWO PAGES.**

Experience:

1977- Visiting Instructor in Biology, Western Washington State University, Bellingham Washington.

1977-present Research Scientist Health and Research Division, Oak Ridge National Laboratory, Oak Ridge, Tennessee.

Selected Relevant Publications:

Cristy M. Effect of prolactin and thyroxin on the visual pigments of trout, salmagairdneri. Gen. Comp. Endocrinology. 1974;23:58.

Cristy M. Effects of temperature and light intensity on the visual pigments of rainbow trout. Vision Res. 1976;16:1225.

Allen DM, Cristy M. Thiourea does not block visual pigment responses to prolactin in trout. Vision Res. 1978;18:859.

Coffee JL, Cristy M, Warner GG. Specific absorbed fractions for photon sources uniformly distributed in the heart chambers and heart wall of a heterogeneous phantom. J. Nucl. Med. 1981;22:65.

Cristy M. Representative brease size of reference female. Health Physics 1982;43:930.

Cristy M. Applying the reciprocal dose principle to heterogeneous phantoms:Practical experience from Monte Carlo studies. Phys. Med. Biol. 1983;28:1289.

Cristy M. Calculation of annual limits of intake of raionuclides by workers: Significance of breast as an explicitly represented tissue. Health Phy. 1984;46:283.

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BIOGRAPHICAL SKETCH

Give the following information for key professional personnel listed on page 2, beginning with the Principal Investigator/Program Director. Photocopy this page for each person.

NAME	TITLE	BIRTHDATE (Mo., Day, Yr.)
M. Guven Yalcintas	Ph.D.	

EDUCATION (Begin with baccalaureate or other initial professional education and include postdoctoral training)

INSTITUTION AND LOCATION	DEGREE (circle highest degree)	YEAR CONFERRED	FIELD OF STUDY
Univ. of Ankara, Ankara, Turkey	B.S.	1965	Physics
Univ. of Rochester, Rochester, New York	M.S.	1971	Health Physics
Univ. of Rochester, Rochester, New York	Ph.D.	1974	Radiation Biology
Argonna Natl. Laboratory, Argonna, Ill.	Post Doc. Fellow	2974-1975	Human Radiobiology

RESEARCH AND/OR PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order previous employment, experience, and honors. Include present membership on any Federal Government Public Advisory Committee. List, in chronological order, the titles and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. **DO NOT EXCEED TWO PAGES.**

Experience:

1975-1976	Director of Medical Physics, EGE University Medical School, Izmir, Turkey.
1976-1977	Corporate Health Physicist, Research and Devlopment, EMI Medical Inc., Northbrook, Illinois.
1977-present	Staff Member, Metablism and Dosimetry Group, Health and Safety Research Division, Oak Ridge National Laboratory, Oak Ridge, Tennessee.

Publications:

*	1981	"Experimental Validation of Monte Carlo Calculations for Organ Dose Procedures," Radiopharmaceutical Symposium, 1980 Oak Ridge.
*	1983	"Comparison of Risk Associated with Doses from Computerized Tomography and other Diagnostic Procedures," Health Physic 39, 1051, 1980.
	1980	"An Index of Relative Health Hazard from Selected Radionuclides," Health Physics 39, 1042, 1980.
*	1980	"Measurement and Dose Reduction in Diagnostic CT Scanning Procedures," Health Physics, Midyear Symposium, 1980 Hyannis.
*	1980	"Estimation of Dose due to Accidental Exposure to a Co-60 Therapy Source," Health Physics 38, 187, 1980.
*	1979	"Estimation of Dose and Risk Associated with Co-60 Accident," Health Physics 37, 846, 1979.
	1979	"Dosimetric and Health Effects Analysis for Airborne Radioactive Pollutants," Health Physics 37, 816, 1979.
*	1979	"A Method for Dose Determination in Computerized Tomography," Health Physics 37, 543, 1979.

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*	1979	"Estimating the Risk Associated with Computerized Tomograpahy Doses," Proceedings of the American Nuclear Society, November 1979.
*	1979	"Curriculum and Laboratory Experiments for Training in Health Physics and Medical Physics," Proceedings of Health Physics Midyear Symposium, December 1979.
	1978	"An Analysis of the Radiological Impact of Thorium Mining and Milling," Nuclear Safety 20, No. 3, 1979.
	1978	"Thorium Mining and Milling: An Analysis of Potential Radiological Impact," Health Physics 35, 902 (1978).
*	1978	"Evaluation of Patient Dose in Computerized Tomography," Health Physics 35, 887 (1978).
*	1977	"An Accident durint the Transfer of Co-60 Therapy Source," Health Physics 33, 675 (1977).

Numerous presentations at Scientific Meetings.

* Indicates Dr. Yalcintas is principal author.

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OTHER SUPPORT

(Use continuation pages if necessary)

For each of the professionals named on page 2, list, in three separate groups: (1) active support; (2) applications and proposals pending review or funding; (3) applications and proposals planned or being prepared for submission. Include *all* Federal, non-Federal, and institutional grant and contract support. If none, state "none." For each item give the source of support, identifying number, project title, name of principal investigator/program director, time or percent of effort on the project by professional named, annual direct costs, and entire period of support. (If part of a larger project, provide the titles of both the parent project and the subproject and give the annual direct costs for each.) Describe the contents of each item listed. If any of these overlap, duplicate, or are being replaced or supplemented by the present application, delineate and justify the nature and extent of the scientific and budgetary overlaps or boundaries.

PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR:

(1) ACTIVE SUPPORT:

1. Research Foundation of CHNMC grant for the "Experimental verification of calculated organ-absorbed doses for projections common in pediatric radiology." Thomas Fearon, 10% effort, current direct costs $7,430.00; project period 5/1/85 - 4/31/86.

