

Comment to the NFPA opposing the requirement for Isolated Power Systems in Operating Rooms

During the Public Comment Cycle for NFPA 99-2009, a proposal was submitted to define all Operating Rooms as Wet Locations. This change would indirectly require isolated power systems (IPS) in all operating rooms, and it is the intent of this comment on proposal to defend the fact that the majority of operating rooms are not actually wet locations, and that there is little evidence to suggest an increase in patient safety due to the installation of isolated power systems (IPS) in operating rooms (ORs).

To defend this claim a survey was administered to various medical, facility, and biomedical staff in Kaiser Permanente Medical Centers throughout California, Colorado, Hawaii, Maryland, Ohio, and Virginia. The survey asked questions pertaining to electrical incidents in operating rooms with the intent of comparing the number and type of incidents found in operating rooms with traditional grounded systems to that of operating rooms with IPS. A total of 130 Kaiser Staff answered the survey (47 technical and 83 non-technical¹), representing 48 different Kaiser Permanente Medical Centers and 396 Kaiser Permanente operating rooms. In total, 65% of Kaiser’s licensed procedure rooms were represented in the survey, 22% of which were reported to have IPS currently installed.

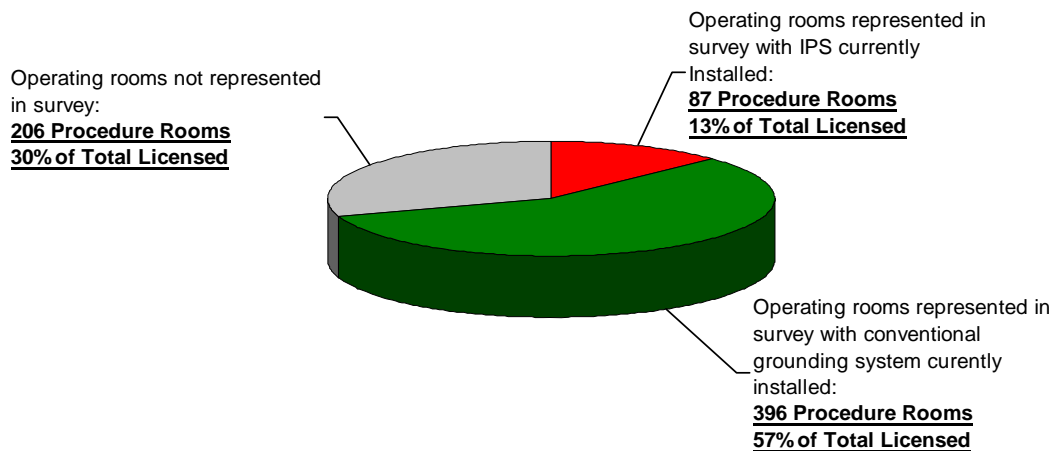


Figure 1 - Survey Response

Are All Operating Rooms Really “Wet Locations”?

In the survey participants were asked about the frequency of pooling or ponding of fluids on operating room floors during a procedure. The staff reported that, on average, 5% of operating room procedures had pooling or ponding of fluids on the floor. Also, 18% of staff reported never having experienced pooling or ponding of fluids on the floor of any operating room during their tenures. In addition to the survey findings, the ECRIⁱⁱ, Department of Defense, and The Association for the Advancement of Medical Instrumentation all defend that operating

rooms are not necessarily wet locationsⁱⁱⁱ. This demonstrates the excessive nature of trying to define all operating rooms as wet locations and suggests that individual Medical Centers should remain in control of defining the “wetness” of their operating rooms.

The Reality of Shocks – IPS vs. Conventional Grounded System

A common, secondary argument for IPS is that the alarm on first fault feature provides an enhanced level of protection against shocks and fires because, in the case of the first fault, there is an insufficient return path for current to flow into a foreign body, such as a person or combustible medium.

Of those surveyed only 8% had actually experienced or heard of an electric shock in an operating room (wet or not wet) during their career, and 45% of those instances could be related back to conditions not preventable by an IPS.^{iv} Considering that some survey participants are drawing on more than thirty years of experience in operating rooms, this data implies that roughly 96% of the survey participants have never experienced or heard of a preventable electrical shock in an operating room during their entire career as a medical professional. This trend is also reflected in the fact that throughout its history as a medical provider, Kaiser Permanente Risk Management has never processed any work-related injuries resulting from electric shock in an operating room. This data suggests that in ORs without IPS there are few historic incidents that could have been prevented by their installation.

The limited number of electrical shock incidents may be partially due to increased safety requirements for the electrical equipment used in medical procedures. While one of the primary reasons for development of the IPS in the late sixties and early seventies was to prevent stray ground currents from entering the heart, these increased equipment requirements (particularly the mandatory electrical isolation of patient leads) have all but eliminated this threat, in turn providing an inherently safer operating environment for both patients and staff.^v

Although there is no history of injury due to electrical shock at Kaiser Permanente, there are rare instances of minor electrical shock, such as an incident in which a nurse touched a live fuse. In this particular incident the shock was delivered in an operating room that had an IPS installed. The IPS may have limited the current, thus limiting the overall sensation of the shock to the nurse; however, it should be noted that without factual evidence with which to compare the magnitude of electric shocks between systems, further research needs to be done before the NFPA uses this concept as a basis to enact any IPS requirement.

