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Bureau Study Shows Cataracts Not Linked to Low-Level Microwave Exposure

A study by the Bureau's Division of Biological Effects has shown that repeated exposure to low-level microwave oven radiation (less than 10 milliwatts per square centimeter) does not cause cataracts in rabbits. The results confirm earlier observations on rabbits exposed repetitively to 10 milliwatts per square centimeter in an anechoic chamber.

The recent study involved placing rabbits--whose eyes closely resemble the human eye in size--in front of a microwave oven that was deliberately altered to leak at a rate of 10 to 12 milliwatts per square centimeter. (The Federal microwave oven performance standard limits leakage radiation to 1 milliwatt per square centimeter at the time of purchase and to 5 milliwatts per square centimeter over the lifetime of the oven.) After 1 hour of exposure every day for 12 weeks, the rabbits' eyes were as clear of cataracts as they were before the experiment began. The lowest exposure level at which cataracts have been observed is 180 milliwatts per square centimeter, accumulated at the rate of 1 hour a day for 20 consecutive days.

In another investigation—the results of which were reported at the June 1978 IMPI Symposium in Ottawa, Canada, by Dr. Russell L. Carpenter of the Division of Biological Effects--Bureau scientists examined the eyes of 51 rabbits that had been exposed to a cataractogenic dose of 2.45-gigahertz continuous-wave radiation and removed at periods ranging from 12 hours to 123 days after irradiation. The purpose was to characterize the tissue changes associated with microwave-induced cataracts.

According to Dr. Carpenter, some changes, such as swelling of some of the lens fibers and distortion of the epithelial cells at the lens equator, were observed as early as 18 hours post-irradiation, and the changes became more marked during the second and third post-irradiation days. By 3 to 5 days post-irradiation, there were many nucleate cells and fibers in the posterior cortex as well as cysts and vesicles containing debris from degenerated fibers. After 4 days, mitotic division and posterior migration of the equatorial epithelial cells was seen. No mitotic activity was observed after the sixth day, but the degenerative changes continued. Lenses preserved at post-irradiation intervals of 2 to 5 weeks exhibited balloon cells, degenerate fibers, cysts, vesicles, and displaced epithelial cells. These changes, which were still evident at 123 days, are responsible for the opacities observable by ophthalmoscopic or slit-lamp examination. With respect to thickness of the posterior capsule, no significant differences between irradiated and non-irradiated lenses could be identified.

This study suggests that, although the initial clouding of the posterior layers of the lens cortex may be due to microwave heating, the definitive opacities, or cataracts, are the result of changes induced directly in the equatorial epithelial cells by microwaves. These cell changes more nearly resemble those caused by exposure of the eye to ionizing radiation than they do the changes caused by heat.

The findings also confirm that the thickening and roughening of the posterior capsule, which have been reported in cases of human cataract of alleged microwave origin, do not occur in rabbit cataracts known to have been caused by microwaves.

New Mailing System for BRH Technical Publications Now in Operation

This issue of the BRH BULLETIN is being mailed to approximately 3,500 individuals who specifically indicated their interest in receiving it when responding to the Bureau's notices regarding retention on the BRH BULLETIN mailing list and the master mailing list for BRH technical reports. The retention notices had been sent to previous BRH BULLETIN addressees in January 1978 and to addressees on the technical reports mailing list in April 1978. Both lists now have been merged into one mailing system that incorporates coding for addressee interest, as indicated on the returned notices.

The new system is being maintained by the Bureau's Technical Information Staff on the text editing equipment used for preparation of publications. With this one master system, the mailing lists for the Bureau's various publications can be kept current by rapid and regular updating, and the publications can be distributed more accurately according to recipients' real interests.

Some new readers of the BRH BULLETIN may find, after receiving a few issues, that it does not contain the type of information they expected. If this is the case, please return the mailing label from the last page along with a request that your name be deleted only from the mailing list for the BRH BULLETIN. You will continue to receive the other BRH technical reports you have requested.

Bureau Staff Members Honored at FDA Awards Ceremony

Thirteen Bureau of Radiological Health staff members and three Bureau groups were recognized for outstanding contributions to the Bureau's programs and administration at the Food and Drug Administration's Eighteenth Annual Honor Awards Ceremony, July 13, 1978, in Rockville, Maryland. One staff member received the FDA Award of Merit, three individuals and three groups received FDA Commendable Service Awards, nine Commissioned Officers were awarded Public Health Service Commendation Medals, and one individual received the FDA Equal Opportunity Achievement Award.

James S. Benson, Deputy Director of the Bureau, was presented the FDA Award of Merit--the highest honor conferred by the Agency--for "technical and managerial excellence in increasing the effectiveness of FDA radiation use programs to improve radiological practices and reduce unnecessary radiation exposure to the citizens of the United States."

The FDA Commendable Service Awards went to:

Linda L. Brubach, Office of the Associate Director for Administration, in recognition of "sustained superior performance as an administrative officer and exceptional dedication to the service of Bureau employees."