2. Applications pending: None

3. Applications being prepared for submission: None

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RESOURCES AND ENVIRONMENT

FACILITIES: Mark the facilities to be used at the applicant organization and briefly indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Use "other" to describe the facilities at any other performance sites listed in Item 9, page 1, and at sites for field studies. Using continuation pages if necessary, include an explanation of any consortium arrangements with other organizations.

[X] Laboratory: Laboratory space has been requested. It is anticipated that 200 ft^2 of space in a modern laboratory will be provided contingent upon approval of this proposal. The space will be used for the thermoluminescent analyzer system.

[X] Clinical: GE CT/T 9800 scanner, Department of Radiology

[ ] Animal:

[X] Computer: VAX 11-750 with 4 Mbyte core memory located at Children's Hospital
IBM 3033 at Oak Ridge National Laboratories

[X] Office: Located within the Department of Radiology

[ ] Other (_____):

MAJOR EQUIPMENT: List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.

General Electric CT/T 9800 scanner, Children's Hospital, Dept. of Radiology
VAX 11-750 Computer, Children's Hospital, Department of Radiology
IBM 3033 Computer, Oak Ridge National Laboratory
Philips Maximus M-100 x-ray generator/Machlett (0.3mm focal spot) x-ray tube, angio suite, Children's Hopsital, Department of Radiology

ADDITIONAL INFORMATION: Provide any other information describing the environment for the project. Identify support services such as consultants, secretarial, machine shop, and electronics shop, and the extent to which they will be available to the project.

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A. Specific Aims

Although there exists a substantial volume of information for the estimation of absorbed dose from internal and external radiation exposures to the adult, the paucity of similar data for the child is striking. Radiation exposure as a consequence of diagnostic and therapeutic procedures to the child involves a significant fraction of the pediatric population. In order to properly evaluate the risk-benefit ratio of diagnostic radiologic examinations, accurate knowledge of the absorbed dose to specific organs is necessary. Our proposal has the following major objectives:

1. Develop an anatomical model for "standard" child phantoms from X-ray CT images for the following classes of patient: newborn, 1 year, 5 year, 10 year, and 15 year. The results will be input to detailed Monte Carlo calculations of radiation transport in the body to be undertaken in collaboration with Oak Ridge National Laboratory. The calculations will be used to estimate organ absorbed doses for common pediatric X-ray diagnostic projections.

2. Provide measured normalized organ-absorbed doses for pediatric sized patients for common diagnostic projections from anthropomorphic phantoms representing an average newborn, 1 year old, 3 year old and 6 year old patient. These data will be utilized to verify the Monte Carlo calculations of organ-absorbed dose in pediatric patients undergoing diagnostic X-ray examinations.

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B. Significance

One of the most difficult problems encountered in radiation protection is the estimation of absorbed dose delivered to various organs from internal and external irradiation. Extensive review of the relevant radiobiological data over the past decade has revealed that for both internal and external irradiation, carcinogenesis is the major biological effect of concern overshadowing genetic effects (UNSCEAR 1977; NAS 1980; NCRP 1980; ICRP, 1977), and all tissues of the body must be considered at cancer risk. In order to properly evaluate the risk-benefit ratio of diagnostic radiologic examinations, accurate knowledge of the absorbed dose to specific organs is necessary. The ideal study of toxic effects of any agent requires a knowledge of the dose delivered to each of a number of individuals and a gradation of such doses among individuals and the critical organ of interest. Therefore, the calculational model used to arrive at an estimated organ absorbed-dose must be reasonably accurate in order to assess the associated risk of cancer production in the organ of interest.

Realization of the importance of accurate dosimetric information resulted in the development of theoretical methodologies for the estimation of organ doses (Warner et. al. 1968; Jones T. et. al. 1973), accompanied by an awareness of the need to ensure experimental verification of these estimates and to provide guidance on the limitations of the methodologies (Loewinger and Berman, 1968; Snyder et. al. 1975; NCRP, 1985). While computational and experimental methodologies have been developed to estimate organ dose in adults (Fisher and Snyder 1966, 1967), relatively little effort has been devoted to similar estimates for children based upon actual physical measurements. In order to estimate organ absorbed dose in children, transformed adult phantoms have been used (Atkinson, 1962; Ellis, 1961; Snyder and Cook 1971; Hilyer, Snyder and Warner, 1972; Snyder and Ford 1973). These similitude phantoms were obtained by transforming the adult standard man phantom by choosing three orthogonal scaling factors for each body section such that the body dimensions would approximate that of a child of a given age (Jones et. al. 1976; Hwang et. al. 1976 a,b,c). These phantoms represent a reference newborn, one, five, ten and fifteen year old child.

The major problem with this procedure is that the volumes, shapes, and positions of the internal organs are all determined by scaling factors that may not be appropriate for a particular organ. Geometrical considerations in phantom design are critical. Large differences between the shape and orientation of an organ in the phantom and the corresponding shape and size of the corresponding organ in the human can lead to significant errors, particularly for low energies. Another serious problem with the scaling technique is that active bone marrow distribution is not accurately described (Atkinson, 1962; Ellis, 1961). This is a most crucial flaw when one considers that children may be more sensitive to radiation-induced leukemogenesis by a factor of approximately two (Beebe et. al. 1978). Cristy (1981) has addressed each of these concerns in his series of pediatric phantoms; however, he still notes the lack of detailed cross-sectional anatomy for children, which he judges crucial to the development of phantoms.

The Center for Radiological Devices and Health (CRDH) has made estimates of the doses delivered to specific organs in a standard man for most x-ray studies (Rosenstein, 1976). This information has been used to determine the risk of cancer rendered by such examinations (Laws and Rosenstein, 1978). Others have made use of average tissue doses (Gregg, 1977) or area-exposure products (Bengtsson, 1978) to estimate the cancer risks of various x-ray examinations. All of these studies assume a patient of a given size (standard man approach). The CRDH extended their Monte Carlo calculations to include the pediatric population (Rosenstein et. al., 1979; Beck and Rosenstein, 1979) through use of similtude phantoms (Hwang et. al., 1976 a, b, c, Jones et. al., 1976).

