BRH BULLETIN
bureau of radiological health

Monday, January 22, 1979 • Volume XIII, No. 2

Bureau Evaluating Feasibility of Reopening Utah Thyroid Cancer Study

The Bureau of Radiological Health is evaluating the feasibility of reopening an earlier study of the association between exposure to fallout from nuclear weapons testing and the risk of thyroid neoplasms. The feasibility study was initiated in response to President Carter's November 27, 1978, directive that HEW investigate further the possible link between the atomic bomb tests that were conducted in Nevada in the 1950's and the subsequent development of thyroid cancer in some Utah residents.

The earlier study, conducted in the 1960's, involved a survey of 4,831 school children attending grades 6 through 12 in selected counties in Utah, Nevada, and Arizona. The exposed group consisted of children who were residing in the Utah and Nevada counties prior to January 1, 1959. The internal controls were children who had moved into these counties after January 1, 1959, and therefore were unlikely to have been exposed to the fallout, and the external controls were children in an Arizona county where minimal exposure had been recorded. Medical and demographic information on each child in the study population was obtained by means of a questionnaire, and physicians from the U.S. Public Health Service examined each child annually from 1965 to 1968 for evidence of thyroid disease. In addition, laboratory tests were performed on the sera of all children with evidence of thyroid abnormalities and on the sera of selected "normal" children.

Although the data failed to reveal an increase in the incidence of thyroid nodules or tumors among the exposed children, the latency period for thyroid neoplasia may be as long as 30 years. Hence, a followup of the original study population at this time (mean risk period of 26 years) could provide more definitive information on whether exposure to nuclear fallout is associated with an increased incidence of thyroid or other cancer in residents of southwestern Utah and Nevada. The feasibility study is expected to indicate whether a resurvey of the original population can be done and, if not, whether alternative approaches can be used to produce the necessary epidemiologic information.

Specifically, the objectives of the feasibility study are to determine whether: (1) the basic records from the earlier study are available in such form as to permit further investigation, (2) the study population can be reconstructed so the necessary followup data can be obtained, and (3) the records can be linked with the Rocky Mountain Cancer Data System for followup information about cancer incidence in exposed and nonexposed survey groups. Completion of this study will require about 18 months.

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE • Public Health Service
Food and Drug Administration • Bureau of Radiological Health • Rockville, Maryland 20857

Microwave Diathermy Applicator Leakage Evaluated in Clinical Tests

Clinical measurements of the radiation leakage from a specially designed 2450-megahertz direct-contact microwave diathermy applicator have shown that phantom models of parts of the human body can be used effectively to predict the leakage levels existing under actual human treatment conditions. The study was performed in 1978 at the U.S. Public Health Service Outpatient Clinic in Washington, D.C., by engineers from the Bureau's Division of Electronic Products. The applicator was designed for the Bureau by Transco Products, Inc., and its design has been dedicated to the Food and Drug Administration for public use (BRH BULLETIN, Auugust 28, 1978).

The objectives of the study were to: (1) obtain sets of data on the leakage levels existing in the immediate vicinity of the applicator during tests on standard arm, thigh, and trunk (back) phantoms and during simulated microwave diathermy treatments on two human volunteers, (2) determine the relationship between the leakage levels observed for the phantoms and those observed for the humans, and (3) compare the leakage radiation and heating effectiveness in phantoms for the new direct-contact applicator versus conventional non-contact types. Although the Bureau's draft proposed performance standard for microwave diathermy equipment calls for specific tests on phantoms only and purposely omits any tests involving human subjects, a comparison of phantom and human test data was needed to confirm the usefulness of phantoms as models.

During the study, the volunteers were minimally exposed for 1-minute intervals to low-power (1 to 1.5 watts of net power) simulated treatments while leakage fields were mapped around the area where the applicator was in contact with the body. The measurements were made with a commercially available isotropic radiation survey instrument and a Bureau-developed miniature E-field probe. The mapping was performed manually at a 5-centimeter distance from the applicator/subject interface.

