

Critical Utility Protection of Laboratory Performance: A System for Ensuring the Integrity of Electrical Power

by Raymond L. Hecker

Often overlooked in efforts to produce consistently accurate and reliable laboratory results, unknown fluctuations in the electrical power provided to instruments and other devices can critically affect laboratory performance and profitability. Category III-3 Laboratory Protection System (LPS)¹ devices that prevent such fluctuations can also prevent electrically caused unreliability and directly improve laboratory profitability at essentially no net cost. An LPS device smooths out the electrical power by first filtering and converting (rectifying) the incoming alternating current (AC) power to direct current (DC). It stores this rectified current in a battery for use in low-power conditions or to provide supplemental power when none is available from the utility. It then reconstructs (inverts) the DC power into AC power using a computer and another circuit called an inverter. A final correction involving high-frequency filtering and wave modeling ensures the generation of essentially perfect AC power for the laboratory instrument. This application note discusses the importance of critical utilities in optimizing laboratory performance and profitability.

To the laboratory operator, whether in a clinical or research operation, finding the *sine qua non* for laboratory efficacy is the silver bullet that makes the difference between a successful set of reportable results or the management tension of just trying to keep the workload running smoothly. *Sine qua non* from *Late Latin* literally translates as “without which cause not,” but the colloquial meaning for the laboratory is more appropriately given as “an essential condition or element; an indispensable thing; an absolute prerequisite.”²

In the clinical laboratory, there are a number of factors that lead to the true effectiveness of the operation. Managing each one of these factors requires foresight, understanding, and control. Determining the most essential of these key factors, the *sine qua non*, will substantially save

the laboratory time and money, as well as establish a very reliable foundation for the laboratory's first step in overall instrumentation effectiveness and regulatory compliance.

Key factors for laboratory efficacy

The clinical laboratory director or principal investigator must manage each of the following key factors to produce economically sound reportable results in a timely manner:

- Qualified staffing
- Approved instrumentation systems
- Coordinated automation and robotics
- Informatics management and quality control
- Regulatory compliance
- Critical utilities.³

All of these factors have an impact on clinical results and the laboratory's profitability. When interfacing with procedural and diagnostic testing reimbursement such as Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology (CPT), and other Centers for Medicare-Medicaid Services (CMS) codes, being prepared is crucial to efficient and profitable operation. Add in College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA) certification, along with the FDA's 21 CFR Part 11, Current Good Clinical Practice (cGCP), and Current Good Laboratory Practice (cGLP) regulations, and the laboratory has a number of very good reasons to find the single key factor that keeps its instrumentation and reportable results process running smoothly (see *Appendix I*).

Staffing impact factors

As reported by the American Association for Clinical Chemistry (AACC),⁴ the Clinical Laboratory Management Association (CLMA),⁵ and others,⁶ the clinical laboratory market continues to face a shortage of qualified personnel to

staff its operation. Managing in an environment with a staffing shortage is tedious at best.

As a result of the staffing shortage, a number of laboratories have turned to automation and robotics in an effort to improve their operations and overall financial performance. With an increased investment in automation, the laboratory calculates a reduction in its labor requirements. The staffing reduction is planned with a simultaneous increase of reportable results due to automation. Increasing the number of reportable results, while decreasing retests and staffing, leads to improved return on investment (ROI) for the entire operation, which is the objective. In today's laboratory, it is becoming commonplace to see instrumentation systems with more capability and automation via robotic enhancements.

Higher performance to yield better ROI

Does more performance with a finely tuned sample processing system result in higher throughput and a better cost picture? Not necessarily. If all of the key factors required for laboratory efficacy are not addressed and managed, installing larger, more capable and faster instrumentation/equipment will not produce the desired results. In fact, troubleshooting and incident reporting within the laboratory will increase exponentially with highly integrated and interdependent systems that are not operating with sound foundations. Those foundations are the laboratory's critical utilities. The laboratory's essential and absolute prerequisite for reliable and consistent results is to ensure that the critical utilities are qualified and secure.

