



# Isolated Power Systems (IPS) and Wet Locations in Healthcare Facilities



## Abstract

*The National Fire Protection Association (NFPA) Standard for Healthcare Facilities (NFPA 99) requires that wet location patient care areas be provided with “special protection against electric shock.” This paper will list the hazards associated with electric shock and the interruption of electrical power.*

*An Isolated Power System (IPS) is one way of providing such protection, and has the inherent advantage of not requiring an interruption of the power supply should a phase-to-fault condition occur. This paper explains the design principles and requirements behind an IPS and a Ground Fault Circuit Interrupters (GFCI) and the components they use, and why an IPS is advantageous versus a GFCI at minimizing the hazard of electric shock.*

*A brief discussion of regulatory requirements and inconsistencies therein, is also given with regard to the definition of “wet location”. Finally, an analysis of the cost implications of GFCI devices versus isolated power systems is given.*

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## References

The technical papers, recommended practices, and standards that are the references for this paper are:

- The 2005 Edition of NFPA 70 (National Electrical Code—NEC)
- The 2005 Edition of NFPA 99 (Health Care Facilities)
- IEEE Standard 602-1996—IEEE® Recommended Practice for Electric Systems in Health Care Facilities (IEEE White Book)
- The 2007 Edition of the Hospital Accreditation Standard published by the Joint Commission on Accreditation of Healthcare Organizations
- Square D® Publication 4800CT9801—dated February 1998

Portions of these documents will be directly quoted or referred to within the body of this paper. In addition, much of the information in section ten is quoted directly from the 2004 Edition of the Clinical Engineering Handbook.

## History

Inhalant anesthetic agents employed within the United States of America during the nineteenth century, and most all of the twentieth century, were extremely flammable. The use of candles and lanterns for lighting during surgical procedures commonly resulted in explosions and fires when such flammable anesthetic agents were openly employed or even present. With the advent of electric lighting in clinics and operating rooms the number explosions and fires were initially dramatically reduced. However, in the early part of the twentieth century as the population of the country dramatically increased a corresponding number of large clinics and hospital were built.

At the same time hospitals were also beginning to commonly administer oxygen to help ventilate a patient's lungs during surgical procedures. The ignition of flammable anesthetic agents from electrical sources as faulted circuits and static electrical discharges in surgical clinics and operating room in the presence of oxygen resulted in an even greater number explosions and fires. Developments in institutional medicine and the expansion of medical procedures ran parallel to the expanding utilization of electrically operated medical equipment. Subsequently, the explosions and fires resulted in a greater number of injuries and deaths along with a significant amount of property damage to clinics and hospitals. As the electrification of clinics and hospital dramatically increased in the 1920s and 1930s, the devastating effects of explosions and fires in these same facilities began to be a serious concern of various fire protection agencies and associations.

Common flammable and explosive anesthetic agents are gases and vapors, such as fluroxene, cyclopropane, divinyl ether, ethyl chloride, ethylene, and ethyl ether, which may form flammable or explosive mixtures with surrounding air, oxygen, or reducing gases as nitrous oxide.

In the late 1930s, engineering experts began a series of serious studies in an attempt to produce a national safety standard relating to clinics, hospitals, dental facilities, and medical facilities. (The general or all incorporating term "healthcare facilities" was not formulated or used during these early periods.) The concept and dynamics of the "fire triangle" was just beginning to be constructed and understood. The origins or sources of the various ignition components for explosions and fires in the dental and medical facilities of the times were also beginning to be identified and listed. The advent of World War II delayed the results of the research and studies. However, in 1944 the NFPA published "Safe Practiced in Hospital Operating Rooms". As part of the 1944 NFPA® requirements, the design and installation of an IPS in surgical clinics and operating rooms was employed and required as a means to dramatically reduce arcing and sparking from faulted electrical circuits as a source of energy to ignite flammable anesthetic agents. An IPS is an ungrounded electrical power distribution system to be employed in specific hospital areas. Although the early NFPA standards were not generally adopted in new hospital construction until 1947, an IPS has been employed in every anesthetizing area since 1948. Various new grounding standards were also required during the early 1940s to reduce the build up of static electrical charges (static electricity) as another possible ignition source.

## New Standards

However, even with the dramatic changes and enhancements to the electrical codes and standards at the time, it soon became apparent that the initial standards fell short of providing the necessary guidelines for the construction of hospital rooms where combustible agents would be administered. Consequently, the NFPA appointed a committee to revise the 1944 standards. In 1949 this committee published a new standard entitled,

NFPA No. 56. (NFPA No. 56 later evolved to become the bases for our present national standards related to healthcare facilities.)

The editions of the NEC published between the 1930s through the 1950s only included general provisions for healthcare facilities. However, the early 1950s editions of the NEC did include a section on combustible anesthetics under Article 510 (Hazardous Locations) The 1956 Edition of the NEC clearly established the need for ungrounded and isolated power distribution systems in designated areas of a healthcare facility where combustible gases might be utilized. Also, in 1959 Edition of the NEC, the NFPA® standards were incorporated into the body of the national electrical code. Article 517 (Flammable Anesthetics) was first introduced in the 1965 Edition of the NEC. In the 1971 Edition of the NEC the title of Article 517 was changed from “Flammable Anesthetics” to “Health Care Facilities”. By 1971 much of the contents of NEC® 517 were electrical provisions and requirements already established in NFPA 99.

## Isolated Power Systems

The increased use of Isolated Power Systems (IPS) correlated with a dramatic reduction in explosion and fires where flammable anesthetic agents were present. These systems have also reduced the incidence of fire in other areas within healthcare facilities where they have been utilized. In the later part of the twentieth century, non-flammable anesthetic agents such as chloroform, halothane, methoxyflurane, nitrous oxide, trichlorethylene, and influrane were developed and began to be widely utilized. With the advent and use of more non-flammable anesthetic agents, the necessity to adhere to strict requirements for isolated power systems began to be discussed by some engineering firms and hospitals and also began to be questioned by fire protection agencies and associations. However, some of the aerosol and liquid germicides and antiseptics, along with some tinctures and solutions of disinfecting agents, used in anesthetizing area today are flammable (Refer to Article 13.4.1.2.2, along with its Tentative Interim Amendment, in NFPA 99).