Identical leakage measurements also were made on the arm, thigh, and trunk phantoms. For all three phantoms, the data obtained were in good agreement (within a factor of 2) with the human treatment data for the corresponding portion of the anatomy, as long as the leakage was higher than the background instrument noise levels.

The investigators have extrapolated the data from these tests to determine the leakage levels that would exist under effective treatment conditions (defined as 235 watts per kilogram delivered to the phantom muscle material). Based on the low-power test data for the trunk phantom and the lower back of the human patient (lumbar region, excluding the spinal area), the leakage levels for full-power treatments were calculated to be less than 0.2 and 0.5 milliwatt per square centimeter, respectively. Similar calculations for the thigh phantom and the human thigh indicated that the leakage levels under full-power conditions would be less than 2.3 and 2.9 milliwatts per square centimeter, respectively. Analysis of the arm phantom data showed that leakage of less than 9.6 milliwatts per square

Glaser ✓

centimeter would exist during full-power treatments, while analysis of the upper and lower arm data for actual patients indicated that leakage under full-power conditions would be less than 11.9 and 8.3 milliwatts per square centimeter, respectively. Since the particular applicator used was not designed for arm treatments, the leakage levels for the arm were higher than those for the thigh and back.

Limited tests of the most frequently used, conventional non-contact applicators (Burdick types B and E) with only a planar phantom have shown that the energy deposition was low (less than 103 watts per kilogram) when the manufacturer's recommended power levels were used. Conversely, when input power to the non-contact applicators was increased so that the energy deposited in the phantom muscle material was 235 watts per kilogram, high leakage levels (greater than 35 milliwatts per square centimeter) were measured at 5 centimeters from the interface of the applicator and phantom.

The results of this study have been published in a Bureau report entitled "Leakage in the Proximity of Microwave Diathermy Applicators Used on Humans or Phantom Models" (FDA) 79-8073. Limited, single copies may be obtained upon request from the Bureau of Radiological Health (HFX-28), 5600 Fishers Lane, Rockville, Maryland 20857. The report also is being made available for purchase from the National Technical Information Service (NTIS), and ordering information will be placed in the BRH BULLETIN as soon as the accession number and price are received from NTIS.

> NOTE: Prior to initiation of the clinical portion of this study, the use of human volunteers was approved by the Bureau's Scientific Review Committee and the Food and Drug Administration's Research Involving Human Studies Committee.

"Study of Health Effects from Radiofrequency Radiation Initiated"

The American Health Foundation, under contract with FDA's Bureau of Radiological Health, has initiated a study of the possible adverse health effects associated with exposure to low-level radiofrequency radiation from microwave and shortwave diathermy equipment.

The contract calls for a group of male physical therapists and their offspring to be studied through the use of a mailed questionnaire, with several followups planned for nonrespondents. The feasibility of conducting such a survey was determined by a pretest, and the full-scale survey was initiated in October 1978 with the mailing of questionnaires to male members of the American Physical Therapy Association.

The objective of the study is to determine whether physical therapists or their offspring demonstrate adverse health effects related to occupational use of

diathermy equipment. For the therapists, the study will consider such health effects as cataracts, high blood pressure, sterility, and persistent fatigue, dizziness, insomnia, or headaches. For the offspring, consideration will focus on such items as fetal and infant mortality, low birth weight, and congenital malformations.

Therapists are being asked to supply information about medical and work histories for themselves and their wives. Items regarding smoking, as well as exposure to ionizing and nonionizing radiation and to chemicals, are included in the questionnaire. Analysis of the data will attempt to relate health and reproductive outcomes to the use of diathermy equipment so the possible associations can be identified.

Although sources generating radiofrequency energy have increased greatly in the past 30 years, there have been relatively few studies of the possible biological effects in human populations. The present study will contribute to the body of knowledge needed as a basis for the development of guidance concerning occupational and general population exposures.

