The 1960s saw both the advent of open-heart surgery and the increasing use of cardiac catheterization procedures. More and more patients with externalized transarterial catheters, usually enclosing leads that could be quickly connected to an external cardiac pacing system, were appearing in the new cardiac care or special care units of hospitals. When physicians realized that this highly conductive pathway not only bypassed the usually protective layers of relatively resistive body tissues, but that it also directed current to the heart, they realized that this highly conductive pathway not only bypassed the usually protective layers of relatively resistive body tissues, but that it also directed current to the heart, they realized that this highly conductive pathway not only bypassed the usually protective layers of relatively resistive body tissues, but that it also directed current to the heart, they realized that this highly conductive pathway not only bypassed the usually protective layers of relatively resistive body tissues, but that it also directed current to the heart, they realized that this highly conductive pathway not only bypassed the usually protective layers of relatively resistive body tissues, but that it also directed current to the heart, they realized that this highly conductive pathway not only bypassed the usually protective layers of relatively resistive body tissues, but that it also directed current to the heart, they realized that this highly conductive pathway not only bypassed the usually protective layers of relatively resistive body tissues, but that it also directed current to the heart, they realized that this highly conductive pathway not only bypassed the usually protective layers of relatively resistive body tissues, but that it also directed current to the heart, they realized that this highly conductive pathway not only bypassed the usually protective layers of relatively resistive body tissues, but that it also directed current to the heart.

The theoretical phenomenon, in which an ES patient might be induced into fatal ventricular fibrillation by the passage of a small level of current through the transarterial catheter, came to be known as electrically susceptible (ES) or electrically sensitive patients (ESPs). Laboratory experiments indicated that the levels of current that could trigger potentially fatal ventricular fibrillation were indeed significantly lower than the levels associated with conventional electrocution — on the order of tens of microvolts. Tests also established that the now-familiar phenomenon of current "leakage," as well as the process of relatively large currents passing through low resistance grounding conductors, could easily send high magnitude currents into the exposed conductive pathways.

The concept of equipotential grounding, in which substantial (green) grounding conductors are used to connect all exposed conductive surfaces to a central grounding point in a star configuration, was developed as a prime defensive measure against this new hazard. Others championed the use of isolation transformers as the best way to reduce leakage current in the ground circuits of the hospital's electrical distribution system. Several regulatory and standards-setting organizations began taking notice.

In April 1968, the division of medical malpractice of the National Research Council (NRC) held a two-day workshop on "Electrical Hazards in Hospitals" that was attended by more than 100 people. The proceedings of this workshop were edited by Dr. Carl Walters and later published by the influential National Academy of Sciences (Walter, 1970). Carl Walter was a renowned surgeon at the Peter Bent Brigham Hospital in Boston, a member of the faculty at Harvard Medical School, and chairman of the committee on hospitals of the National Fire Protection Association (NFPA). Dr. Walter has been credited with establishing one of the world's first blood banks in a basement room at Harvard in 1934, and later (1949) with the invention of the blood bag, which ended the cumbersome and dangerous procedure of pumping blood directly from donor to patient via paraffin-coated glass tubes. In addition, his insight and pioneering work with the Cardiac catheterization procedure led to the introduction of high pressure steam sterilizers (sometimes called large currents passing through low resistance grounding conductors, could easily send high magnitude currents into the exposed conductive pathways.

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autoclave) for reprocessing surgical instruments. Before the autoclave, surgical instruments were simply "sterilized" in boiling water.

At the 1968 NRC-sponsored workshop, Dr. Walter first speculated on the probable incidence of death by "microshock" in US hospitals. During a discussion of the statistics on electrocution that were available at the time, he claimed that an incidence rate of 1200 electrocutions annually in hospitals was "an adventure," and the deaths occurred during resuscitation efforts unrelated to the patient's primary disease or during application of electrical appliances. He also stated the statistics were calculated in accordance with the NFPA and to show why the Commission has not recognized the problem (i.e., during a lifesaving venture, those involved may not perceive what is going on). Walter claimed to have encountered three such instances in a recovery room himself and further stated that when the situation was recreated, the same defibrillator was used exactly which showed the trouble. Even though he went on to assert there were at least a dozen analyses in existing literature of the patient electrocution risk and claimed that is why so many doctors were becoming interested in electrical safety.