## Wet Locations

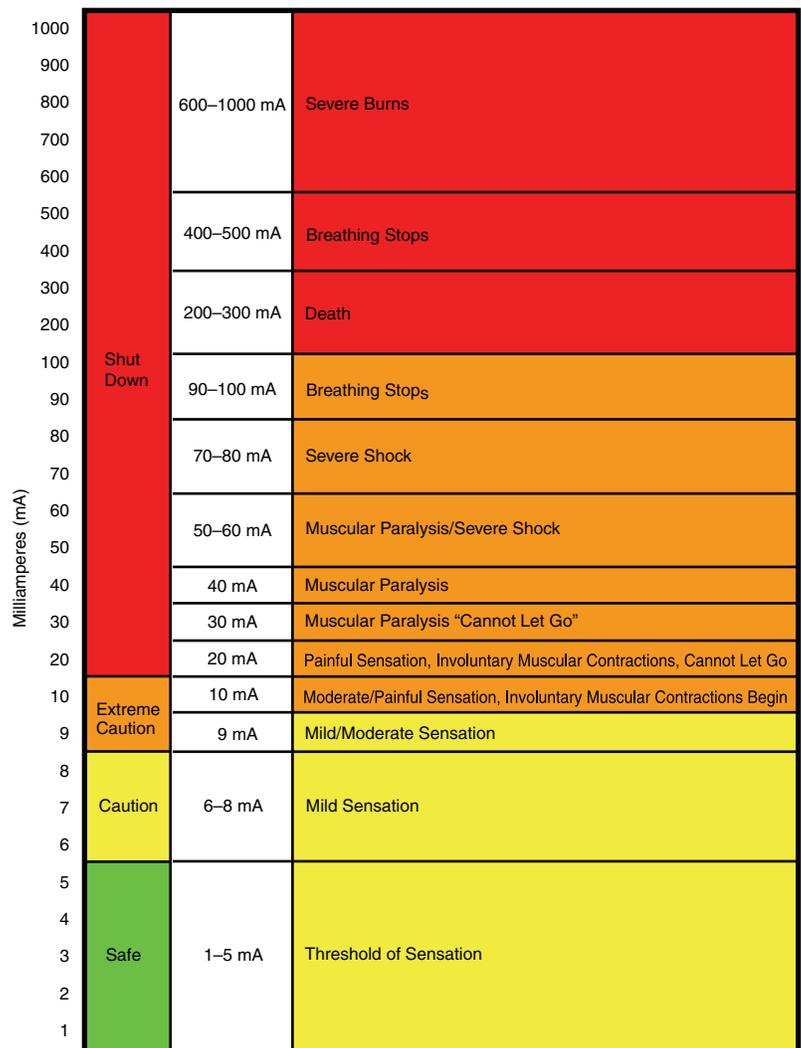
Although grounded lighting and power circuits could be safely employed in many areas where only non-flammable anesthetic agents would be utilized, there was continued concerns regarding the necessity for isolated power systems in surgical clinics, operating rooms, and patient care areas where there was likely to be wet areas. Per the requirements of Article 4.3.2.2.8 in NFPA 99, all patient care areas that are deemed or determined to be wet location patient care areas shall be provided with special protection against electrical shock. Blood, irrigation solutions, normal saline solutions, sweat and urine and other conductive liquids are regularly present and are routinely drained or spilled onto drapes, tables, and floors in emergency rooms, surgical clinics, operating rooms, and numerous other patient care areas. Also, the walls and floors of emergency rooms, operating rooms, surgical clinics, and many other patient care areas are regularly washed down and scrubbed with disinfectant solutions and cleaning agents. Consequently, specific surgical areas also qualify as wet locations and are usually required to employ IPSs. In addition to providing protection in anesthetizing areas, IPSs can be employed to provide valuable protection from electrical shock in all areas of any healthcare facility deemed, determined, identified, or likely to be a wet location.

## The Hazards Associated with Electric Shock

The voltage necessary for lethal electrocution depends on the current drawn by the body. Using Ohm's Law, [where Voltage (V) = Current (A) x Resistance ( $\Omega$ )], the flow of current depends on the resistance of the body. The surface contact resistance of human skin varies from person to person and can vary throughout the day. In general, dry skin in a healthy condition has a contact resistance of approximately 10,000 Ohms ( $\Omega$ ). However, damp skin from blood, chlorinated tap water, sweat, urine, or other conductive fluids can have a resistance of approximately 1,000  $\Omega$  or lower.

On average, males have higher contact skin resistances than females. Infants are more susceptible to electric shock because of their lower body resistance. In addition, the capability of a conducting material to carry a current depends on its cross section area or mass of the human body. This partially explains why more males are injured or killed from the effects of electrical shock than female.

This scale illustrates the increasing magnitudes of current flow through the body and its affects on bodily functions.



Fatality to adult humans often occurs from currents as low as 0.1–0.3 A. However, the surface contact resistance of skin is not applicable to the human vascular systems or internal organs since the average human body consist of 70% saline water. The human vascular systems and internal organs are excellent conductors of electricity.

Using Ohm’s Law, refer to Table 1 below to assess the relationship and various levels of currents and voltages that can affect the human body.

**Table 1: The Effects of Current and Voltage on the Human Body**

Electric Current in Amperes (A) <sup>1</sup>	Voltage (V)		Maximum Power in Watts (W)	Physiological Effect
	Body Resistance =10,000 (Ω)	Body Resistance =1,000 (Ω)		
1–6 A or (1000–6000 mA)	10,000–60,000	1,000–6,000	100,000–600,000	Sustained ventricular contraction followed by normal heart rhythm when these directed currents are employed as the operation parameters for a Defibrillator. However, temporary respiratory paralysis and burns to internal organs are possible.
0.1–0.3 A or (100–300 mA)	1000–3000	100–300	100–900	Ventricular fibrillation. Breathing stops. Is often fatal.
0.050 A or (50 mA)	500	50	25	Ventricular interference, pain, respiratory difficulty.
0.01–0.02 A or (10–20 mA)	100–200	10–20	1–4	Sustained muscular contraction. The “cannot let go” current.
0.005 A or (5 mA)	50	5	0.25	Maximum current which may still be harmless to most humans.
0.001 A or (1 mA)	10	1	0.01	Threshold of feeling an electric shock.

<sup>1</sup> 1 mA = one milli-ampere = 1/1000 of an Ampere

## Definitions and Descriptions

### Critical Care Areas

Critical Care Areas, as defined by Article 3.3.138.1 in NFPA 99 are, “Those special care units, intensive care units, coronary care units, angiography laboratories, cardiac catheterization laboratories, delivery rooms, operating rooms, post anesthesia recovery rooms, emergency departments, and similar areas in which patients are intended to be subjected to invasive procedures and connected to line-operated, patient care related electrical appliances”.

In the NEC this definition is slightly abbreviated. Critical Care Areas, as defined by NEC® 517.2 are, “Those special care units, intensive care units, coronary care units, angiography laboratories, cardiac catheterization laboratories, delivery rooms, operating rooms, and similar areas in which patients are intended to be subjected to invasive procedures and connected to line-operated, electro-medical devices”.

### General Care Areas

General Care Areas, as defined by NEC® 517.2 are, “Patient bedrooms, examining rooms, treatment rooms, clinics, and similar areas in which it is intended that the patient will come in contact with ordinary appliances such as a nurse call system, electrical beds, examining lamps, telephone, and entertainment devices. In such areas, it may also be intended that patients be connected to electro medical devices (such as heating pads, electrocardiographs, drainage pumps, monitors, otoscopes, ophthalmoscopes, intravenous lines, etc.)”.