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Computerized axial tomography (CT) offers the potential for obtaining more accurate anatomical information crucial to accurate dose calculations in critical geometry situations. The body can thus be viewed as a series of thin cross-sectional slabs, i.e., a serial slab geometry with each slab having a thickness on the order of one centimeter. The overall size, shape and outline of organs for various slabs would be determined from serial CT scans. Calculation of the radiation transport by Monte Carlo techniques in serial slab-geometry phantoms would appear not to be hampered by the piecemeal representation of either the internal organs or the total body. In fact, the amount of body tissue overlying a critical organ is an extremely important parameter in estimating the dose to that organ from external irradiation, and the serial slab-geometry phantom would provide a more realistic representation of the total body than the simple geometrical surfaces presently used. Even determination of which organ a spatial point resides in (a point at which a radiation event occurs) would appear to be facilitated by reducing search procedures from a three-to-two dimensional problem, as the third coordinate would uniquely determine the slab of interest. The scoring of radiation interactions within the slab of interest could be further facilitated by the adaptation of a special look-up algorithm for the serial slab geometry. Regions of the phantom can be identified as representing either skeleton, lung or soft tissue, thus providing-the proper attenuation characteristics for the calculations of depth dose and internal energy spectrum in soft tissue organs. This approach is inadequate for the calculation of absorbed dose in red bone marrow since it is impossible to model the intricate intermixture of marrow and bone in the skeleton. Simple geometrical forms simply cannot be used to approximate the actual geometrical forms of the trabecular bone laminae and the marrow cavities. An approach to solve the problem associated with estimation of absorbed dose to the active red marrow has been developed at Oak Ridge National Laboratory (Eckerman and Cristy, 1984).

This approach is ammenable to serial slab-geometry phantoms. The resolution of the problem involved consideration of the radiation transport of secondary radiations along with probability distributions of pathlengths through the trabecular laminae and marrow cavities. The approach has been used in the dosimetry of internally deposited radionuclides, but it is independent of the origin of the primary radiation and thus would be applicable to external dosimetry.

A dosimetric study utilizing an anthropomorphic phantom (Alderson Rando phantom) and thermoluminescent dosimetry (Gray et. al., 1981) has demonstrated reasonable agreement with absorbed-organ doses calculated by means of the Monte Carlo method for the adult sized model. No verification of the pediatric dose calculations has been carried out and only sparse estimates of radiation exposures to pediatric patients exist in the literature (e. g., Wesenberg et. al., 1977; Aspin, 1965, Webster et. al., 1974; Bushong, 1978; Spach and Capp, 1962; Mallie et. al., 1985).

Our first objective is the compilation of computed tomography (CT) scanner images of pediatric patients undergoing CT examinations of the head and body. In addition, total body serial scans will be performed on pediatric cadavers for each of the following age classes: newborn, 1 year, 5 year, 10 year and 15 year old. This data will allow the construction of a three dimensional "average" digital serial slab-geometry phantom for each age class. Since the data will be obtained from actual patients, this representation will be an improved approximation to actual body and organ dimensions and organ location. The digital phantoms will then be used as input to Monte Carlo radiation transport calculations for external irradiation from common pediatric diagnostic x-ray procedures. Normalized organ absorbed doses for standardized radiographic examinations will be tabulated.

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As a second objective we will measure absorbed dose in testes, thyroid, eyes, uterus, breast and active bone marrow in pediatric sized anthropomorphic phantoms representing an average sized newborn, one, three, and six year-old child for common diagnostic examination projections. These organ doses will verify the absorbed-organ doses calculated using the slab-geometry phantom calculation results. In addition, comparisons will be made with the organ doses calculated using the currently available phantom (Rosenstein et. al., 1979;Beck and Rosenstein, 1970).

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C. Preliminary Studies

The developmental efforts at Oak Ridge National Laboratory associated with detailed organ dose estimation for internal and external irradiation of man dates back to the 1960's and the work of Walter Snyder and his research group. The development and refinement of these calculations continues today as these calculations are critical to the revision of our understanding of the risk associated with radiation exposure both from occupational and medical exposure. These calculations are critical to such standards setting bodies as the National Council on Radiation Protection and Measurements, the International Commission on Radiological Protection, the United Nations Scientific Commission on the Effects of Atomic Radiation, and the Medical Internal Radiation Dose Committee of the Society of Nuclear Medicine. Accurate knowledge of the absorbed dose in an organ sensitive to radiation damage (i.e., active bone marrow, and mammary tissue) in children is critical in the evaluation of the risk-benefit ratio. The potential risk associated with radiation exposure is significantly greater in children than in adults (Beck et. al., 1978, Shore et. al., 1977; Boice and Monson, 1977; Baral et. al., 1977).

The use of CT images of actual patients will greatly improve our understanding of the dosimetric aspects of medical radiation exposure. The joint project proposed has in fact already begun. We have obtained the appropriate source codes from GE that will allow us to transfer CT images between Children's Hospital National Medical Center and Oak Ridge National Laboratory. Data transfer has been accomplished successfully. An agreement with Dr. Keith Eckerman of Oak Ridge National Laboratory has been reached in which Oak Ridge will develop from the CT scans a series of digital phantoms, modify their existing Monte Carlo transport codes to use such phantoms and will perform an extensive set of calculations in this phantom series. We are beginning to make dosimetric measurements for comparison with actual patient measurements (i.e., skull examination with scatter dose to the thyroid and abdomen examination with scatter dose to the testes). In addition, we have obtained a commitment from Humanoid Systems for the production of three year, one year and newborn anthropomorphic phantoms (Appendix A).

