Subject 60601-1 (187, 544, 61010A-1)
(In reply, refer to Subject 60601-1)

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TO: **Standards Technical Panel (STP) for Medical and Dental Equipment and Related**
Subscribers to UL's Standards Service for
Medical Electrical Equipment
Medical and Dental Equipment
X-Ray Equipment
Electrical Equipment for Laboratory Use
Manufacturers of
Medical and Dental Equipment, Professional (KFBQ)
Medical and Dental Equipment, Professional – Disposal Systems and Accessories (KFBY)
Power Supplies for Use in Health Care Facilities (KFCG)
Uninterruptible Power Supplies for Use In Health Care Facilities (KFFG)
Magnetic Resonance Imaging Equipment (PAZB)
Medical Equipment (PIDF)
Medical Equipment Classified in Accordance with Specified Medical Standards (PIKF)
Medical and Dental Equipment Power Supplies – Component (QQHM2)
X-Ray Equipment (ZQOR)
X-Ray Equipment, Accessories (ZQVQ)

SUBJECT: **Modified Effective Date for Withdrawal of UL 187 and UL 544 with Corresponding Replacement by UL 60601-1**

Summary of Topics

UL announces the modification of previously established effective dates for the withdrawal of UL 187 and UL 544.

UL's August 5, 2002 bulletin indicated that Standards UL 544 and UL 187 would be withdrawn when the IEC harmonized Standard UL 60601-1 became effective. The withdrawal date for UL 544 and UL 187 was projected to be January 1, 2005. However, UL received significant input to consider postponing the withdrawal date.

Most products covered under the scope of UL 544 and UL 187 have been re-evaluated to comply with Standard UL 60601-1. Generally, X-ray and medical and dental- type equipment are frequently re-designed to integrate the latest technology. However, some equipment types fit into niches of the marketplace where products are not redesigned for a significant time, and these products have not been evaluated to UL 60601-1.

UL now plans to postpone the withdrawal of Standards UL 544 and UL 187 until January 1, 2010 to provide for a longer transition period for products that are not frequently redesigned. Based on the previously announced schedule, effective January 1, 2003, all new products have been evaluated to UL 60601-1. The effective date for all currently Listed products to comply with UL 60601-1 will be January 1, 2010.

The postponement will allow for the continued certification of products under UL 187 and UL 544, with one very important proviso: that there can be no product changes (changes that would require revision of the FUS Procedure) to currently certified products subsequent to January 1, 2005. Until January 1, 2005, a manufacturer will be able to modify the existing product for compliance with UL 187 and UL 544 requirements when the changes are not substantial.

Inherent in UL's decision is the acknowledgement that the safety requirements in Standards UL 187 and UL 544 are sufficient and that the products that are covered by the postponement to withdraw these Standards have demonstrated an acceptable safety record.

It is anticipated that UL will initiate the Industry File Review for compliance with UL 60601-1 approximately one year prior to January 1, 2010 when Standards UL 187 and UL 544 are to be withdrawn. At that time, any products covered by UL 187 or UL 544 that have not been re-evaluated to UL 60601-1 will be withdrawn unless they are shown to comply with UL 60601-1.

It was proposed that several product categories would be withdrawn when Standards UL 187 and UL 544 are withdrawn. Due to the postponement for withdrawal, the following categories will be maintained until 2010:

KFBQ – Medical and Dental Equipment, Professional
PAZB – Magnetic Resonance Imaging Equipment
ZQOR – X-Ray Equipment
ZQVQ – X-Ray Equipment, Accessories

Since the following categories will also be maintained after January 1, 2005, UL staff will contact manufacturers to review their products (conduct a File Review) to determine compliance of currently certified products with the UL 60601-1 requirements:

KFBY – Medical and Dental Equipment, Professional – Disposal Systems and Accessories
KFCG – Power Supplies for Use in Health Care Facilities
KFFG – Uninterruptible Power Supplies for Use In Health Care Facilities
QQHM2 – Medical and Dental Equipment Power Supplies – Component

The Guide Information pages for these categories and any Standards referencing UL 544 and/or UL 187 for medical/dental aspects of the product will be revised to reference only Standard UL 60601-1. Accordingly, Listing, Recognition, or Classification of products that have not been evaluated to UL 60601-1 will be withdrawn on January 1, 2010.

Product Categories for the C-UL Mark Program

CSA indicates that they will be implementing an equivalent postponement for X-ray products that were evaluated to the Canadian National Standard CSA 22.2 No. 114. UL is working with CSA to maintain the parameters of the postponement of the withdrawal of Standards equivalent; however, CSA indicates they will not postpone the withdrawal of products that were evaluated to the CSA 22.2 No. 125 standard (covering medical and dental equipment). As a result, UL cannot extend the CUL Mark usage to medical and dental products evaluated to CSA 22.2 No. 125 beyond January 1, 2005.

Accordingly, all equipment previously manufactured and certified to the requirements in the CSA C22.2 No. 125 standard must comply with the requirements of the CSA C22.2 No. 601.1, Part 2 Series and Collateral Standards, as applicable, as of January 1, 2005. UL will have to review the following CUL product categories by January 1, 2005 to ensure that all products comply with CSA 22.2 No. 601.1: KFBQ7 and 8, KFBY7, KFCG7, KFFG7 and 8, and QQHM8.

For the CUL Mark program, similar changes in the product categories that cover the Listing, Recognition and/or Classification of products to Canadian National Standard CSA 22.2 No. 114, which corresponds to UL 187 (X-Ray equipment), will be withdrawn on January 1, 2010. After that date, all equipment previously manufactured and certified to the requirements of standard C22.2 No. 114 must comply with the requirements of CSA Standard C22.2 No. 601.1, Part 2 Series, and Collateral Standards, as applicable, Consequently, UL will have to review the following CUL product categories to ensure all products comply with CSA 22.2 No. 601.1 as of January 1, 2010: PAZB7 and 8, ZQOR7 and 8, and ZQVQ7.

Note: If CSA alters their position on any of the above coverage dates, UL may find it necessary to make a corresponding adjustment to the above certification withdrawal dates.

Questions regarding interpretation of requirements should be directed to the responsible UL Staff.

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