In NFPA 99 the definition of “General Care Areas” is also slightly abbreviated when compared to NEC® 517.2. General Care Areas, as defined by Article 3.3.138.2 in NFPA 99 are, “Patient bedrooms, examining rooms, treatment rooms, clinics, and similar areas in which it is intended that the patient will come in contact with ordinary appliances such as a nurse call system, electric beds, examining lamps, telephones, and entertainment devices”.

## Health Care Facilities

Health Care Facilities, as defined by Article 3.3.68 in NFPA 99 and NEC® 517.2 are, “Buildings or portions of buildings in which medical, dental, psychiatric, nursing, obstetrical, or surgical care are provided”. Article 517.2 in the NEC also incorporates the additional definition of “health care facilities” as, “Health care facilities include, but are not limited to, hospitals, nursing homes, limited care facilities, clinics, medical and dental offices, and ambulatory care centers, whether permanent or movable”. (Definitions of hospital, nursing home, ambulatory health care facility, and limited care facility correlate with the corresponding definitions found in NFPA 101, Life Safety Code.)

## Hospital

Hospital, as defined by NEC® 517.2 is, “A building or part thereof used for the medical, psychiatric, obstetrical, or surgical care, on a 24-hour basis, of four or more inpatients”. Hospital, wherever used in the NEC, “shall include general hospitals, mental hospitals, tuberculosis hospitals, children's hospitals, and any such facilities providing inpatient care”.

## Isolated Power System (IPS)

An Isolated Power System or IPS, as defined by Article 3.3.85 in NFPA 99 and NEC® 517.2 is, “A system comprising an isolating transformer or its equivalent, a line isolation monitor, and its ungrounded circuit conductors”.

## Isolation Transformer

An isolation transformer, as defined by Article 3.3.86 in NFPA 99 and NEC® 517.2 is, “A transformer of the multiple-winding type, with the primary and secondary windings physically separated that inductively couples its ungrounded secondary winding to the grounded feeder systems that energizes its primary winding”.

## Line Isolation Monitor (LIM)

A line isolation monitor or LIM, as defined by Article 3.3.99 in NFPA 99 and NEC® 517.2 is, “a test instrument designed to continually check the balanced and unbalanced impedance from each line of an isolated circuit to ground and equipped with a built-in test circuit to exercise the alarm without adding to the leakage current hazard”.

## Patient Care Areas

Patient Care Areas, as defined by Article 13.2.4 in NFPA 99 and NEC® 517.2 are, “Areas of a health care facility in which patient care is administered are classified as general care areas or critical care areas, either of which may be classified as a wet location. The governing body of the facility designates these areas in accordance with the type of patient care anticipated and with the following definitions of the area classification”.

NEC® 517.2 also incorporates the additional definition of “patient care area” as, “Any portion of a health care facility wherein patients are intended to be examined or treated”. Per Article 3.3.138 in NFPA 99 and fine print note (FPN) associated with Article 517.2 in the NEC, “Business offices, corridors, lounges, day rooms, dining rooms, or similar areas typically are not classified as patient care areas”. (Definitions or descriptions for the three categories or types of patient care areas, general care areas, critical care areas, and wet location areas, are defined separately within paragraph 5.0 of this document.

A “Patient Care Area”, as defined by Article 3.3.138 in NFPA 99 is, “Any portion of a health care facility wherein patients are intended to be examined or treated”.

The definition of patient care area applies to hospitals as well as patient care areas in outpatient facilities. A patient bed location in a nursing home can be considered a patient care area if a person is examined or treated in that location. However, it excludes such areas as laundry rooms, boiler rooms, and utility areas, which, although routinely wet, are not patient care areas. The governing body of the health care facility may elect to include such areas as hydrotherapy areas, dialysis laboratories, and certain wet laboratories under this definition. Lavatories or bathrooms within a health care facility are not intended to be classified as wet locations. For infection control purposes, many patient and treatment areas have a sink for hand washing, which also is not intended to be a wet location.

### **Ungrounded Circuit Conductors Associated with IPSs**

The ungrounded circuit conductors associated with IPSs are branch circuits to be employed to power specialized medical equipment and specific circuitries associated with patient care. Such ungrounded circuit conductors have no direct or intentional reference or connections to earth. The identification requirements for ungrounded branch circuit conductors are prescribed by NEC® 210.5(C). NEC® 210.5(C) reads, “Where the premises wiring system has branch circuits supplied from more than one nominal voltage system, each ungrounded conductor of a branch circuit, where accessible, shall be identified by system. The means of identification shall be permitted to be by separate color coding, marking tape, tagging, or other approved means and shall be permanently posted at each branch-circuit panelboard or similar branch-circuit distribution equipment”.

### **Wet Locations**

Wet Locations, as defined by NEC® 517.2 are, “Those patient care areas that are normally subject to wet conditions while patients are present. These include standing fluids on the floor or drenching of the work area, either of which condition is intimate to the patient or staff. Routine housekeeping procedures and incidental spillage of liquids do not define a wet location”.

Wet Locations, as defined by Article 3.3.185 in NFPA 99 are, “The area in a patient care area where a procedure is performed that is normally subject to wet conditions while patients are present including standing fluids on the floor or drenching of the work area, either of which condition is intimate to the patient or staff.”

### **Design, Installation, and Operational Requirements of an IPS**

In modern healthcare facilities today the IPS is an enclosed stand alone and UL® Listed unit that is typically constructed with a relatively small distribution class transformer or isolation transformer that supplies a single phase, 120/240 Vac load center containing up to sixteen branch circuit breakers that supply power to all of the receptacles and lighting circuits associated with the IPS. Three phase IPS transformer are also available but rarely employed.

The purpose of the transformer within the stand alone unit is to isolate the primary power distribution system of a healthcare facility from all branch circuit connected to the IPS by creating a unique and separately derived power system. The secondary windings of the IPS transformer have no direct connections or intentional reference to earth other than a very small amount of leakage current resulting from capacitive or inductive coupling associated with the length of the branch circuits. Also, there are no direct electrical connections between the healthcare facilities primary or secondary power distribution systems and any branch circuit associated with the IPS.

## Listed Equipment

Per the design and installation requirements of NEC® 517.61(A)(2), “Where an isolated power system is utilized, the isolated power equipment shall be listed as isolated power equipment, and the isolated power system shall be designed and installed in accordance with 517.160”.

An official listing from a nationally recognized testing laboratory, as Underwriter’s Laboratories (UL®) is a necessary requirement when applying and installing any IPS. It is extremely important that an IPS be listed for the intended location and purpose. Refer to Figure 1.