The Department of Pathology of Children's Hospital and the Department of Radiology have both granted approval to do CT examinations of pediatric cadavers as part of the data collection required for this project.

Previously, we have conducted an extensive dosimetry project involving pediatric patients undergoing CT examination. Copies of the reprint are enclosed as Appendix B.

The Research Advisory and Awards Committee of Children's Hospital has provided a pilot grant to begin clinical and anthropomorphic phantom dosimetry studies. The grant has provided an Humanoid Systems six year old anthropomorphic phantom. Personnel at the Center for Devices and Radiological Health will provide, on a limted basis, the use of their thermoluminescent analyzer system.

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D. Methods

1. Serial Slab - Geometry Phantoms

The data collection phase of this segment of this proposal will involve the compilation of routine CT examinations from pediatric patients in each of the following age classes: newborn, one, five, ten, and fifteen year old patients. The data from the CT examinations will be obtained for CT examinations conducted under normal clinical protocols. No additional radiation is required, no discomfort to the patient is involved and the integrity of the examination is not jeopardized in any respect. Patient identification information will remain confidential. Three to five pediatric cadavers within each age class will also be serially scanned from head to toe in 10 mm slices.

These scans will provide a basis set for the phantom in each nominal age class. Phantom classification will be based primarily on patient size and mass. Clinical scans will be used to address the question of the impact that death may have on the placement, composition and shape of the organs. Normal slices of the appropriate size will replace abnormal slices as a result of pathology or other changes noted in the cadaver scans. All scans will be performed on a General Electric CT/T 9800 whole body scanner located in the Department of Radiology. Standard pediatric technique factors will be used. Scanner performance parameters (resolution, linearity, slice thickness and noise) will be checked periodically. In addition, a linearity scan will be performed with each cadaver scan. The contrast scale conversion from CT number to linear attenuation coefficient will be investigated as a possible addition to attenuation and spectral calculations. The error associated with volume averaging effects on the quantitative determination of the linear attenuation coefficient for this application will be investigated. However, the possibility of increased accuracy in determining absorbed dose does exist in using the actual attenuation coefficient rather than lumping tissue into three categories of soft tissue, lung and bone. This data may prove to be of particular value in the determination of the active bone marrow absorbed doses.

The results of the data collection scheme will be used to tabulate organ size and attenuation characteristics in a serial slab-geometry configuration for each age class and sex. It is anticipated that it will require approximately two years to accumulate the required number of cadaver scans. The Department of Pathology handles approximatley 160-180 cadavers per year with about 70% of these being newborns to 1 year old. The remaining cadavers are uniformly distributed up to age 16. Therefore, the older cadaver scans will require a longer time period for accumulation.

Radiation Transport Calculations

The Monte Carlo radiation transport calculations will be carried out using a revised version of the codes (written in FORTRAN IV) developed by the Metabolism and Dosimetry Research Group, Health and Safety Research Division at Oak Ridge National Laboratory led by K. F. Eckerman. The codes will be modified and run on a contractual basis with Oak Ridge on an IBM 3033 located at Oak Ridge National Laboratory. Data transfer will be accomplished with magnetic tape. The software needed to read CT images has already been developed with the cooperation of General Electric Co.

The desired base quantity is the tissue-air ratio for each target organ of interest. The tissue-air ratio is defined as the ratio of the absorbed dose at a given point of interest in a tissue-equivalent phantom to the absorbed dose measured at the same point in air within a volume of tissue equivalent material just large enough to provide maximum electronic build-up at the reference point (ICRU 1973). For ease in application the tissue

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air ratio may have the denominator expressed as exposure free-in-air at the point of interest since the exposure can be readily calculated from a knowledge of the photon energy and fluence. The fact that the tissue-air ratio is only a function of the depth of the point of interest and the field size at the plane of the point of interest and is independent of the source image distance (SID) permits a divergent beam to be simulated by a plane parallel beam for the purposes of determining scattered radiation. This assumes that the intensity and field size of the parallel beam are the same as the divergent beam at the point of interest. The concept can be extended to volume elements such as organs. The Monte Carlo radiation transport techniques will be applied with each phantom description as input to generate a data base of tissue-air ratios from which organ tissue-air ratios can be obtained for a large variety of pediatric diagnostic x-ray projections.

For each serial slab-geometry phantom a rectangular coordinate system will be generated with the origin located at the center of the slice at the base of the torso. A system of grid elements will be superimposed on the x-z midplane of the phantoms for AP and PA projections and in the y-z plane for lateral projections. Advantage of body symmetry is utilized in order to reduce the number of grid elements for which photon histories are required. For each grid element within each slab a Monte Carlo transport calculation is carried out for a large number of photon histories (approximately 60,000). The number of photon histories required is determined by the required statistical accuracy desired. For volumes of interest within the beam the standard deviation should be of the order of 2%. For a given monoenergetic photon normally incident within a grid element the point of interaction is randomly selected. The path of the photon is traced by simulating the successive interactions. The energy at each point of interaction is tabulated. A data base of organ tissue-air-ratio as a function of incident photon energy is thus generated for each grid element for each projection and each phantom.

Tissue-air ratios will be calculated for each grid element (approximately 160 elements per view) for an AP, PA and lateral view of each phantom for up to seven monoenergetic energies per view. The programming required to implement and run the phantom data will be carried out at Oak Ridge. It is anticipated that the newborn, one year, and five year old phantom calculations will be completed within the first two years and the remaining two phantoms will be completed in the final year of the proposed project period.

Organ Dose Estimation from Common Pediatric Diagnostic Projections

Calculation of organ dose estimates for common pediatric diagnostic projections will be carried out collaboratively on a combination of the Oak Ridge IBM 3033 and the VAX 11-750 at Children's Hospital. Oak Ridge will develop the software that will allow calculation of organ doses from common pediatric projections. The software will be run on the VAX 11-750 at Children's Hospital. This segment of the project should commence in the second year of the project.