Electrical power—the overlooked critical utility

A great deal of expense, technical staffing, and energy have been and will be devoted to opti-

mizing laboratories to improve their profitability. Integrated systems are choreographed and managed by large-scale software packages and the laboratory information management system (LIMS). These systems are dependent on reliable power delivery within the laboratory system's operating specifications. However, a dilemma is faced by the laboratory: The power that is available to the laboratory can no longer be taken for granted. Too many episodes of rolling brownouts and blackouts have occurred and will continue for the next five years until adequate power generation capacity is available.⁷

Whether electrical power is considered a critical utility or not, managing a laboratory operation without reliable power is not exercising business foresight. This is especially important where laboratory technology is available to provide perfect power (Figure 1) that is always on,⁸ without any real cost to the laboratory.

In today's highly developed automated laborato-

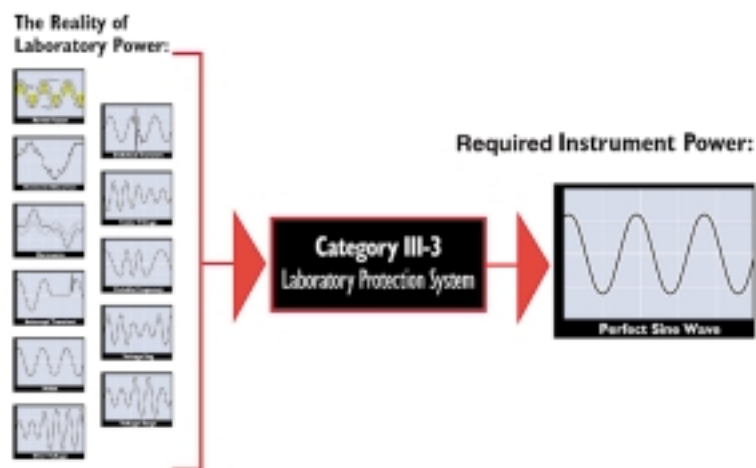


Figure 1 Available vs required laboratory power.

ry, robotic sample processing, higher test throughput, reporting, quality assurance analysis, and posttest sample storage are all managed digitally. This arrangement works well until the lights go out or, even worse, the laboratory experiences a power delivery perturbation and anomaly. For those laboratories that are protected by external generating capability for their emergency power, it is impossible to get through the transient switchover without adequate 100% on-line instrumentation-grade ride-through capability.

The worst of these conditions occurs within the laboratory itself, where all of the systems and their computers/controllers compete for and contaminate the laboratory's own power. In nearly all

cases, the laboratory director is not even aware of the cost the operation is bearing, due to unreliable power availability and the ever-present and ubiquitous electrical power glitch.

With the current threat of bioterrorism and terrorist actions, the electric utility and associated distribution systems are prime candidates for addition to the critical utility list. Not since Y2K has the focus been on the status and vulnerability of instrumentation systems to their primary source of energy and power. Electrical power is so critical that without it for even an instant (≈ 30 msec), these laboratory and production workhorses fail to operate at all.

Additionally, the FDA and CMS are specifically interested in ensuring that all environmental influences affecting automation, robotics, and instrumentation systems associated with electronic reporting and electronic signatures of 21 CFR Part 11, as well as CLIA certification, are compliant. Without a sound foundation of consistent and reliable electrical power, it is impossible to comply with Part 11 software certification and regulatory compliance.