**Figure 1: Isolated Power Equipment**



It is necessary to the insulating material on all branch circuit conductors associated with IPSs to have high dielectric constants and dielectric strengths in order to reduce capacitive or inductive leakage currents and provides resistance to mechanical stresses. Per the requirements of Article 4.3.2.6.2.1 in NFPA 99, the impedance (capacitive and resistive) to ground of either conductors of an isolated system shall exceed 200,000  $\Omega$  when installed including all connected receptacles. For example, on a 120 Vac IPS, an impedance of 200,000  $\Omega$  equates to a total maximum leakage current of 600  $\mu$ A (0.6 mA or 0.0006 A) between all IPS branch circuit conductors and earth.

## Conductor Insulation

Per the FPN No. 2, associated with NEC® 517.160(A)(6), and the information in Annex A.4.3.2.6.2.1 in NFPA 99, using conductor insulations with a dielectric constant less than 3.5 and insulation resistance constant greater than 6100 Megohm-meters (20,000 Megohm-feet) at 16°C (60°F) reduces leakage from line to ground, reducing the hazard current”. The type THHN/THWN conductor insulation, employed in most electrical installation today, does not satisfy these high dielectric insulation resistance values. The type XHHW insulation and XHHW-2 insulation are types of conductor insulation that is often selected for branch circuit conductors with an IPS.

## Conductor Length

All IPS branch circuits are usually limited in length as another means to limit capacitive and inductive leakage currents. A reduction in the total magnitude of capacitive or inductive leakage current is primarily accomplished by minimizing the total length of all branch-circuit conductors. Every foot of each branch circuit conductor directly contributes to the total magnitude of leakage current resulting from capacitive or inductive reactance. Therefore, an engineering emphasis should be placed on locating an isolation panel as close as possible to all intended connected loads or expected utilization equipment. An assessment of the expected utilization equipment should consider all stationary medical equipment and all probable portable medical equipment likely to be connected to any branch circuit associated with an IPS.

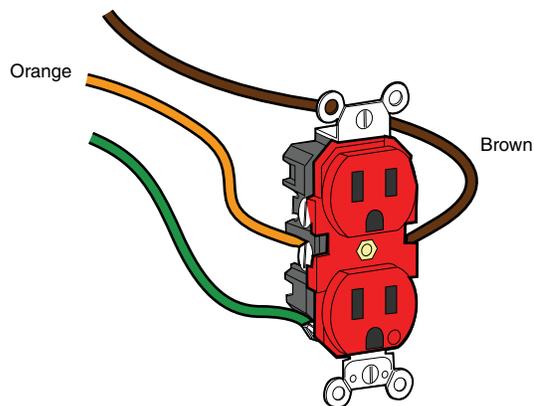
## Conductor Identification

All IPS branch circuits require special identification markings and specific color coding. Article 4.3.2.6.2.1 in NFPA 99 and NEC® 517.160(A)(5) require that the conductors associated with an IPS have specific identifying colors. NEC® 517.160(A)(5) reads, “The isolated circuit conductors shall be identified as follows:

- (1) Isolated Conductor No. 1 — Orange
- (2) Isolated Conductor No. 2 — Brown

For 3-phase systems, the third conductor shall be identified as yellow. Where isolated circuit conductors supply 125-volt, single-phase, 15- and 20-ampere receptacles, the orange conductor(s) shall be connected to the terminal(s) on the receptacles that are identified in accordance with Article 200.10(B) for connection to the grounded circuit conductor” (Refer to Figure 2).

**Figure 2: Orange Conductor Connection**



The 1999 NEC clarified that an orange conductor is required to be connected to the terminal on the receptacle that is intended for the grounded conductor.

## Isolation Transformers

Most of the isolation transformers employed in stand alone IPS units are sized relatively small in KVA rating in order to limit capacitive and inductive leakage currents on the secondary side. The sizes of these transformers can range from 3 KVA to 25 KVA. However, per the FPN No. 1, associated with NEC® 517.160(A)(6), and the information in Annex A.4.3.2.6.2.1 in NFPA 99, it is desirable to limit the size of the isolation transformer to 10 KVA or less and to use conductor insulation with low leakage to meet impedance requirements. In addition to limiting capacitive and inductive leakage currents by limiting the KVA size of the isolation transformer, a smaller transformer also allows for smaller isolation panel units to be employed in areas where available utilization space is an issue to designers and engineers. Therefore, unless there is a special equipment application or requirement, it is recommended that the sizes of isolation transformers range from 3 KVA to 10 KVA.

## Leakage and Fault Current Monitoring

It is a necessity and requirement to constantly monitor the magnitude of all leakage currents associated with the secondary terminals of the transformer in the IPS stand alone unit. In addition, it is also a necessity and requirement to constantly monitor all of all branch circuit conductors of an IPS to determine the presence of any inadvertent connection or contact with either the phase or the neutral conductor and earth (ground).

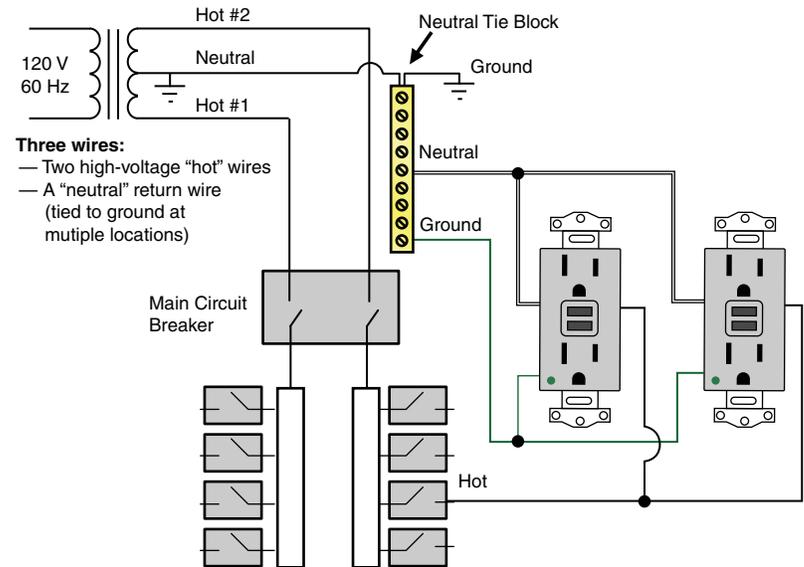
In addition to the usual control and overcurrent protective devices, per the requirements Article 4.3.2.6.3.1 and Article 4.3.2.6.3.2 in NFPA 99, each isolated power system shall be provided with an approved (listed) continually operating line isolation monitor that indicates possible leakage or fault currents from either isolated conductor to ground. The monitor shall be designed such that a green signal lamp, conspicuously visible in the area where the line isolation monitor is utilized, remains lighted when the system is adequately isolated from ground. An adjacent red signal lamp and an audible warning signal (remote if desired) shall be energized when the total hazard current (consisting of possible resistive and capacitive leakage currents) from either isolated conductor to ground reaches a threshold value of 5.0 mA under nominal line voltage conditions. The line isolation monitor shall not alarm for a fault hazard of less than 3.7 mA. Article 517.160(B)(1) in the NEC mandates basically these same requirements. These monitoring functions are continually performed by the line isolation monitor or LIM that is an integral component of a listed isolated panel system unit and provides a means for audible alarms and visual indications when leakage current flow exceeds a maximum preset value of 5.0 mA.