On January 27, 1969, a report titled, "Accidental Electrocutations Claim 1200 Patients a Year" was published in Electronic News (Electronic News, 1969). The report quoted microshock statistics obtained from Dr. Walter during a telephone interview. These same statistics were repeated again during presentations made by Dr. Walter and others at the 71st Annual Meeting of the American Hospital Association in Chicago in August 1969. After the proceedings of the NRC workshop were published in 1970, these statistics were repeated at a press conference and widely reported throughout the national press. In the spring of 1971, a report titled, "Is 1200 electrocutions annually in hospitals an adventure?" appeared in the IEEE wire service that Ralph Nader, an attorney and consumer activist, had alleged in a speech that 5000 deaths attributable to microshock occurred each year in the nation's hospitals. That day Mr. Nader had presented independent substantiation of his figure.

In March 1971 the Ladies Home Journal ran an article quoting Ralph Nader titled, "Ralph Nader's Most Shocking Exposure," which stated that, "at the very least, 1200 Americans are electrocuted annually during routine diagnostic and therapeutic procedures, including "medication." The letter from Dr. Haider von der Mossen, chairman of the Subcommittee on Electrical Safety of the Association for the Advancement of Medical Instrumentation and safety consultant to New York City's Health Services Administration, believe that the number might be ten times as high as the conservative estimate of 1200" (Nader, 1971). This is the same estimate that was the sometimes quoted "estimate" of 12,000 deaths per year! Interestingly, this same article stated that, "Only three hospitals in the country have biomedical engineers on their staffs to supervise the operation and maintenance of complex machines; Downstate Medical Center in New York City; Sinai Hospital in Baltimore; and Charles S. Wilson Hospital in Boston."

By the mid-1970s, the NFPA's Committee on Hospitals had developed and distributed for public comment some proposed amendments to Article 517 of the 1971 edition of the National Electric Code (NEC) that would require all hospitals to have isolation transformers to minimize microshock. The potential financial impact of this proposal shocked the health care community. The technical inadequacy of the proposed solution also shocked the embryonic clinical engineering community.

In the spring of 1971, shortly before the Annual NFPA Meeting in San Francisco at which the Committee on Hospitals' proposed amendment would be voted on, the Hill-Burton Program Committee convened a private meeting in Rockville, Maryland, at which the proposed solutions were presented. "The Hill-Burton Program Committee's findings were never published, but the committee did inform the NFPA that if isolated power in all special care areas was required by the NFPA in its forthcoming standards, the committee would terminate its long-standing requirement that hospitals receiving its funds comply with NFPA's standards. This was a substantial threat—at that time virtually all new hospital construction and renovations were subsidized with federal funds from the Hill-Burton Program.

With the proposed amendments to the NEC were presented at the NFPA Annual Meeting in San Francisco in May 1971, they prompted a very lively floor debate, after which adoption was deferred and they were returned to committee by a 106 to 38 vote of the membership of the electrical section.

In the works of Dr. Walter's later publications, he clarified the discussion about the reality or non-existence of this new, perhaps life-threatening hazard, and the uncertainty about whether or not the various proposed countermeasures and elaborate safety tests could eliminate or reduce the threat, a battery of new electrical safety requirements appeared. Many of these requirements persist today in the form of an additional safety margin over and above the "microshock" era. These include, among other things, the implementation of an NFPA standard for the protection of patients from microshock. This standard (NFPA 70-1980) established the "safe" level of 15 microamps. However, it was unclear whether or not this level of protection was adequate.

In 1970, the standard addressing anesthetizing locations (NFPA 56-Code for the Use of Flammable Anesthetics) had been renumbered as NFPA 56A and given a battery of new electrical safety requirements. Many of these requirements per-
advocates of the less stringent approach required considerably more professional courage and belief in their analyses than those advocating the "safer," more extravagant solution. One approach that proved useful in bringing some uncertain observers around to the more radical position was the use of a probabilistic illustration to semi-quantify the level of risk, documented in Guidelines for Clinical Engineering Programs: Part III: The Risk of Electric Shock In Hospitals (Ridgway, 1981).

There have been no significant adverse trends in electrical accidents in operating rooms over the past 20 years. The predominant categories of equipment-related misadventures in the operating room continue to be patients accidentally burned by poorly implemented electrosurgical procedures, and patients injured by pressure sores resulting from extended contact with the unyielding surface of the surgical table. Both of these problems are often misdiagnosed as accidental burns.

References