

CURRICULUM VITAE

STEPHEN L. GRIMES, FACCE SHIMSS

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US Citizen

EDUCATION

1974 PURDUE UNIVERSITY, West Lafayette, IN
BS Biomedical Engineering (*interdisciplinary*)

PROFESSIONAL EXPERIENCE:

2002 to Present GENTECH, Saratoga Springs, NY
Senior Consultant & Analyst

Providing healthcare technology consulting services in the areas of :

- √ Clinical / biomedical engineering program audits including mission analysis, organization/staffing and productivity
- √ Management including business plan development, strategic planning, vendor management and risk management
- √ Planning including comparative evaluation, TCO analysis, acquisition and integration
- √ Education services related to the effective use and maintenance medical technology systems
- √ Compliance issues including audits, gap analysis & remediation for
 - ▶ HIPAA Security Rule
 - ▶ Quality Assessment and Performance Improvement
 - ▶ JCAHO Environment of Care
- √ Investigation of incidents involving medical technology

1998 to 2002 TECHNOLOGY IN MEDICINE, Holliston, MA
Project Manager, HIPAA Compliance (2000 to July 2002)

- √ Analyzed & interpreted Health Insurance Portability & Accountability Act of 1996 (HIPAA) proposed and final rules (with special emphasis on Security rule and its implications for biomedical devices and systems).
- √ Continuously monitored trends & developments in status of HIPAA ... including issuance of final rules, guidelines, other HHS & Congressional actions, advisory group recommendations & reports, and stakeholder feedback
- √ Assembled and maintained an extensive *e*-library of literature, reference material, programs on HIPAA, *e*-Health and related topics
- √ Attended, contributed and organized HIPAA and *e*-Health related conferences and other forums ... becoming a nationally recognized authority on HIPAA Security and its implications for medical technology
- √ Developed gap analysis tools & compliance guidelines necessary for a client to achieve HIPAA compliance with respect to medical technology. These tools & guidelines are designed to facilitate delivery of Security compliance services to healthcare clients ... services ranging from education, consultation, project management, gap analysis, & planning.

Senior Consultant & Analyst (1999 to July 2002)

- √ Through research and client surveys, conducted analysis of healthcare industry and identified major trends & opportunities for technology management services.
- √ Outlined various business & marketing strategies and scenarios to address major trends (i.e., *e*-Health, HIPAA, integration of medical & information technology services)

Project Manager, Y2K Compliance (1998 – 2000)

- √ Designed overall Y2K compliance plan, software & data collection methodologies, client deliverables
- √ Collected biomedical equipment inventory information from 70 healthcare clients
- √ Identified 10,000 + unique categories of medical devices & systems and continuously updated research on Y2K compliance status of each category
- √ Based on risk represented by non-compliant categories, developed client's plan of action with appropriate priorities and financial impact analyses

1984 to GENTECH, Saratoga Springs, NY

1998 Director of Operations

- √ Developed formal business and marketing plans for startup operation serving as basis for obtaining capital
- √ Directed clinical engineering service operations that provided biomedical device inspection & repair, medical device-related incident investigations, pre-purchase consulting, and training to healthcare facilities in northeastern New York and Vermont. Developed system to performed on-going analysis of delivered services and use results to improve effectiveness of company's services as well as to identify and report client's problem areas
- √ Subsequently expanded service operations to include consulting, training, and technical service on computer systems, peripherals and networks. Became authorized sales and service for Novell (Gold reseller), Microsoft, Compaq, Hewlett Packard as well as other major manufacturers
- √ Designed and authored computer program to manage technology assets, track scheduled & monitor non-scheduled services, provide quality assurance analyses. The software program was used for internal company operations and was also successfully marketed as a commercial product.

1983 TECHNOLOGY IN MEDICINE, Upper Newton Falls MA

Director, Marketing & Sales

Developed marketing program for clinical engineering shared service covering New England states. Successfully established new clients and converted existing clients in multi-year contracts thereby strengthening client relationship and allowing more sales effort to be directed at new business. Broadened sales into new geographic regions and new technology management services.

1980 to INTERNATIONAL SHARED SERVICES, Plymouth Meeting, PA

1982 Manager, NY Operations

Managed clinical engineering services at 40 hospitals across New York. Supervised 3 technical service managers in regional offices with staffs of 25 who conducted testing, inspection and repair of medical devices and systems in clinical areas ranging from special care, operating suite, respiratory therapy, clinical laboratory, physical therapy to medical imaging. Insured that services met client needs while complying with JCAH and relevant state regulations.