Prior to 1981, a magnitude of 2 mA of potential leakage current was permitted to flow before the LIM alarm sounded. To eliminate some of the so call "nuisance alarms", the allowable leakage current pickup points were increased in the 1981 Edition of the NEC and NFPA 99 to permit a 5 mA alarm level. The revised 5 mA alarm level allowed for more electrical equipment to be connected to an IPS without signaling an alarm. However, the 5 mA LIM alarm level does not provide the same level of protection against electric shock as lower alarm levels.)

## Design, Installation, and Operational Requirements of a GFCI

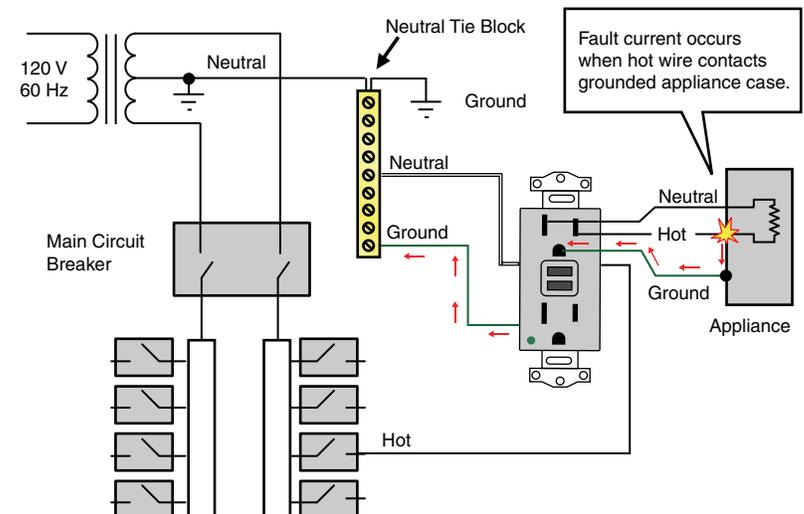
Per NEC® 100, “A Ground-Fault Circuit Interrupter (GFCI) is a device intended for the protection of personnel that functions to de-energize a circuit or portion thereof within an established period of time when a current to ground exceeds the values established for a Class A device. A Class (A) ground-fault circuit interrupters trip when the current to ground has a value in the range of 4–6 mA.” Unlike an IPS, a GFCI can only be employed on solidly grounded power distribution systems.

**Figure 3: Requirements of Ground Fault Circuit Interrupters**



A GFCI is specifically designed and intended to provide protection for personnel from electrical shock by interrupting a branch circuit when there is a specified difference in the current flow between the phase or energized conductor and the grounded conductor or neutral conductor of the same branch circuit. A specified difference in the current flow between a phase and neutral conductor of the same branch circuit is deemed or sensed to be a diversion of current usually associated with unintended leakage current or an unintentional human contact with either the phase or neutral conductor (See Figure 4).

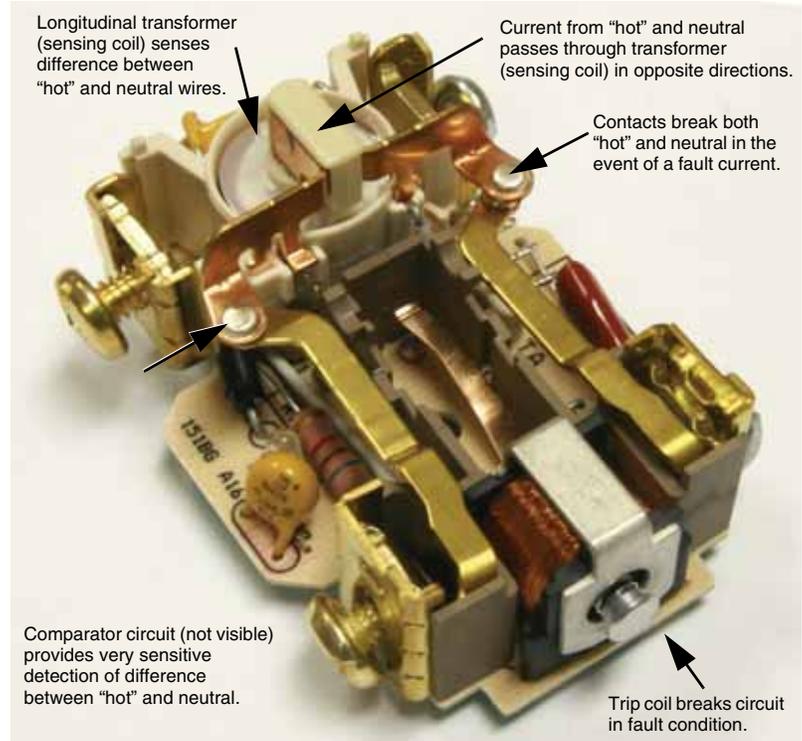
**Figure 4: Ground Fault Current Path**



## GFCI Construction

A GFCI is a compact and rather sophisticated current sensing device. The phase and neutral conductors of the same branch circuit are routed through the center of a zero sequence sensing coil.

**Figure 5: Components of a Receptacle Type GFCI**



At any point in time during normal circuit operation the current flowing in each conductor is equal in magnitude, but conducting opposite direction exactly 180 degrees apart. Consequently, the vector sum of the current flow through the center of the sensing coil is zero if the two currents are exactly equal and opposite. A current-carrying wire produces an alternating magnetic field that is external to the wire. A current other than zero would induce a voltage into the sensing coil of the GFCI.

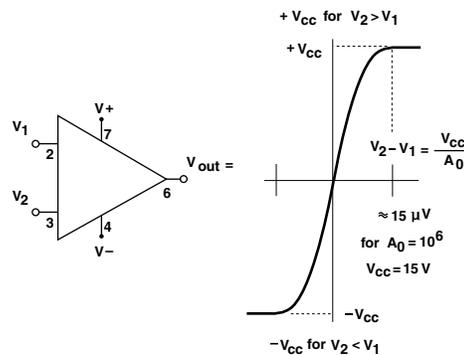
The windings associated with the internal zero sequence sensing coil of the GFCI are wound longitudinally in order to be affected more by the magnetic field associated with a branch circuit conductor passing through the center of the sensing coil. The net effect is to create a more sensitive current sensing detector. Consequently the difference in current flow that the internal zero sequence sensing coil can detect is very small. Any differences in current flow causes a current to flow in the zero sequence sensing coil. The output of the coil initiates the sensor circuitry. The sensor circuitry then removes power from an internal solenoid and contacts are forced apart by a spring that interrupts the flow of electricity. The device is designed and intended so that a preset magnitude of imbalanced current initiates the interruption of the branch circuit a fraction of a second, thus greatly reducing the affects or chances of a dangerous electric shock.