William J. Fulton, Division of Training and Medical Applications, for "outstanding performance and dedication as an administrator and exceptional management accomplishments beyond those usually expected of an administrative officer."

Donald J. Sauer, Office of the Associate Director for Administration, in recognition of "exemplary performance resulting in increased efficiency and effectiveness in the management of radiological health resources."

The BENT Staff of the Division of Training and Medical Applications for "outstanding accomplishments in establishing a national program to reduce the radiation exposure of women during mammographic x-ray examinations."

The Television Products Section of the Division of Compliance in recognition of "outstanding accomplishments in implementing and supporting the Agency's standards and regulations governing television products."

The Training Productions Center Staff of the Division of Training and Medical Applications for "outstanding accomplishments in developing a highly effective multimedia training program for the Bureau."

The Commissioned Corps Officers receiving Public Health Service Commendation Medals were:

Malcolm C. Bruce, Division of Electronic Products, for "innovative systems engineering of the Bureau's automated Image Analysis Laboratories, pioneering development of laboratory management systems, and expert consultation on applications and implementation of minicomputer technology."

Elmon S. Crumpler, Division of Compliance, in recognition of "sustained high quality work performance in the application of creative imagination to the approach of enforcing the compliance programs for diagnostic x-ray systems."

Neil S. Goldstein, Office of the Associate Director for Administration, in recognition of "outstanding performance in the management of computer system services in support of the Bureau."

Robert H. James, Division of Electronic Products, for "outstanding and sustained scientific excellence in the development and maintenance of high accuracy laser power measurement laboratories in support of field compliance programs for nonionizing radiation."

Stephen H. Lieberman, Division of Compliance, in recognition of "outstanding performance and high quality leadership in managing the administrative functions of the Division of Compliance."

James L. Morrison, Division of Training and Medical Applications, for "effectiveness in developing and carrying out programs to reduce radiation exposure from medical procedures and successful application of systems management to the analysis of Bureau programs."

Richard W. Peterson, Division of Training and Medical Applications, for "exceptional management and technical capability in implementing public health programs to reduce the hazards of lasers and other light-emitting devices."

Stephen W. Smith, Division of Electronic Products, in recognition of "outstanding scientific investigation in the field of diagnostic ultrasound imaging techniques and leadership in the promotion of the safe and efficacious use of this modality."

Nancy M. Obold of the Office of the Associate Director for Administration received the FDA Equal Opportunity Achievement Award. Ms. Obold was commended for "outstanding leadership in the development and implementation of an effective Federal Women's Program in the Bureau."

Corrective Action Program Approvals

During the period from May 15 through June 22, 1978, the Bureau of Radiological Health approved four corrective action programs for products that were found defective under the Radiation Control for Health and Safety Act of 1968 or failed to meet the requirements of applicable Federal radiation safety performance standards. The programs were approved for:

- 5 Searle computed tomography (CT) systems, model PHO/TRAX 4000, serial numbers 718001 through 750005, which provide a laser means for aligning the patient in the proper position pior to the CT scan. The units were manufactured and introduced into commerce by Searle CT Systems, Division of Searle Diagnostics, Inc., between May 5, 1977, and March 10, 1978. They were in noncompliance with the Federal performance standard for laser products because a beam attenuator was not provided in each unit and the required labels were not affixed to each unit. The manufacturer's corrective action program, which was carried out at no cost to users, consisted of replacing the laser system with an incandescent light system to provide the

required alignment of the patient, thus converting the product into one which is not subject to the laser standard.

- 22 AECL beam teletherapy units, model Theratron 780 (serial numbers 143 and on) and model Eldorado 78 (serial numbers 32 and on), manufactured and marketed by Atomic Energy of Canada Limited. Field modifications of the units were initiated by the manufacturer in response to user reports of problems with the potentiometer controls. The controls are used during patient setup operations to control collimator "X and Y" field size motions, collimator rotation, and hand control station monitors on isocenter units. The problems involved a mechanical failure in the potentiometer controls which resulted in the potentiometer failing to return to the zero position and the source housing assembly continuing on in a forward motion. Although no injuries have been reported, a potential hazard to the patient could exist if the source housing assembly continued in a motion unobserved by the operator. A warning notice describing the problem and potential hazard has been sent to all users. In addition, an authorized AECL service technician will visit the site of each unit to inspect the potentiometer controls, make any required adjustments or replacements, and add "deadman" switches to the collimator drive circuits. Final modifications, also to be performed by AECL service technicians, will consist of a repeated test of the controls, replacement of the complete hand control station to include a "deadman" switch, and minor changes in the circuitry, components, and operating manual.