1976 to ECRI, Plymouth Meeting, PA

1980 Manager, Clinical Engineering

Played a significant role in the development and management of a shared clinical engineering service that grew from a client base of 3 hospitals in Philadelphia area to 170 hospitals over a four state region. Developed management tools, procedures, reporting formats and established client relationships that facilitated this growth.

Project Manager, Risk Management Services

Developed guidelines to assess and manage identified risks associated with use of medical technology in the hospital environment. Managed program and staff of surveyors to deliver these services to 150 hospitals in New York and Minnesota. Under contract to a major risk management consulting firm, served as principal developer of risk assessment & management guidelines for outpatient health facilities. Guidelines included review of medical/clinical procedures & reporting, staff credentialing, maintenance of physical plant and use of medical technology.

1974 to 1976 BETHESDA HOSPITALS, Cincinnati, OH

1976 Director, Clinical Engineering Services

Designed, developed and implemented first clinical engineering program for two hospitals (combined 650 beds). Assessed organization's technical needs, established budgets, created policies & procedures, specified necessary test equipment & facilities for acquisition, and hired & trained staff. Successfully guided clinical engineering to meet needs of medical technology users as well as addressing JCAH and other regulatory requirements. Developed a manual used by Purdue University's Biomedical Engineering Program as a guideline for education of prospective clinical engineers.

PROFESSIONAL AFFILIATIONS:

- ❑ Member of **American College of Health Care Executives (ACHE)**
- ❑ Member of **Healthcare Information and Management Systems Society (HIMSS)**
 - *Chair, Medical Device Security Workgroup 2004 – Present*
 - *Member, Privacy & Security Steering Committee 2004 – Present*
 - *Awarded Senior Member Status 2005*
- ❑ Member of **American College of Clinical Engineering (ACCE)**
 - *Board Member & Officer (President-Elect 2004 to Present; Vice President 2003-4; Secretary 1992-4)*
 - *Chair, Membership Committee 2001 – 2002*
 - *Awarded Fellow Member Status 2002*
 - *Chair, HIPAA Task Force 2002 – present*
 - *Member, IHE Task Force 2003 – present*
 - *Recipient of 2003 American College of Clinical Engineering's Professional Advocacy Award*
 - *Recipient of 2005 American College of Clinical Engineering's Professional Achievement in Technology Award*
- ❑ Member of the **Association for the Advancement of Medical Instrumentation (AAMI)**
- ❑ **Institute of Electrical and Electronic Engineering's (IEEE) Engineering in Medicine and Biology (EMB) Magazine, Associate Editor (Clinical Engineering)**
- ❑ **Journal of Clinical Engineering, Regular Columnist (Information Technology)**

PUBLICATIONS & PRESENTATIONS:

SCHEDULED as of February 2005

- Grimes, SL "*Healthcare Technology Management.*" Advanced Clinical Engineering Workshop (*Project Leader & Lecturer*). Buenos Aires, Argentina. Fall 2005.
- Grimes, SL "*Developing a Manufacturer Disclosure Statement for Medical Device Security*" CARS 2005 (Computer Assisted Radiology and Surgery) International Congress and Exhibition. Berlin, Germany. June 24, 2005
- Grimes, SL "*Information Security for Medical Technology.*" Association for the Advancement of Medical Instrumentation (AAMI) Annual Conference and Exhibition. Tampa, FL. May 14, 2005.

PAST

- Grimes, SL "*Convergence of Clinical Engineering and Information Technology Services.*" US Department of Health and Human Services (HHS) Indian Health Service Annual Clinical Engineers Conference. Rapid City, SD. March 23, 2005
- Grimes, SL "*Issues on Medical Device Security & HIPAA Compliance.*" US Department of Health and Human Services (HHS) Indian Health Service Annual Clinical Engineers Conference. Rapid City, SD. March 22, 2005
- Grimes, SL "*Future of Clinical Engineering.*" US Department of Health and Human Services (HHS) Indian Health Service Annual Clinical Engineers Conference. Rapid City, SD. March 22, 2005
- Grimes, SL "*New Tools and Initiatives for Addressing Medical Device Security.*" Annual Healthcare Information and Management Systems Society (HIMSS) Conference & Exhibition. Dallas, TX. February 17, 2005.
- Grimes, SL. "*Planning Security Compliance – Including Biomedical Technology.*" HIMSS Audio Conference. December 9, 2004
- Grimes, SL. "*IHE – Key to the Future of the Digital Hospital.*" Journal of Clinical Engineering. October/November 2004. Vol 29 No 4, pp 170-171