**NOTE:** Most op-amps will not actually produce  $V_{CC}$  or  $-V_{CC}$  at output, but on the order of  $\pm 13 V$  for  $V_{CC} = \pm 15 V$ . Refer to Figure 6

Depending on the manufacturer, a GFCI is designed to initiate the opening of a branch circuit in a range between 4 mA to 6 mA of leakage current or imbalanced current between the phase and neutral conductors. The exact trip setting can be chosen by the manufacturer of the device and is typically 5 mA within 25 milliseconds. However, the exact imbalanced current threshold and circuit opening times are approximate and preset by the manufacturer and are not adjustable. For example, a 5 mA current difference associated with a 20 A branch circuit equates to a 0.025% deviation. The internal components are designed to sense such a small deviation in current flow. The internal circuits developed to perform the deviation analyses are comparator circuits that incorporate an “op-amp comparator”. The output voltage of the zero sequence sensing coil is rectified and applied to the input of the sensitive comparator. The comparator activates a trip coil which opens both the phase and neutral conductors simultaneously via a spring release mechanism.

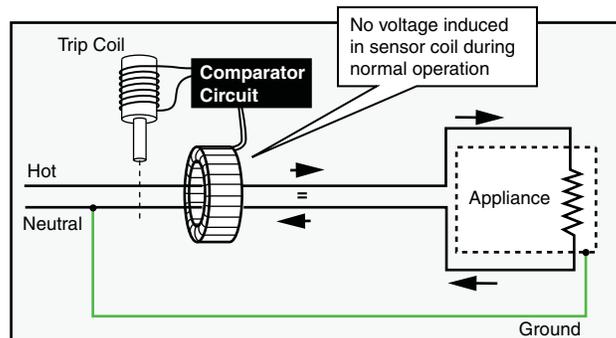
Because of sensitivity of the internal current sensing circuitry, a GFCI receptacle is prone to nuisance tripping, especially when utilized in damp, moist, or wet locations. In addition, the operational characteristics of a GFCI receptacle can be negatively affected by age, contamination, internal deterioration of components and insulation, external damage, or harsh external environments.

**Figure 6: Op-Amp Comparator**



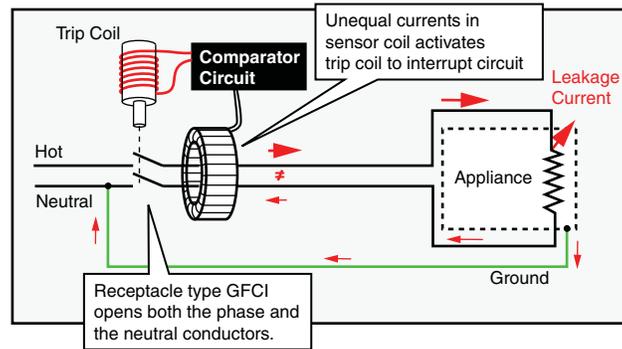
If all branch circuits were terminated with the correct polarity, just opening the phase conductor wire would be sufficient to interrupt the circuit. However, since it is quite common for the polarity of receptacles or utilization equipment to be routinely terminated with a reverse polarity, the construction of the GFCI incorporates a design to open both phase and neutral conductors (Refer to Figures 7 and 8).

**Figure 7: Normal Operation (GFCI Receptacle)**



**NOTE:** Because of sensitivity of the internal current sensing circuitry, a GFCI receptacle is prone to nuisance tripping, especially when utilized in damp, moist, or wet locations. In addition, the operational characteristics of a GFCI receptacle can be negatively affected by age, contamination, internal deterioration of components and insulation, external damage, or harsh external environments.

**Figure 8: Trip Coil Activation (GFCI Receptacle)**



## GFCI Types

### Receptacle Type GFCI

This type of GFCI is used in place of the standard duplex receptacle and is often found in homes and special commercial and institutional locations. This type of GFCI is installed in standard wall outlet boxes wherever an electrical appliance can be plugged into the outlet. Most receptacle-type GFCIs are also installed so that they also protect other downstream electrical outlets in the same branch circuit.

### Circuit Breaker Type GFCI

A circuit breaker type GFCI may be installed in a load center, lighting panel, or power panel. The circuit breaker type GFCI serves a dual purpose to open the circuit breaker in the event of a ground fault condition and also functions as a standard thermal-magnetic circuit breaker to open the branch circuit in the event of a short circuit or over load condition.

### Portable Type GFCI

Where a permanent GFCI is not practical, a portable GFCI may be used. One type contains the GFCI circuitry in a plastic enclosure with plug blades in the back and receptacle slots in the front. It can be plugged into a receptacle, then, the electrical product is plugged into the GFCI. Another type of portable GFCI is an extension cord combined with a GFCI. It adds flexibility in using receptacles that are not protected by a GFCI.

In the early 1970s most GFCI devices were of the circuit breaker type. The circuit breaker type GFCI devices experience many false trips due to the poor leakage current characteristics of 120 Vac insulation, especially in circuits having longer cable lengths. Also, there is often so much leakage current along the length of the conductors' insulation that the circuit breaker might trip with the slightest increase of current unbalance. However, the most commonly used GFCIs since the early 1980s are built into wall outlet receptacles.

In structures built to comply with the NEC, GFCI protection is required for most outdoor receptacles (since 1973), bathroom receptacle circuits (since 1975), garage wall outlets (since 1978), kitchen receptacles (since 1987), and all receptacles in crawl spaces and unfinished basements (since 1990).

Per the requirements of NEC® 517.20(A), "All receptacles and fixed equipment within the area of the wet location shall have ground-fault circuit-interrupter protection for personnel if interruption of power under fault conditions can be tolerated, or be served by an isolated power system if such interruption cannot be tolerated". In areas that are designated patient care wet locations by the governing body of the facility, GFCI protection is required for the protection of receptacles and fixed equipment if a circuit interruption can be tolerated. Otherwise, an isolated power system is required.