Furthermore, in all the operating rooms defined by personnel as wet locations, only one of the survey participants had ever experienced or heard of electric shock or equipment failure as a direct result of excessive irrigative or biological fluids. Zero incidents were reported in “dry” operating rooms. Considering the magnitude of the survey pool, the varying lengths of tenure,

and the predicted frequency of procedures, the evidence suggests that the electrical operating room environment may not be as susceptible to fluids as previously considered.

The trends identified here are also supported by previous IPS studies. For example, in 1996, one California hospital removed all of its IPS. As of 2004, an estimated 96,000 procedures later, zero electrical incidents had been reported in that facility^{vi}.

The Reality of Fires – IPS vs. Conventional Grounded System

Of those surveyed only 14% have experienced or heard of a fire or explosion in any (wet or non-wet) operating room during a procedure; of that percentage, 100% of those incidents could be directly related to the use of electrosurgical tools or other conditions not preventable by an IPS^{vii}. This lack of IPS preventable fires can be attributed to the fact that flammable anesthetic gasses are no longer used in most hospitals; therefore, the ignition of the ambient environment from arcing or sparking is no longer a viable threat to staff or patient safety. This data also suggests that there are few historic incidents of fire or explosion that could have been prevented by the installation of an IPS.

Challenging the Proposal's Substantiation

The basis of the substantiation for the proposed change^{viii} is that "...there are frequent instances of standing pools of saline, water, blood and urine on the floor [of an operating room]. Also intravenous fluids frequently drip on electronic equipment. The surgeons use irrigating fluids in many procedures. These fluids often end up on the floor." From the data collected in the survey, it is apparent that, on average, 95% of procedures have no pooling of fluids on the floor, proving that this substantiation is empirically inaccurate.

In regard to the example provided in the substantiation for the proposed change (the hot air warmer incident) the IPS caused the warmer to blow smoke into the patient area when it shorted internally, because it prevented a sufficient current from flowing to open the circuit breaker. If it had been a traditional grounded system, the breaker would have opened and there would have been no contamination of the patient environment.

Practicality & Sensibility

When the IPS requirement for operating rooms that do not use flammable anesthetic agents was removed from the code, Kaiser Permanente replaced most of its existing IPS with traditional grounded systems^{ix}. The benefit of IPS, when put into practice, was so slight that the maintenance requirements and inherent complexity of the system necessitated a capital outlay in order to remove it from operating rooms. In fact, over the estimated 30 year life of an IPS, a healthcare incurs \$197,000 per operating room in operating costs^x. Considering the reaction to

previous code changes and the number of operating rooms owned and operated by some healthcare providers, it seems unreasonable to again require the installation of IPS.

In addition to operating costs the purchase and installation of IPS costs roughly \$71,500 per operating room for retrofits and \$42,900 per operating room for new construction.^{xi} Although this NFPA change would only require IPS installation in new construction and in operating rooms undergoing other renovations, it sets a precedent as to what is nationally accepted as a “safe” healthcare environment. With both liability and good practice in mind, most healthcare providers would be indirectly pressured into installing IPS throughout their existing facilities. The financial and practical impact of such a pressure is immense. For example, in addition to the 100 operating rooms planned for construction before 2013, Kaiser Permanente has 602 operating rooms currently in operation (78% of which do not have IPS installed). As a result of the pending IPS requirement, Kaiser National Facilities Services estimates a first-cost of over \$56,000,000, and a maintenance cost over the life of those systems of roughly \$140,000,000^{xii}. With no historical or empirical evidence to support that IPS actually increases patient safety, this is an extremely low value proposition that prevents healthcare providers from providing other high value options for their patients. In other words, by spending this capital on IPS, healthcare providers lose the opportunity to upgrade their operating rooms with new medical equipment, new wiring, or better maintenance procedures that could offer proven improvements to patient and staff safety.

When a panel of healthcare professionals at the ASHE 45th Annual Conference & Technical Exhibition were tasked with debating whether all operating rooms should be considered wet locations, the participants (approximately 120 members) unanimously voted to have ASHE oppose the change^{xiii}.

Furthermore, the ECRI Institute has performed detailed analysis of IPS dating from the present back to 1971. In 1996, they stated that “In today’s cost-conscious environment, we believe that investing in these systems (isolated power and equipotential grounding systems) is both unreasonable and unnecessary. It is not clear that they enhance safety, and they present an ongoing testing and maintenance burden.”^{xiv}

Conclusions and Recommendations

- A. Most operating rooms are not “wet locations”. To promote the stability of the healthcare industry, and to prevent unreasonable financial burdens, the NFPA should stand-by its previous ruling of NFPA 76BT § 2062, “...[t]he governing body of the hospital shall be responsible for designating locations where wet conditions are likely to be encountered; and shall take appropriate protective measures.”