- Grimes, SL “*HIPAA Compliance for Biomedical Technology: Meeting the April 2005 Deadline.*” ECRI Audio Conference. November 10, 2004
- Grimes, SL “*Healthcare Technology Management.*” Advanced Clinical Engineering Workshop (*Project Co-Leader & Lecturer*). Prishtinë, Kosovë. October 11-15, 2004
- Grimes, SL “*HIPAA: Real Impacts on Medical Equipment Technology Management*” 11th Annual Virginia Biomedical Association 2004 Meeting. Charlottesville, VA. September 17, 2004.
- Grimes, SL “*Medical Device Security.*” IEEE Engineering in Medicine and Biology Society (EMBS) Annual International Conference. San Francisco, CA. September 5, 2004
- Grimes, SL. “*Security: A New Clinical Engineer Paradigm.*” IEEE Engineering in Medicine and Biology Magazine, July/August 2004, Vol 23, No 4, pp 80-82
- Grimes, SL. “*The Future of Clinical Engineering.*” Clinical Engineering Handbook (Dyro JF, *editor*). Elsevier Academic Press. San Diego, CA. June 2004.
- Grimes, SL. “*HIPAA’s Implications for Clinical Engineering.*” Clinical Engineering Handbook (Dyro JF, *editor*). Elsevier Academic Press. San Diego, CA. June 2004.
- Grimes, SL. “*A Retrospective on Y2K and Clinical Engineering.*” Clinical Engineering Handbook (Dyro JF, *editor*). Elsevier Academic Press. San Diego, CA. June 2004.
- Bauld TJ, Dyro JF, Grimes SL. “*Clinical Engineering and Nursing.*” Clinical Engineering Handbook (Dyro JF, *editor*). Elsevier Academic Press. San Diego, CA. June 2004.
- Grimes, SL. “*Clinical Engineers: Stewards of Healthcare Technologies.*” IEEE Engineering in Medicine and Biology Magazine, May/June 2004, Vol 23, No 3, pp 56-58
- Grimes, SL. “*Medical Device Security – A Change in Perspective.*” Journal of Clinical Engineering. April/June 2004. Vol 29 No 2, pp 54-55.
- *Information Security for Biomedical Technology: A HIPAA Compliance Guide.* ACCE ~ ECRI. Plymouth Meeting, PA. May 2004 (SL Grimes - Author).
- Grimes SL, Rosow E. “*Technology’s Implications for Healthcare Quality.*” Nursing Administration Quarterly. Vol. 27, No. 4, pp. 307–317
- Grimes, SL “*HIPAA’s Final Security Rule.*” ACCE Teleconference. November 20, 2003
- Grimes, SL “*Health Information Security ~ Setting the Agenda.*” National Institute of Standards and Technology (NIST) / URAC / Workgroup for Electronic Data Interchange (WEDI) Conference. Washington, DC. November 17, 2003. (*panel member*)
- Grimes, SL “*Why Clinical Engineering should be concerned with HIPAA.*” Journal of Clinical Engineering. Vol. 28, No. 3, pp. 145-146
- Grimes, SL “*HIPAA’s Implications for Clinical Engineering.*” American Society of Hospital Engineering (ASHE) 40th Annual Conference and Technical Exhibition. San Antonio, TX; July 16, 2003
- Grimes, SL. “*Counting Down Towards Compliance: What is the Final Security Rule’s Impact on Clinical Engineering?*” Association for the Advancement of Medical Instrumentation (AAMI) Annual Conference. Long Beach, CA; June 17, 2003
- Grimes, SL. “*Clinical Engineering in the Next Decade: Can We Adapt?*” American College of Clinical Engineering (ACCE) Annual Symposium. Long Beach, CA; June 14, 2003
- Grimes, SL “*HIPAA Security Rules and Medical Technology.*” ECRI Audio Conference. May 21, 2003
- Grimes, SL. “*The Future of Clinical Engineering: The Challenge of Change.*” IEEE Engineering in Medicine and Biology Magazine, Vol 22, No. 2, pp. 91-99, March/April 2003
- Grimes, SL “*HIPAA & Biomedical Devices/Systems: Is Your Security Back Door Wide Open?*” Annual Healthcare Information and Management Systems Society (HIMSS) Conference & Exhibition. San Diego, CA; February 11, 2003.
- Baretich MF, Dyro JF, Grimes SL, Wear JO. “*Advanced Clinical Engineering Workshop Syllabus.*” American College of Clinical Engineering (ACCE) / World Health Organization (WHO). January 2003 (*co-editor & contributing author*)
- Grimes, SL. “*HIPAA Implementation and Future Challenges.*” Health Industry Group Purchasing Association (HIGPA) International Expo. Orlando, FL, October 17, 2002.
- Grimes, SL. “*Finding & Developing IT Skills.*” Biomedical Instrumentation & Technology. Vol 36, No 6, September/October 2002; pp 62-64
- Grimes, SL “*Healthcare Technology Management.*” World Health Organization (WHO) / Pan American Health Organization’s (PAHO) Advanced Clinical Engineering Workshop (*Lecturer*). Guayaquil, Ecuador. September 9-16, 2002
- Grimes, SL. “*Implications of the HIPAA Security Rule for Biomedical Devices & Systems.*” Emerging Technologies & Healthcare Innovations Congress (ETHIC 2002). Washington, DC; June 21, 2002
- Grimes, SL. “*Strategic Solutions for HIPAA Security.*” Association for the Advancement of Medical Instrumentation (AAMI) Annual Conference. Minneapolis, MN; June 4, 2002