## The Advantages of an IPS Versus a GFCI

- An IPS is intended to operate as a strictly ungrounded power system. GFCI can only be utilized on solidly grounded power systems. The benefits of utilizing an IPS are not only the minimizing of arcing, sparking, and fault currents that may ignite an explosion or fire. IPSs can also reduce shock hazards from the inadvertent contact with a phase conductor and can allow for the continuation of electrical appliance or machine if a phase conductor of the branch circuit were to experience an actual phase-to-ground fault condition. If a GFCI were to sense an actual phase-to-ground fault condition, then the power in the branch circuit would be interrupted.
- An IPS is designed and specifically constructed to limited leakage current that may initiate an electrical shock. An IPS can be calibrated and set to alarm and annunciate at an exact present milliampere value. The magnitude of leakage current at which a GFCI devices will initiate to open a branch circuit is preset within a prescribed tolerance by the specific manufacturer of the device. GFCI devices are non-adjustable.
- Per the requirements of Article 4.3.2.6.3.2 in NFPA 99 and NEC® 517.160(B)(1), the LIM associated with an IPS must provide continuous monitoring of leakage current. However, there are no mandates or requirements for the monitoring of any GFCI device in either the NEC or NFPA 99.
- Per the requirements of Article 4.3.3.3.2 and Article 4.3.4.2 in NFPA 99, the LIM circuitry associated with an IPS must be tested after installation. A permanent record must be created and maintained that documents the date of the test, location of the test, and whether or not the LIM and IPS met performance requirements.

However, other than the visual inspection, the verification of the continuity of grounding circuit, the confirmation of terminal polarity, and retention force value inspection of the ground prong, as required by Article 4.3.3.2 in NFPA 99, there are no other initial inspections or testing requirements mandated for any GFCI device. This includes whether or not the ground fault protective functions of any GFCI device actually operates as designed and intended. There are no readily available testing requirements in the NEC regarding GFCI devices.

Article 4.3.3.4 in NFPA 99 provide for a requirement to functional test, via electrical testing methods prescribed by the manufacturer, each level of equipment ground fault protection when such systems are first installed. However sadly, neither NFPA 99 nor the NEC provides for any testing mandates or requirements for any GFCI device.

- Per the requirements of Article 4.3.4.1.4 and Article 4.3.4.2 in NFPA 99, the LIM circuitry associated with an IPS is mandated and required to be regularly maintenance tested at least once a month after installation. A permanent record must be created and maintained that documents the date of the test, location of the test, and whether or not the LIM and IPS met performance requirements.

Although Article 4.3.4.1.3 in NFPA 99, mandates and requires that receptacles at patient bed locations and in anesthetizing locations not listed as hospital grade to be tested at least once annually. However, the specific testing requirements are not described or outlined. Again, there is no clear requirement to determine, test, or verify if the ground fault protective functions of any GFCI device actually operates as designed and intended

- The requirements associated with Article 4.3.2.6.3.2 in NFPA 99, and NEC® 517.160(B)(1), limit the amount of allowable leakage current associated with an IPS to exactly 5.0 mA. Article 4.3.2.2.8.1 in NFPA 99 allows a GFCI device to have a maximum leakage current of 6 mA. The magnitude of 6 mA associated with a GFCI device is not an exact magnitude of current. The value of 6 mA in NFPA 99 document for a GFCI device is based on a manufacturing average and not a repeatable or exact test value. Again, it is very important to clearly note here that GFCI devices operate in a predetermined and prescribed average range of between 4 mA to 6 mA.
- It is common practice to terminate several standard receptacles on a load side of a single GFCI. Consequently, it is not always readily apparent if a standard hospital grade appearing receptacle is in fact protected by a GFCI device. Receptacles associated with an IPS are constructed with heavy phenolic and are readily identifiable by their red color.
- A GFCI device cannot protect against electric shock where current flows through a person from phase-to-neutral or phase-to-phase. For example, a situation where a finger touches both live and neutral contacts in a light fitting or the prongs of a receptacle plug. It is virtually impossible to provide electrical protection against such shocks as there is no way for a device to differentiate between current flow causing an electrical shock to a person and normal current flow through an appliance. Protection against electrical shock of this nature must be through mechanical means (guards or covers to protect against accidental contact) and procedure (e.g. switching off power before undertaking maintenance).

- GFCI devices are more prone to nuisance tripping than LIMs are to nuisance alarming. There are several reasons for this. However, the most common reasons for GFCI devices nuisance tripping are associated with the internal configuration of the various and uncontrolled appliances, devices, and equipment plugged into GFCI devices along with the associated length of cord or cords.
- The interruption of electrical power to critical piece of medical equipment from the tripping of GFCI device, from either an actual phase-to-ground fault or a nuisance tripping condition, is a primary reason for employing an IPS. If a GFCI device were to interrupt electrical power to a life sustaining piece of medical equipment the results could result in the death of, or serious and prolonged injury to, a patient before electrical power could be restored.

## Financial Evaluation of IPS vs. Grounded Power

First, it is important to understand that using grounded power in an Operating Room must still meet the same basic criteria as IPS. Is the location considered wet. Construction of surgical facilities today is becoming more generic in that the operating rooms are multi-purpose. They can be used for endoscopy, which, typically, is not a 'wet procedure'. They can also be used for cystology of orthopedic procedures, which are both considered very wet procedures. This would be considered a wet location and will require at least protection with GFCI circuits. This means that the grounded power panel feeding the OR will have GFCI breakers for each circuit. This is an added cost to just the panel. There is also the added expense in labor and materials because the GFCI cannot share the ungrounded current carrying conductor (neutral). Grounded power is not uncommon in ORs today but the cost difference should not be the deciding factor. The costs of installing IPS in the place of grounded power consist of two major factors. While the panel may cost twice as much as a grounded panel with GFCI breakers, the extra labor, and material to install an IPS is about 15% more than the grounded power panel.

When comparing the cost difference the price of the panels, both grounded and ungrounded, and the labor cost must be considered. A grounded power panel used in a wet location must have GFCI breakers. The cost of the panel is higher than a normal grounded panel due to the breakers, but the cost to feed to panel becomes a factor. Typically the panel is fed from a 208/120 source which usually requires a transformer, which becomes a factor. By the time all things are considered, the difference in the panels alone, with the feeders, can be as little as 10% and as much as 30%. The labor and material cost are usually no more than a 15% increase over grounded power.

## Deaths in Hospitals from Electrical Shock <sup>[B1]</sup>

During the 1960s open-heart surgery and cardiac catheterizations became common medical procedures throughout the United States. Arterial catheters were inserted into an increasing number of cardiac patients as part of diagnostic or surgical procedures or cardiac medical treatment. Arterial catheters inserted into a specific point of a patient's circulatory system could then be connected externally from the patient's body via enclosed leads to external medical devices as cardiac monitors or pacemaker located within cardiac care unit or intensive care units of hospitals. Physicians later became concerned that patients could be electrocuted by the passing of electrical currents directly into a patient's circulatory system or the chambers of the heart.

Patients with externally accessible conductive pathways leading directly to the heart came to be known as electrically susceptible (ES) or electrically sensitive patients (ESPs). The theoretical phenomenon, in which an ES patient might be induced into fatal ventricular fibrillation by the passage of small level of current through a transarterial catheter, became known as

“silent electrocution” or “microshock”. Concerns about this potential scenario were published as early as August 1961 in an editorial in the journal *Circulation* titled, “Hidden Hazards of Cardiac Pacemakers”. 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. 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 and external arterial catheters.