- B. The primary substantiation of the proposal, referenced above, is factually incorrect. The survey shows that, on average, 95% of operations have no pooling of fluids on the floor; therefore, the Technical Committee should reevaluate its votes.
- C. There is insufficient historical data involving shock or fire related incidents that would necessitate IPS. Further research should be done to investigate and legitimize the existing risks, and the ability of IPS to circumvent those risks, before the NFPA reenacts an IPS requirement.
- D. IPS is an extremely low value safety proposition for healthcare providers. Because there is no historical or empirical data that shows a measurable impact on patient safety, IPS should not be required in operating rooms because its installation may supplant other patient safety driven measures.

ⁱ Technical Staff Includes: Facility Service Directors, Senior Biomedical Engineers, and Clinical Systems Engineers. Non-Technical Staff Includes: Directors and Managers of Perioperative Services, Operating Room Managers, Nurse Managers, Chiefs of Service Anesthesiology, Anesthesiologists, and Managers of EH&S.

ⁱⁱ ECRI Institute, Description: “For nearly 40 years, ECRI Institute, a nonprofit organization, has been dedicated to bringing the discipline of applied scientific research to discover which medical procedures, devices, drugs, and processes are best, all to enable you to improve patient care. As pioneers in this science, we pride ourselves in having the unique ability to marry practical experience and uncompromising independence with the thoroughness and objectivity of evidence-based research.”
(<https://www.ecri.org/About/Pages/default.aspx>)

ⁱⁱⁱ “ECRI continues to advocate that ORs do not need to be designated as wet locations.” “Electrical Safety Q&A. A Reference Guide for the Clinical Engineer.” *Health Devices* (Feb. 2005), p. 69.

The Association for the Advancement of Medical Instrumentation’s Electrical Safety Manual (2004) also supports the position that operating rooms are not necessarily wet locations.

The U.S. Department of Defense’s 2002 Military Handbook: Department of Defense Medical Military Facilities Design and Construction Criteria (MIL-HDBK-1191) specifies that “Operating rooms, delivery rooms, cystoscope rooms, oral surgery, cardiac catheterization rooms, and other such rooms are not wet areas.”

^{iv} Conditions not wholly preventable by an IPS include (but are not limited to) the following: accidental contact between a nerve stimulator and wet clothing, defibrillator discharging on a table while persons were touching table, unplugging energized equipment, and continual use of broken or frayed power cords.

^v Since the original requirement for IPS, both the NFPA and FDA have enacted multiple medical equipment requirements pertaining to electrical safety. NFPA 99 now contains several restrictions on electrified medical equipment, as does the FDA. Some examples include:

- NFPA 99, 8.4.1.3.2, 2005: Requires the limit of resistance between the chassis of the equipment and its ground wire be no more than 0.5 ohms.
- NFPA 99, 8.5.2.1.5, 2005: Leads for equipment connected directly to the heart or inserted into the heart via catheterization must meet further requirements, such as having isolated patient leads specifically designed for this purpose.
- NFPA 99, Art. 9, 9-2.1.10.4, 1999: Low-voltage equipment “shall be directly isolated from the power distribution system.”

All of these restrictions on medical equipment limit the degree to which the patients or staffs are exposed to electrical energy in sufficient quantity as to be hazardous.

^{vi} Vernon, Walt. *Isolated Power: The Final (Two) Words*. Mazzetti Nash Lipsey Burch. p. 6.

^{vii} Conditions unpreventable by an IPS include (but are not limited to) the following: fires occurring during cauterizing procedures when O₂ gas was present or when flammable prep solution was not allowed to fully dry before the procedure began, and when light fiber cables shine directly onto drapes causing smoke.

^{viii} *NFPA 2009 Annual Revision Cycle Report on Proposals*, Proposal #99-68 regarding 3.3.185 “Wet Locations”.

^{ix} “In approximately 1992, Kaiser chose to forbid the use of isolated power systems in its ORs, having decided that the risk of hazard, considered as described in old NFPA 76BT, was insufficient to justify the added expense.”
Vernon, Walt. *Isolated Power: The Final (Two) Words*. Mazzetti Nash Lipsey Burch. p.5.

^x Estimate given in 2008 dollars, adjusted for inflation at 4.6% per year based on the 2005 estimate from *Isolated Power: The Final (Two) Words*.
Vernon, Walt. *Isolated Power: The Final (Two) Words*. Mazzetti Nash Lipsey Burch. p.5.

^{xi} Estimate given in 2008 dollars. Estimate provided by Kaiser Permanente Construction Services in conjunction with Kaiser National Facilities Services.

^{xii} Estimate given in 2008 dollars, and takes into account the number of operating rooms, adjusted for inflation at 4.6% per year based on the 2005 estimate from *Isolated Power: The Final (Two) Words*.
Vernon, Walt. *Isolated Power: The Final (Two) Words*. Mazzetti Nash Lipsey Burch. p.5.

^{xiii} Regulatory Advisory: Operating Rooms to be Considered Wet Locations. American Society for Healthcare Engineering. 18 August 2008
<http://www.ashe.org/ashe/codes/advisories/wet080812.html>

^{xiv} “Isolated Power and Equipotential Grounding Systems.” *Health Devices* (Jan. 1996): pp. 23-24.