The dose to a specific organ from a specified x-ray examination is calculated using the tabulated tissue-air-ratios and examination parameters. The width and height of the x-ray field at the image receptor is converted to the width and height at the plane of the organ of interest. The center and perimeter of the field at the organ plane of reference is located on the grid array, and the tabulated tissue-air-ratios are summed for each incident monenergetic energy. Fractions of grids are taken into account by utilizing the fraction of the grid covered times the tissue-air ratio for that grid element. An appropriate x-ray spectrum consistent with the kVp and HVL used in the examination is selected. The tissue-air-ratio contributions are weighted as a function of the exposure

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per energy range. Interpolation between measured energy values is required to complete the spectrum. The organ tissue-air-ratio is converted to an absorbed dose using the specific entrance exposure free-in-air corrected by inverse square to the reference plane of interest. Absorbed dose to testes, ovaries, active bone marrow, thyroid, breast, and eyes will be calculated for the pediatric diagnostic x-ray examinations listed in Table 1.

2. Anthropomorphic Phantom Measurements and Calculation Verification

Four anthropomorhpic pediatric phantoms (Humanoid Systems; Carson, California) representing a newborn, 1 year, 3 year and 6 year old child will be used in conjunction with thermoluminescent dosimetry to measure normalized organ doses per unit entrance exposure in air for projections common in pediatric radiology. Standard positioning will be used for each examination. A Phillips Maximus M-100 1200 mA three phase generator with a Machlett x-ray tube (0.3mm, 1.0 mm nominal focal spot sizes) will be used for all exposures. The calibration of the x-ray generator will be verifed with a Machlett Dynalyzer II and the half value layer of the x-ray beam will be adjusted to at least 3.0 mm of aluminum at 90 kVp by the addition of added aluminum. Li F (Harshaw TLD-100) and CaF_2 (Harshaw TLD-200) thermoluminescent dosimeters will be calibrated against an MDH x-ray monitor (Model 10X5-6; Radcal Corporation, Monrovia, California) using a lucite tank (30x30x20 cm) filled with water. The TLD's will be positioned within the primary x-ray beam for primary plus backscatter and primary plus forward scatter calibrations. Scattered energy spectra calibrations will be carried out with TLD's positioned 90 degrees to, and outside of, the primary x-ray beam. The distance from the x-ray target to the front surface of the lucite tank will be 100 cm. The TLD's will be batched such that the standard deviation of the response of the TLD's in each batch is less than 3%, for a uniform exposure of about 1R(6.258mC/kg) for each of the energy spectra. A standard annealing process of 1 hour at 400°C followed by 1 hour at 100° C will be followed for the TLDs. Prior to reading, the chips will be preannealed at 100°C for 15 minutes to deplete the low energy electron traps in the crystal structure and thereby suppress low temperature peaks and stabilize the response of the TLD's. This is particularly important for the CaF_2 TLD's since they demonstrate marked fading of response as a function of time due to the response of the low energy electon traps. The TLD chips will be read out on a thermoluminescent analyzer (Model 2000 B Thermoluminescent, Analyzer System, Harshaw Chemical Co., Solon, Ohio) under a nitrogen atmosphere. The thermoluminescent output of the TLD-100 dosimeters will be intergrated between 150°C and 240°C. The thermoluminescent output of the TLD-200 dosimeters will be integrated between 100°C and 285°C. Thermoluminescent response will be converted to absorbed dose by means of the following equation:

$$D=fRC$$

Where:

D=absorbed dose in tissue, rad
f=Roentgen to rad conversion factor for tissue
R=thermoluminescent response of irradiated TLD, Coulombs
C=calibration factor, Roentgen/unit thermoluminescent response in Coulombs

The anthropomorphic phantoms to be used in these studies will be obtained from Humanoid Systems (Carson, California). The phantoms mimic the attenuation and energy absorption properties of human patients at diagnostic energies for newborn, one year, three year, and six year old children.

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The phantoms are constructed of human skeletons impregnated with tissue equivalent material encased in tissue equivalent material that is molded to resemble a pediatric patient of the appropriate size. Lungs are molded of a plastic foam material that is adjusted to water equivalence. The molded phantom is cut into 2.5 cm thick slices and each slice contains a matrix of 5 mm holes at 1.5 cm spacing. Tissue and lung equivalent plugs with internal cavities to accomodate TLD chips are inserted in the grid holes. Attenuation measurements will be made in order to verify that the phantom material approximates that of tissue in the diagnostic energy range.

Absorbed dose to the testes, ovaries, thyroid, uterus, eyes, breast and active bone marrow will be measured for the common diagnostic projections listed in Table 1. The phantoms will be positioned such that scatter is minimized. Collimation of the beam will be to the area of interest and to the film size. A screen-film system will be used to record the area exposed. The distance from the vertex of the head of the phantom to the center of the screen-film system will be recorded along with film size to accurately locate the beam entrance.

Table 1. Common Pediatric Diagnostic X-Ray Projections to be Used in this Study

Examination	Projection		
	Anteroposterior	Posteroanterior	Lateral
Chest	X	X	X
Lumbar Spine	X	X	X
Cervical Spine	X		X
Renal	X		
GI	X	X	X
Ear	X		X
Pelvis and Hip	X	X	X
Skull	X	X	X
Gallbladder	X		

After each exposure for a given projection, the phantom will be removed and an MDH model 10x5-6 ionization chamber (Radcal Corp. Monrovia, CA) will be positioned in air at the location where the central beam impinged on the phantom. An exposure in free air is measured at this position at the same technique factors as used for the phantom measurement. From this measurement the organ absorbed dose can be normalized to the entrance exposure free in air.

The absorbed dose to active bone marrow will be determined from the sum of weighted sampled measurements of active bone marrow sites. The weighting factors are derived from the active bone marrow distribution in the skeleton for the appropriate age.