In April 1968, the division of medical sciences of the National Research Council (NRC) held a two-day workshop on “Electrical Hazards in Hospitals”. The proceedings of the workshop were edited by Dr. Carl Waldemar 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 hospital of the National Fire Protection Association (NFPA). 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 national statistics on electrocution that were available at the time, he claimed that there were 1200 misdiagnosed electrocutions annually in hospitals between 1964 and 1965. That would have amounted to one “misadventure” annually within one out of every seven hospitals in this country. Dr. Walter reported that these misadventures were classified as cardiac arrest, but the deaths occurred during resuscitation efforts unrelated to the patient’s primary disease or during the application of electrical appliances.

On January 27, 1969, a report titled, *Accidental Electrocutions Claim 1200 Patients a Year*, was published in *Electronic News* (*Electronic News* 1969). The report quoted microshock statistics obtained from Dr. Walter. These statistics were repeated at press conferences and widely published throughout the national press. For example, *TIME Magazine* published an article in its April 18, 1969 edition titled, “Too Many Shocks” that repeated Dr. Walter’s claim of 1200 annual inpatient deaths from electrical shock within U.S. hospitals. However, within the same *TIME Magazine* article, a spokesman for the AMA indicated that the number of electrical shock deaths in hospital was closer to only 25 annually. These same statistics of 1200 deaths 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.

In June 1970, a report was distributed by the UPI wire service that Ralph Nader, an attorney and consumer activist, had alleged in a speech that 5000 deaths attributed to “microshock” occurred each year in the nation’s hospitals. In March 1971, the *Ladies Home Journal* ran an article quoting Ralph Nader titled, *“Ralph Nader’s Most Shocking Exposé”*, which stated that, *“at the very least 1200 Americans are electrocuted annually during routine diagnostic and therapeutic procedures”*. Mr. Nader’s article claimed that, *“too many hospitals are hazardous electrical horror chambers”* and that *“most electrical accidents in hospitals occur because safety measures that can reduce risks are grossly neglected or even unknown among hospital staff”*. Within Mr. Nader’s article medical engineers such as Professor Hans von der Mosel, co-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 is reported to have stated that he, “believes that the number might be ten times as high as

the conservative estimate of 1200. The 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*”. However, to this day, neither Mr. Nader nor Professor Hans van der Mosel has provided any independent substantiation for their figures.

As a result of Dr. Walter's claims and the national emotional stir created by Ralph Nader and the lay media, several congressional hearings were held and many legislative and regulatory bills were quickly passed on the federal and state level. By the mid-1970's, 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 NEC<sup>®</sup> that would require all hospitals to have isolation transformer-based “Safe Patient Power Centers” in all special care areas of the nation's approximately 6000 hospitals. In spite of the period of spirited discussion about the reality or non-existence of this new, perhaps life threatening microshock 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 only slightly modified form as part of various regulations. The Joint Commission on Accreditation of Hospitals issued new standards that prescribed quarterly documented electrical safety testing for all of a facility's patient care equipment.

Another consequence of Dr. Walter's claims, and the national emotional stir created by Ralph Nader and the lay media, were numerous equipment related malpractice suits that began to be filed in the 1970s<sup>[B2]</sup>. Being very sensitive to the dramatic and looming economic impact from potential medical claims, increased regulations, increased equipment cost, and significant upgrades to existing electrical distribution systems the American Medical Association (AMA) and the hospital industry appeared to have closed ranks and denied Dr. Walter's claims of patient electrocutions. In August 1975, a report appeared in the journal *The Medical Staff* under the heading, “*The Myth of Iatrogenic Electrocution—Its Effect on Hospital Costs*.” The report discussed Dr. Walter's widely publicized claim that there were 1200 electrocutions a year in US hospitals and how the charge was reported regularly thereafter in the lay press. The report went on to point out that evidence supporting Walter's claim had never been produced. Almost immediately after Dr. Walter's claims of “microshock” became public, all public access to available information on the subject of deaths in hospitals from electric shock appeared to have dried up and vanished. To this day there is no specific information available to the public with respect to dysfunctional medical equipment that may have resulted in deaths from electric shock in operating rooms, cardiac care units, intensive care units or emergency rooms. Any published information on the subject of deaths in hospitals or equipment related malpractice suits is restricted or has apparently been removed from public access and review. Specific medical journal containing articles or specific information on microshock have apparently been removed from access or circulation. In addition, Dr. Walter appears to have been discredited and rebuked by the medical establishment that once considered him a leader and pioneer in the field of medical research and development.

However, a by-product of the microshock episode in the late 1960s was the realization that the existing quality of maintenance of the typical hospital's ever expanding inventory of electronic equipment was inadequate. A new high intensity focus on equipment maintenance and safety was born. For example, Article 517 in the 1971 Edition of the NEC<sup>®</sup> was significantly enhanced and expanded to include six separate parts (Part 'A' through

Part 'F'). Article 517 in the 1971 Edition of the NEC® introduced Part D, "Electrically Susceptible Patient Area". The fine print note employed below the new Article 517-50 introduced and attempted to explain the hazards from the introduction of possible sources of electrical currents which can traverse a patient's body from instruments directly connected to a patient's body. In the early 1970's dramatic and evolutionary changes were introduced and mandated within the healthcare industry. It was during this period that the NFPA's Committee on Hospitals was successful in advocating the use of isolated power system (IPS) in other special care areas if the hospital has a safeguard against microshock.

## Concluding Comments

NFPA 99 addresses electrical safety as well as explosion and fire prevention in healthcare facilities. Historically, NFPA 99 has collected and consolidated 12 individual and separate NFPA documents or standards into one single reference document. It is alarming and surprising that many consulting and hospital engineers consider the NEC as the sole electrical code as their standard for reference and are unaware of the existence or requirements of NFPA 99. In fact, the NEC is a "minimum" installation requirement document. Minimum installation requirements are not applicable for such necessary and valuable operations as healthcare facilities.

The design and installation of an IPS in surgical clinics and operating rooms was originally employed and required as a means to dramatically reduce arcing and sparking from faulted electrical circuits as a source of energy to ignite flammable anesthetic agents. However, with the understanding of microshock and electrically sensitive patients, the expanded use of an IPS can prevent patient shock electrocutions, and the interruption of electrical power to critical and life saving medical equipment. Consequently, the utilization of an IPS is a significantly more reliable source of electrical power than any GFCI device.

[B1] Much of the information for Section 10 originated from the 2004 Edition of the Clinical Engineering Handbook.

[B2] Clinical Engineering: An In-Depth Review of Its Economic Potential, Michael J. Shaffer, Medical Care, Vol. 15, No. 7 (Jul., 1977), pp. 552-567