Corrective Action Program Approvals

During December 1978, the Bureau of Radiological Health approved four corrective action plans for electronic products that failed to meet the requirements of applicable radiation safety performance standards or were found defective under the Radiation Control for Health and Safety Act of 1968. The plans were approved for:

- 5 ETEC Corporation MEBES (Manufacturing Electron BeamExposure System) laser interferometers, manufactured and introduced into commerce between August 2, 1976, and September 12, 1978. The units were in noncompliance with the laser product performance standard because the protective housing failed to prevent human access to laser radiation in excess of the accessible emission limits of Class I and also because they lacked a certification label, a caution label for the noninterlocked protective housing, and the required user instructions and purchasing and servicing information. Corrections, to be performed by the resident ETEC field engineer at purchaser locations, will consist of: (1) installing on each unit a new protective housing cover which blocks straight-line access to laser radiation and which also contains an identification/certification label, (2) affixing to each unit a set of noninterlocked protective housing caution labels, and (3) providing each purchaser with an addition to the instruction manual which contains the required information.

- 1,100 Philips Medical Systems, Inc., beam limiting devices, model numbers 9804 602 60501, 9804 602 60601, 9804 602 60701, and 9804 602 60901,

manufactured and marketed between August 1, 1974, and November 27, 1978. The devices were in noncompliance with the performance standard for diagnostic x-ray systems because the light localizer system could fail to provide the required illuminance of 160 lux, the assembler instructions for adjustment of light localizer intensity were inadequate to assure compliance, and the center of the x-ray field could deviate from the center of the image receptor by more than 2 percent of the source-to-image distance. The manufacturer's corrective action plan is as follows: (1) purchasers, dealers, and district offices will be notified by certified letter, (2) dealers will be sent an instruction kit and will check each unit and adjust the light localizer intensity and x-ray field centering and alignment to assure compliance, and (3) the dealers will complete a collimator modification report form for each unit and return the form to the manufacturer to verify that the corrections have been made.

- 110 Hewlett-Packard Company measurement laser products, model 5500C/5526A, manufactured and introduced into commerce between August 2, 1976, and December 31, 1977. The units, which are used to provide accurate indications of distance and velocity during machining operations and for the calibration of machine tools, failed to comply with the laser product performance standard because they lacked the required beam attenuator and the required warning labels for the noninterlocked protective housing. The manufacturer has agreed to send customers a notification letter by certified mail along with a "compliance package" that includes a replacement turret, a label, instructions for replacing the turret, instructions for proper placement of the label, and a company-addressed card which is to be completed by the user and returned to the company. The modifications will consist of replacing the front turret with one that contains a beam attenuator and applying the caution label to the frame of the unit under the interlock switch. If users are unable to perform the modifications themselves and request Hewlett-Packard to repair the units, the firm will arrange to make the corrections.

- 94 Ohio Nuclear, Inc., mobile radioisotope cameras, model Sigma 240, with serial numbers ranging from 127 to 236 (however, not all serial numbers in this range are involved). The problem was observed by the manufacturer during assembly of one of the cameras when the shaft attaching the yoke to the main body of the unit broke. This shaft enables the yoke to be tilted to the desired position, but when it is broken, the yoke slowly returns to its equilibrium position rather than remaining tilted. The breakage occurred because the component manufacturer failed to inform Ohio Nuclear that the shaft was not made of the specified carbon steel but rather of stainless steel which becomes brittle when welded with carbon steel welding materials and techniques. While no incidents or injuries have been reported, the patient could be subjected to unnecessary risk if the correct view could not be obtained and a proper diagnosis made or if the camera could not be used after a radiopharmaceutical had been administered. The possibility of unnecessary risk, however, would exist only if no backup camera were

available. Users already have been notified of the problem, and authorized Ohio Nuclear service technicians are to perform a nitric acid test on all 94 units to determine whether the shaft is made of carbon steel or stainless steel. If the shaft is made of stainless steel, it will be replaced within 4 hours.