The experimental normalized absorbed doses will be compared with estimates derived from calculations provided by Rosenstein et. al. (1979) and those derived from the revised estimates that will be derived from the slab geometry model developed here.

It is anticipated that the anthropomorphic dosimetry will be completed within the first two years of the three year project period. All experiments will be conducted at Children's Hospital.

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OAK RIDGE NATIONAL LABORATORY
OPERATED BY MARTIN MARIETTA ENERGY SYSTEMS INC

POST OFFICE BOX X
OAK RIDGE TENNESSEE 37831

June 27, 1985

Thomas Fearon, M.D.
Department of Radiology
Children's Hospital
National Medical Center
111 Michigan Avenue, N.W.
Washington, D.C. 20010

Dear Tom:

National Institutes of Health Proposal

I am pleased to hear of your interest in improving the dosimetric information of diagnostic radiology in pediatrics. We look forward to collaborating with you and your staff in developing this information. The areas you outlined in the draft proposal to NIH are a natural extension of our research interests and the collaborative effort between our staffs which permit accumulation and analysis of the biological data so necessary for improving dosimetric information for the pediatric patient.

Sincerely,

Keith

Keith F. Eckerman, Leader
Metabolism and Dosimetry Research Group
Health and Safety Research Division

KFE:bpw

cc: R. O. Chester (ORNL)
S. V. Kaye (ORNL)

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CHECKLIST

This is the required last page of the application.

(Check the appropriate boxes and provide the information requested.)

TYPE OF APPLICATION

[X] NEW application *(This application is being submitted to the PHS for the first time.)*

[ ] COMPETING CONTINUATION of grant number: _____.
(This application is to extend a funded grant beyond its current project period.)

[ ] SUPPLEMENT to grant number: _____.
(This application is for additional funds to supplement a currently funded grant.)

[ ] REVISION of application number: _____.
(This application replaces a prior unfunded version of a new, competing continuation or supplemental application.)

[ ] Change of Principal Investigator/Program Director.
Name of former Principal Investigator/Program Director: _____.

ASSURANCES *(See GENERAL INFORMATION section of instructions.)*

a. Civil Rights	b. Handicapped Individuals	c. Sex Discrimination	d. Vertebrate Animals *(If applicable)*	e. Human Subjects *(If applicable)*
[X] Filed	[X] Filed	[X] Filed	[X] Filed	[X] Filed
[ ] Not filed	[ ] Not filed	[ ] Not filed	[ ] Not filed	[ ] Not filed

INDIRECT COSTS

Indicate the applicant organization's most recent indirect cost rate established with the appropriate DHHS Regional Office. If the applicant organization is in the process of initially developing or renegotiating a rate, or has established a rate with another Federal agency, it should, immediately upon notification that an award will be made, develop a tentative indirect cost rate proposal based on its most recently completed fiscal year in accordance with the principles set forth in the pertinent *DHHS Guide for Establishing Indirect Cost Rates,* and submit it to the appropriate DHHS Regional Office. Indirect costs will not be paid on foreign grants, construction grants, and grants to individuals, and usually not on grants in support of conferences.

[X] DHHS Agreement Dated: 10/22/84

76 % Salary and Wages *or* _____ % Total Direct Costs.

Is this an off-site or other special rate, or is more than one rate involved? [X] NO [ ] YES
(If "YES," explain and provide the basis for the indirect cost calculation.)

[ ] DHHS Agreement being negotiated with _____ Regional Office.

[ ] No DHHS Agreement, but rate established with _____ Date _____

[ ] No Indirect Costs Requested.

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Appendix A

Letters from Humanoid Systems describing availability of pediatric anthropomorphic phantoms.

HUMANOID SYSTEMS
DIVISION OF HUMANETICS, INC.
17022 MONTANERO STREET
CARSON, CALIFORNIA 90746
(213) 537-7851 TELEX 67-1186

May 14, 1985

Dr. Tom Fearon
Medical Physicist
Department of Radiology
Children's Hospital
11 Michigan Avenue, N.W.
Washington, D.C. 20010

Dear Dr. Fearon,

It was a pleasure speaking to you again, and I look forward to receiving your order for a Pediatric Radiation Therapy Phantom.

As requested, a catalogue and price list are enclosed.

If your institution could provide a newborn skeleton, it would indeed be feasible for us to manufacture a "newborn" Pediatric Radiation Therapy Phantom.

A ballpark price would be $7,500.00, with a ballpark delivery time of 6-8 weeks after our receipt of the skeleton.

Please do not hesitate to contact me if you require further information.

Sincerely,

DAVID WEINER, RT, CNMT
Vice President
Marketing and Sales

DW/mm

Enclosure

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HUMANOID SYSTEMS
DIVISION OF HUMANETICS, INC.
17022 MONTANERO STREET
CARSON, CALIFORNIA 90746
(213) 537-7851 TELEX 69-1186

April 3, 1985

Tom Fearon, Medical Physicist
Department of Radiology
CHILDREN'S HOSPITAL
11 Michigan Avenue, N.W.
Washington, D.C. 20010

Dear Mr. Fearon,

Thank you for your phone call and interest in our Pedo-RT Pediatric Radiation Therapy Phantom.

Regarding the 6-year old Pedo, the January 1, 1985 Radiological Phantoms Price List is still current. Shipment time is currently running 2-3 weeks after receipt of order.

We would indeed be interested in making a 1-year old Pedo-RT. Based on the 1 year having the same specifications as the 6-year old (differing only in size), a ballpark selling price would be $6,000.00, with a 4-8 week delivery. We would be gald to send a formal quote when you are ready to proceed with the project.

Please remember that a 3-year old Pedo-RT is currently available as a standard item at a cost of $ 750.00 over the equivalent model 6-year old standard Pedo-RT.

If you require any further information, please do not hesitate to contact me directly.