Protecting the laboratory's profitability

Ever since the Electric Power Research Institute (EPRI)⁹ announced the Consortium for Electric Infrastructure for a Digital Society (CEIDS)¹⁰ to the U.S. Congress in May 2001, the U.S. Department of Energy,

Congress, and the electrical utilities have been acutely aware of the expanding electrical power shortages in key markets, including the scientific, research, and clinical laboratory markets. Laboratory operators are the most vulnerable of all digital businesses due to the complexity and sensitivity of their instrumentation and automated equipment. The best way to protect the laboratory, its reportable results, its customers, and its profitability is to adequately provide electrical power that is reconstructed and regulated for highly sophisticated instrumentation applications. Adding Category III-3 (Instrumentation Grade) Laboratory Protection System devices to the instrumentation's power sources will not only protect the laboratory's ROI, but will enhance it with increased bene-

fit-to-cost ratios from the investment.

With the addition of Category III-3 LPS devices, the laboratory director can pinpoint the *sine qua non* of laboratory efficacy and manage the most fundamental of all critical utilities—electrical power—to safeguard the entire operation. The best part of this safeguard is that there is no real cost of adding instrumentation protection to the laboratory.

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Appendix I Key Laboratory and Health Care Industry Acronym Definitions

HCPCS	<p>The U.S. HCFA (Health Care Financing Administration, now known as the Centers for Medicare and Medicaid Services) Common Procedure Coding System (HCPCS) is a system for health-care providers, physicians, and medical suppliers to report supplies, professional services, and procedures. HCPCS is a three-level coding system. Each level is its own unique system.</p> <p>HCPCS Level I—CPT: Current Procedural Terminology (CPT) is developed and maintained by the American Medical Association (AMA). It is a five-digit code with a possible two-digit or five-digit modifier (www.hcfa.gov/medicare/03INFOPKtweb.rtf).</p>
CPT	<p>Current Procedural Terminology (CPT) is an AMA-developed, maintained, and copyrighted physician procedure identification and coding system for health-care records and reimbursement.</p> <p>The U.S. Government's Department of Health and Human Services (U.S. HHS) developed the HCPCS system to avoid paying a royalty to the AMA for reimbursements for CPT-identified procedures (HCPCS Level I). As illustrated above, HCPCS Level I procedures are the government's coding identifiers that directly correspond to the AMA's CPT codes (www.ama-assn.org/ama/pub/category/3113.html).</p>
CMS	<p>The U.S. Government's Department of Health and Human Services (U.S. HHS, or HHS) Centers for Medicare-Medicaid Services (CMS) is the current name for the former HHS—Health Care Financing Administration (HCFA) (www.cms.hhs.gov).</p>
CAP	<p>The College of American Pathologists (CAP) is a medical specialty society representing more than 16,000 board-certified physicians who practice clinical or anatomic pathology, or both, in community hospitals, independent clinical laboratories, academic medical centers, and federal and state health facilities (www.cap.org).</p>
CLIA	<p>The Clinical Laboratory Improvement Amendments (CLIA), which is also known as section 42, Code of Federal Regulation, Part 493 (42 CFR 493).</p> <p>CMS regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). In total, CLIA covers approx. 175,000 laboratory entities. The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Medicaid and State Operations has the responsibility for implementing the CLIA program (www.cms.hhs.gov/clia).</p>
cGCP, cGLP	<p>U.S. Food and Drug Administration (U.S. FDA, or FDA) regulations for Current Good Clinical Practice (cGCP) and Current Good Laboratory Practice per U.S. FDA 21 CFR Part 58 (cGLP) (www.fda.gov).</p>
LIMS	<p>Laboratory information management system.</p>
EPRI	<p>Electric Power Research Institute (EPRI) (www.epri.com).</p>
CEIDS	<p>Consortium for Electric Infrastructure for a Digital Society (CEIDS) as part of EPRI (www.ceids.com).</p>
DOE	<p>U.S. Department of Energy (U.S. DOE, or DOE) (www.doe.gov).</p>
ROI	<p>Return on investment (ROI) is a general business performance and measurement term relating to the accounting practice of measuring return on sales (ROS) or return on assets (ROA) or a combination of the two as the overall performance of an investment.</p>