- 64 Siemens Mammomat and Mammomat E diagnostic medical x-ray systems which are used for mammographic examinations and were imported and introduced into U.S. commerce by the Siemens Corporation between August 1, 1974, and September 19, 1977. The units failed to comply with the diagnostic x-ray equipment performance standard because: (1) the beam limiting devices and cassette holders did not have separate certification and identification labels, (2) no statement was provided to users regarding the aluminum equivalence of the minimum filtration permanently in the useful beam in the xeroradiographic mode or the peak tube potential at which the aluminum equivalence was obtained, and (3) no indication was provided at or near the tube housing assembly to signal the operator when the Mammomat E had been selected at the master control panel, which services multiple tubes. The corrective action program is as follows: (1) purchasers will be notified of the noncompliances by a letter that will be hand delivered by Siemens representatives at the time of correction, (2) separate certification and identification labeling will be provided for the beam limiting devices and cassette holders, (3) a revised statement containing the aluminum equivalence of the minimum permanent filtration in the beam and the peak tube potential at which it was obtained will be provided to purchasers, and (4) Mammomat E units will be checked for the presence of a pilot light near the x-ray tube housing, and the pilot light will be installed if missing. Corrections will be performed by Siemens service representatives at purchaser locations free of charge.

- 1,319 Picker radiographic and fluoroscopic medical x-ray control units--specifically, 839 models GX-1050 (catalog number 182654B), 31 models GX-1050 split top version (catalog number 183428B), and 449 models GX-850 (catalog number 182654C)--which were manufactured and marketed by the Picker Corporation between August 1, 1974, and May 5, 1978. The units were in noncompliance with the performance standard for diagnostic x-ray equipment because they could exceed the maximum allowable fluoroscopic entrance exposure rates due to changes in line voltage and temperature. The manufacturer's corrective action program consists of: (1) notifying purchasers by registered mail, (2) modifying the fluoroscopic units by adding a modification kit that provides for replacement of the kVp zener diode with a multiple diode reference of increased temperature stability, the addition of five diodes to the mA control circuitry, and the replacement of two stabilizing capacitors and one emitter resistor with components of higher values, and (3) affixing to those units that operate only in the radiographic mode a label stating that the fluoroscopic modification kit must be installed if the units are upgraded to include the fluoroscopy feature. The modifications will be made by Picker service representatives at purchaser locations without charge to purchasers.

New Bureau Publications

The following publications are available as indicated in the parentheses following the citation.

"9th Annual National Conference on Radiation Control - Meeting Today's Challenges, June 19-23, 1977, Seattle, Washington," (FDA) 78-8054, proceedings compiled by the Bureau of Radiological Health. (Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, Stock No. 017-015-00148-2, $5.75 per copy.)

"The Physical Basis of Electromagnetic Interactions with Biological Systems - Proceedings of a Workshop held at the University of Maryland, College Park, Maryland, June 15-17, 1977," (FDA) 78-8055, edited by Leonard S. Taylor and Augustine Y. Cheung, University of Maryland. (National Technical Information Service, Springfield, Virginia 22161, Accession No. AD-A051218, $13.00 per copy, $3.00 for microfiche.)

"Wavelength Dependence of Ultraviolet-Enhanced Reactivation and Induction of Mammalian Viruses," (FDA) 78-8059, Thomas P. Coohill, Western Kentucky University; Project Officer - Larry E. Bockstahler, Division of Biological Effects. (National Technical Information Service, Springfield, Virginia 22161, Accession No. PB 281 534/AS, $4.50 per copy, $3.00 for microfiche.)

"Survey of Photocopier and Related Products," (FDA) 78-8060, Kenneth R. Envall, Division of Electronic Products. (Superintendent of Documents, U.S.

Government Printing Office, Washington, D.C. 20402, Stock No. 017-015-00149-1, $2.50 per copy.)

August 1978 Calendar of Events

The following is a list of August 1978 meetings of relevance to Bureau activities and the talks to be presented by Bureau personnel at those meetings. The talks generally are presented from outlines, abstracts, or papers that have not yet been published, and copies are not available from the Bureau's publications office. If you wish further information or a copy of the material on which the talk was based, please contact the author(s) directly.

URSI - 19th Assembly - Symposium on Biological Effects of Electromagnetic Waves, Helsinki, Finland, August 1 - 8.

"A Class of New Microwave Diathermy Applicators," James Lin, Wayne State University, and Gideon Kantor, Division of Electronic Products.

"Behavioral Stimulus Properties of Microwave Radiation," John C. Monahan and Wendon W. Henton, Division of Biological Effects.

"Colicin Induction by Exposure to Millimeter-Wave Radiation," Mays L. Swicord, T. Whit Athey, and Barbara A. Krop, Division of Electronic Products, and Frederick L. Buchta, Division of Biological Effects.

"Optical Heterodyne Detection of Microwave Absorption," C. C. Davis, University of Maryland, and Mays L. Swicord, Division of Electronic Products.

NOTE: An incomplete citation was given in the July 1978 Calendar of Events (BRH BULLETIN, June 26, 1978) for the paper entitled, "A Demonstration of the Effect of Reduced Scatter on Information Content and Patient Exposure," which is being presented at the meeting of the American Association of Physicists in Medicine in San Francisco, California, July 30 to August 3. The correct citation is as follows:

"A Demonstration of the Effect of Reduced Scatter on Information Content and Patient Exposure," B. S. Askins, National Aeronautics and Space Administration, Robert F. Wagner, Division of Electronic Products, and G. T. Barnes, University of Alabama.

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