Sincerely,

DAVID WEINER, RT, CNMT
Vice President
Marketing and Sales

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Appendix B

Publication entitled "Pediatric Patient Exposures from CT Examinations: GE CT/T 9800 Scanner" by Thomas Fearon and James Vucich.

TABLE 1: **CTDI Determined Using LiF Thermoluminescent Dosimeters**

Phantom Type: Technique (kVp/mA/s)	Slice Thickness (mm)	CTDI			
		Top		Center	
		rad (cGy)	mrad (10^{-5}Gy)/mAs	rad (cGy)	mrad (10^{-5}Gy)/mAs
Head (diameter = 16 cm):					
120/200/2	10	5.3	13.3	5.2	13.0
120/200/2	5	5.3	13.3	5.1	12.8
120/200/2	3	5.5	13.8	5.1	12.8
120/200/2	1.5	5.1	12.8	5.0	12.5
80/200/2	10	2.5	6.3	2.2	5.5
Body (diameter = 32 cm):					
120/200/2	10	2.6	6.5	1.4	3.5
120/200/2	5	2.6	6.5	1.4	3.5
120/200/2	3	2.6	6.5	1.5	3.8
120/200/2	1.5	2.5	6.3	1.5	3.8

31, 1984 amending 21 CFR 1020 [17] to require manufacturers of CT equipment to furnish dose-profile information with their equipment, using the phantom and CTDI concept defined by Shope et al. [16]. The changes to the standard became effective on November 29, 1984. The CTDI is a figure-of-merit that reflects the dose efficiency of a CT scanner. However, direct comparison to patient exposures may be somewhat misleading, particularly in the case of infants and children, since the size of the standardized phantoms and, therefore, their attenuation characteristics do not closely represent the pediatric patient.

We provide CTDI values for typical pediatric CT examinations for a GE CT/T 9800 scanner operating under typical clinical technique factors and compare them with measurements of entrance absorbed dose of pediatric patients under clinical situations.

Materials and Methods

All dosimetry measurements were conducted on a General Electric CT/T 9800 scanner, using typical clinical technique factors for pediatric patients.

Dose Profiles

Two cylindrical Lucite (1.19 ± 0.01 g/cm^3) phantoms were used for head and body dosimetric measurements as required in 21 CFR 1020.33(c) (2). Each phantom was 14 cm long, which provided an adequate scatter source for the central part of the phantoms. The body phantom was 32 cm in diameter, with holes drilled parallel to the axis at locations lying along eight radii of 0, 5.3, 10.6, and 15.0 cm. The head phantom was 16 cm in diameter, with holes drilled at locations lying along eight radii of 0, 4.95, and 7.0 cm. Single-scan dose profiles perpendicular to the scan plane were measured at the central and top position in each phantom by means of arrays of 40 LiF thermoluminescent dosimeter (TLD) chips. The TLDs were held in position in special holders so that the major planar surface of each chip was parallel to the scan slice. The distribution of chips allowed for a higher sampling in the peak region of the scan profile. The maximum average dose was also measured using three calibrated MDH 1050 radiation exposure meters with model 10X5-10.3 CT pencil ionization chambers (Radcal Corp., Monrovia, CA). All dosimetry holes not containing dosimeters were filled with solid Lucite rods. The chamber exposure readings were corrected for the actual area of the chamber volume exposed and converted to absorbed dose in tissue: f = 0.92 rad/R (35.7 Gy-kg/C).

The LiF TLDs used in this study were provided and processed by the X-Ray Calibration Laboratory of the Center for Devices and Radiological Health, Food and Drug Administration. About 1300 TLD-100 chips (0.32 × 0.32 × 0.09 cm) in three batches were used in the study. The standard deviation of the response of the TLDs in each batch was about 3%, for a uniform exposure of about 1 R (0.258 mC/kg). After standard annealing, the response of the TLDs was calibrated relative to the response to about 1 R (0.258 mC/kg) of x-rays generated at 100 kV constant potential (5.04 mm Al half-value layer, 0.72 homogeneity factor). Calibration exposures were monitored with a secondary ionization chamber (± 3% calibration uncertainty). Due to a lack of specific information, the effective energy of the x-ray photons to which the TLDs were exposed at various points in the phantoms was assumed to be between 50 and 70 keV. In order to account for this variation in photon energy, the response of the TLDs was corrected for differences between calibration and phantom dosimetry measurements (1.10 ± 0.13) [15].

Clinical Measurements

Clinical dosimetry measurements were carried out using small heat-sealed plastic packages each containing five LiF TLDs positioned in a linear array. One package of dosimeters was positioned in the center of the central slice of the area of the patient to be scanned, with the linear dimension of the dosimeters aligned with the scan slices. This orientation was chosen so that the dose at the center of the central slice would be obtained. Positioning of the TLDs was accomplished by means of the table location information provided by the scanner gantry and the laser alignment lights. It was thought that this positioning of the TLD arrays would be less susceptible to systematic variation than if the TLD linear arrays were positioned perpendicular to the slice plane, thereby including the effects of dose fall-off at the edge of each slice. The dosimeter package was left in place for one complete series of adjacent slices and was removed if a second series of scans of the same anatomic area was required (e.g., scans with and without contrast agent). Typical pediatric dynamic scan technique factors as used in our department were used for each examination.

Sixty-eight pediatric patients, ranging from newborn to 20 years, undergoing CT examination of the head, chest, or abdomen were used in the study. Infant head examinations were defined as those examinations on children 6 months of age or under. No restrictions

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of various manufacturers' systems operating under clinical situations; however, phantom absorbed-dose measurements are not necessarily the same as those that may be encountered in actual patient examinations.

Our results suggest that for pediatric patients, typical entrance skin absorbed doses on a GE CT/T 9800 scanner using clinical technique factors for examinations of the chest and abdomen are in the range of 1.0–2.4 rad (cGy). Similarly, entrance skin absorbed doses for pediatric scans of the head are in the range of 2.0–3.4 rad (cGy) and 3.2–4.2 rad (cGy) for infant (≤ 6 months) head examinations.