- Grimes, SL. "*HIPAA Implementation: A Case Study.*" Association for the Advancement of Medical Instrumentation (AAMI) Annual Conference. Minneapolis, MN; June 4, 2002
- Grimes, SL. "*Security of Data Transmitted or Stored by Biomedical Systems.*" American College of Clinical Engineering (ACCE) Annual Symposium. Minneapolis, MN; June 1, 2002
- Grimes, SL. "*Critical HIPAA Issues from the Hospital Perspective.*" CIO Forum & Executive IT Summit. Philadelphia, PA; May 15, 2002
- Grimes, SL. "*HIPAA Update.*" Annual HealthTech Conference. Baltimore, MD; April 23, 2002
- Grimes, SL. "*HIPAA Regulations.*" Short Course at Northeastern Biomedical Symposium. Sturbridge, MA; November 5th 2001
- Grimes, SL. "*HIPAA Security: Impact on Biomedical Systems.*" HIPAA Summit West. San Francisco, CA; June 22, 2001
- Grimes, SL. "*When HIPAA finally comes, will Clinical Engineering be ready?*" American College of Clinical Engineering Annual Symposium. Baltimore, MD; June 5, 2001 (*symposium co-chair & presenter*)
- Grimes SL. "*When HIPAA finally comes, will Clinical Engineering be ready?*" Biomedical Instrumentation & Technology. 2001; Vol 35, No 2, pp 121-125
- Grimes, SL. "*HIPAA's Impact on Clinical Engineering.*" American College of Clinical Engineering (ACCE) Teleconference Series. May 17, 2001
- Grimes, SL. "*HIPAA.*" New England Society of Clinical Engineering. Wallingford, CT; April 26, 2001
- Grimes, SL. "*Clinical Engineering's Role in HIPAA Regulations.*" University of Connecticut, School of Engineering Graduate Seminar. Storrs, CT; January 29, 2001
- Grimes SL. "*Assessing Y2K Readiness for Medical Devices & Systems.*" New England Society of Clinical Engineering Annual Symposium on Health Care Technology. Albany, NY; November 1998
- Bourke M, Grimes SL. "*Networks*" Redmond, WA. SpaceLabs Medical; 1995
- Grimes SL. "*Financial Model of Clinical Engineering.*" Advanced Clinical Engineering Workshop co-sponsored by Pan-American Health Organization, World Health Organization and American College of Clinical Engineering, Washington, DC; May 1991
- Grimes SL. "*Clinical Engineering,*" New England Society of Clinical Engineering Annual Symposium on Health Care Technology, Albany, NY; November 1990
- Grimes SL. "*Selecting an Effective Equipment Management System.*" New England Society of Clinical Engineering Annual Symposium on Health Care Technology. Springfield, MA; November 1989
- Grimes SL, Painter FP. "*Effective Marketing for Clinical Engineering Managers.*" Association for the Advancement of Medical Instrumentation (AAMI) Annual Meeting. Washington, DC; May 1988
- Grimes SL, Painter FP. "*Marketing Clinical Engineering Services.*" Association for the Advancement of Medical Instrumentation (AAMI) Annual Meeting. Chicago, IL; May 1986
- Grimes SL, Painter FP. "*Marketing Clinical Engineering Services.*" Association for the Advancement of Medical Instrumentation (AAMI) Annual Meeting, Boston, MA, May, 1985