

G. Lane

specifically, "New Style Criss-Cross Tie (NST) Coat Aprons" (models 332, 338, 532, 538, and 543), "Wrap Around Special Procedure Radiology Aprons" (models 5-3-32 and 5-3-36), and "Light Weight and Full Lead Coat Aprons" (models 332, 338, 343, 532, 538, and 543). Some 1,050 of these aprons were distributed to approximately 250 x-ray and medical supply wholesale distributors nationwide; there were no retail sales. The garments, which are intended to provide shielding from ionizing radiation and are equivalent to either 3 or 5 millimeters of pure lead, were manufactured with a lead/vinyl shielding material which was found to rip under its own weight. The ripping eventually could cause the shielding material to drop to the bottom of the apron, exposing the wearer to radiation. Since June 1977, some 2,000 aprons have been returned to the manufacturer (not all aprons returned are involved in the recall). The firm's management believes there are less than 100 aprons remaining on the market in the hands of users.

New Bureau Publications

The following publications are available from the National Technical Information Service (NTIS), Springfield, Virginia 22161. Please cite the accession number when ordering from NTIS.

c/a → ("Electromagnetic Fields in Biological Media: Part II - The Scat Program, Multilayered Spheres, Theory and Applications," (FDA) 79-8072; Stanley M. Neuder, Division of Electronic Products. (Accession No. PB 300 904/AS, \$4.00 per paper copy, \$3.00 for microfiche.)

"Quality Assurance for Radiographic X-Ray Units and Associated Equipment: Quality Assurance Series - Diagnostic Radiology," (FDA) 79-8094, prepared under FDA Contract No. AD-39; William R. Hendee and Raymond P. Rossi, University of Colorado Medical Center, and Charles K. Showalter and Lee W. Goldman, project officers for the Division of Training and Medical Applications. (Accession No. PB 80-101 405, \$5.50 per paper copy, \$3.00 for microfiche.)

facility revealed that, during operation of one of the lasers, human access to levels above the limit of Class I was possible between the beam tubes and the rotary solenoid. The firm's corrective action plan consists of sending each purchaser a package containing (1) a notification letter and instructions for modifications, (2) two modified beam tube stands and four 4-40 screws to replace the old ones, and (3) an acknowledgment sheet for the user to sign and return after completion of the modification.

- 89 Shimadzu medical x-ray high-voltage generators and controls, models ED125, ID150G, and HD150B, manufactured by Shimadzu Seisakusho, Ltd., Tokyo, between August 1, 1974, and April 26, 1979, and distributed in the U.S. by Hansen Medical Enterprises, Inc., Northridge, California. The units were in noncompliance with the performance standard for diagnostic x-ray equipment because the maximum cumulative fluoroscopic time of 5 minutes could be exceeded. Modifications, to be performed at purchaser locations by the manufacturer's U.S. distributor, will consist of modifying the fluoroscopic timers for each unit by installing a stopper and spacer to limit the fluoroscopic exposure time to 5 minutes. All costs of modification will be borne by the manufacturer and the U.S. distributor.
- Approximately 33 Xonics XMS medical diagnostic x-ray controls, models A-60000-1 through -4, which incorporate a model A-52627-1 autotransformer assembly and which were manufactured and introduced into commerce by Xonics Medical Systems, Inc., between January 1, 1978, and July 31, 1979. The units were found in noncompliance with the diagnostic x-ray equipment performance standard because the x-ray start signal could be initiated before the autotransformer contact arm made contact with the winding, and if this situation occurred, the actual exposure time would be less than the indicated exposure time by approximately 50 milliseconds. The firm agreed to correct the noncompliance by modifying the exposure circuit to increase the delay in exposure start, thereby ensuring that the autotransformer contact arm has made contact with the winding before the exposure is begun. The modifications are being made by the manufacturer without charge to purchasers.
- 2,000 Toshiba microwave home cooking ovens, model ER-7488T-1, produced by Toshiba Corporation between September 18 and 22, 1979, and imported into the U.S. by Toshiba America, Inc. None have been sold to consumers. The units were in noncompliance with the microwave oven performance standard because excess emissions could result from the misapplication of aluminum tape to cover two small apertures on the chassis of the oven at points where the waveguide is fastened to the top of the oven. Toshiba dispatched a team of technicians to the U.S. to correct all units by removing the existing aluminum tape, properly applying new aluminum tape, and testing for emission at the point of tape application. The modifications have already been completed.
- Approximately 1,078 radiation shielding aprons manufactured by Shielding, Inc., Madras, Oregon, between December 15, 1976, and February 23, 1977--