It is of interest to compare pediatric absorbed doses from CT examinations with those used in radiographic examinations. The maximum absorbed skin dose for biplane cerebral angiography has been estimated to be about 16 rad (cGy) for a 5-year-old and about 23 rad (cGy) for a 15-year-old [18]. Similarly, a four-film excretory urogram delivers a maximum skin dose of about 0.3 rad (cGy) in a 5-year-old and about 0.8 rad (cGy) in a 15-year-old [18]. Abdominal angiography (30 films with magnification and 5 min fluoroscopy) delivers about 10 rad (cGy) for a 5-year-old and about 30 rad (cGy) for a 15-year-old [18]. Of course these doses will vary depending on the screen-film system used, the length of fluoroscopy, and other technical factors used in the study.

A comparison of entrance skin absorbed doses with absorbed-dose measurements in the head and body cylindrical phantoms (tables 1 and 2) when adjusted for mA differences demonstrates that the head phantom more closely predicts actual patient doses to within about 5% for abdomen and chest examinations and to within about 15% for head examinations. The correspondence is not exact, since the attenuation properties of the phantom do not exactly mimic those of the human body (e.g., attenuation inhomogeneities such as lung, bone, etc.) and the fact that patient exposures are measured as entrance skin exposures and phantom measurements are at a depth of 1 cm. The ratio of the dose at a depth of 1 cm to that at the center of the head phantom (8 cm) is 1.1, indicating that the dose across a pediatric patient would be fairly uniform except for the anatomic inhomogeneities. Due to the dimensions of the head phantom, infant head doses are underestimated. The body phantom predicts lower actual patient absorbed doses and also predicts more nonuniformity of the dose across a patient. Moreover, it is virtually meaningless for comparison with all pediatric patients except nearly full-grown adolescents.

Image noise is the ultimate limitation in the accuracy of low-contrast resolution. Image noise, as a result of x-ray photon flux variation at the detector, consists of two components: (1) photon flux variations in the x-ray source and (2) photon flux variations attributable to object size and internal structure density variations [19]. Small patients or body parts (e.g., infant heads) offer low attenuation of the incident primary x-ray beam and, therefore, the variation of photon flux at the detector is decreased relative to larger patients or body parts, so that the dose used can be decreased without reduction of the signal-to-noise ratio. The limit to dose reduction with increasing noise is a complex function of the clinical imaging task and the observers' internal noise or contrast threshold [20]. Scans of the head require good low-contrast resolution; therefore, dose reduction may be limited to some extent, except in infant head examinations, in which case the decreased size of the skull may allow a decrease in entrance exposure while still providing a clinically acceptable scan. As a result of this study, our technique for infant heads has been decreased from 120 mA to 70–100 mA depending on the size of the patient's head, with no clinically apparent degradation of the image due to an increase in noise.

In summary, although the use of the CTDI concept is useful in comparing the dose efficiency of various CT scanners operating at clinically relevant factors, the doses obtained may not be directly comparable to those in clinical practice. Our results suggest that the head phantom proposed by the FDA more closely predicts typical doses for pediatric patients than the body phantom. The doses for infant head CT examinations, however, are underestimated.

ACKNOWLEDGMENTS

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ORO WORK FOR OTHER REVIEW COMMITTEE
PROPOSAL INFORMATION

Prepared by:	Phone:	Energy Systems Approval:	Date:
K. F. Eckerman	4-6251	Chester R Richmond	31 Mar 86

1. DOE Interagency Agreement or Contract No.
ERD-86-574 / 10 fill

2. Outside Sponsor/Customer:
Children's Hospital Natl. Med. Center

3. Title and brief description: "ORGAN DOSE IN PEDIATRIC DIAGNOSTIC RADIOLOGY"
Develop an anatomical model for "standard" child phantoms from X-ray CT images for the following classes of patient: newborn, 1 year, 5 year, 10 year, and 15 year. The results will be input to detailed Monte Carlo calculations of radiation transport in the body to be undertaken in collaboration with Children's Hospital Natl. Med. Center. The calculations will be used to estimate organ absorbed doses for common pediatric X-ray diagnostic projections.

4. How was request originated?
Dr. T. C. Fearon, Children's Hospital Natl. Med. Center contacted K. F. Eckerman of ORNL.

5. Can work be done outside? (If not, why? Does Energy Systems have unique capabilities?) NO.
The Metabolism and Dosimetry Research Group of ORNL has developed the computational models for the anatomy of man presently used world-wide in radiation protection. ORNL's past experience and leadership role represents unique capabilities that do not exist elsewhere.

6. Is this work of programmatic interest to DOE? (If so, how? Give specific B&R No.)
YES - extension of ORNL support of ICRP activities under the following B&R numbers:
DOE - HA 02 01 01 0 NRC - 41 35 55 06 7
DOE - HA 02 04 03 0 EPA - 42 01 54 90 1

7. Will work interfere with ongoing DOE programs?
NO

8. If ORNL, cite reference in approved Inst. Plan.
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9. Are necessary resources (equipment and personnel) currently available to perform this work?
YES

10. Is over 30% of this work to be subcontracted? If so, explain.
NO

11. Estimated Project Cost:	12. Estimated Project Period:	13. Energy Systems Person-years:
a. Total $211,500	4/86 - 3/89	a. Total .20 PY
b. Annual $70K full cost		b. Annual .20 PY

14. Comments
This new task will be directly related to the programmatic activities noted in number 6 above.

Submitted by WFO Office 4-1-86

ORO Review Committee Action: Approved ___ Disapproved ___

Committee Chairman Signature S. T. Marquart Date 4/4/86

Contracting Officer Signature Peter D Dayton Date 4/4/86

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