John W. Jaeckle

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AREAS OF INTEREST

- Influencing and leading global medical device safety and performance standards.
- Strategic medical device regulatory affairs – working alongside global regulators.
- Scientific, robust data (clinical and engineering) for regulator equivalence determination and claims substantiation.
- CT, XR rad and fluoroscopic, and Nuclear Medicine dose, dose optimization, and image quality.
- Risk Assessment / Risk Management

EXPERIENCE:

March 2015 to Present
Chief Regulatory Affairs Engineer / Strategist, Imaging
November 2011to March 2015
Chief Regulatory Affairs Strategist, Healthcare Systems
June 2006 to November 2011
Regulatory Affairs Manager, MI&CT
January 2000 to June 2006
Lead CT Safety & Regulatory Engineer
GE Healthcare, Waukesha WI

Regulatory Affairs Management/Guidance

Responsibility for direction of global regulatory affairs leaders and engineering in CT, PET, NM, XR-Surgery-Interventional-Rad, MR, Workstations. Partner with business leaders for strategic regulatory planning and execution. Drive scientifically substantiated, claim-rich submissions and accurate risk assessments and reporting decisions. Review and approval of pre- and post-market activities. Influence and lead development of international and US standards and regulation with industry, professional societies, and regulators.

Subject matter expert that has lead numerous workshops for developing appropriate regulatory and standards guidelines for development and market access of medical imaging products across numerous regulatory jurisdictions including but not limited to United States, China, European Union, and Japan.

New Product Approvals – United States

Responsible for numerous 510(k) submissions for X-Ray producing, PET, NM, and MR systems, and advanced applications software products. Experienced with 510(k) submissions especially those requiring advanced engineering evaluation and data clinical in a changing FDA and global clearance environment. Expert in 21CFR Subchapter J and IEC testing and compliance. Expert in submission content for pediatrics.

New Product – Science-based Evidence Generation.

Lead new product teams in determining optimized, rigorous scientific data for inclusion in global regulatory approves. Determine best balance of clinical and engineering data for efficient regulatory approvals and claim substantiation without re-work.

- Expertise in leveraging novel and robust engineering evaluation, published literature, and "in-house clinical" evaluation to reduce or eliminate the need for clinical trials/evaluations. Amplify the ability to know ground truth and better quantitation when using well-designed engineering testing.
- Experienced in leading clinical study design and optimized subject selection attributes based on the factors that influence the performance of new features, thus minimizing study size and ensuring acceptance of global regulators.
- Lead development of evaluations for the performance of devices that utilize AI.

New Product – Device Investigations

Responsible for 21CFR812 (investigational device) compliance of pre-clearance external evaluations of devices: determination of non-significant risk, IRB approval, informed consent, labeling, monitoring, sponsor responsibilities, etc.

Standards / Industry Issues

Expert and leader in current initiatives for reducing imaging ionizing radiation, especially CT dose and dose optimization methods. Chair of two IEC working groups developing and updating all international CT standards to keep pace with latest technologies, applications, and dose focus. Chair/Co-Chair of MITA's CT group. Member of AAPM's Alliance for Quality Computed Tomography working group. Extensive expertise in 21CFR Subchapter J X-ray performance standards.

New Product Design / Safety

Provide radiation, mechanical, and electrical safety and regulatory design requirements for new products, perform design reviews, and provide safety and regulatory analysis and compliance plans. Assure compliance and certification with US and international standards. Perform product safety and performance testing in conjunction with NRTLs and international evaluators. Develop and implement risk management for new product programs.

Regulatory Audits

Prepare and interface with global regulators during audits including FDA, EU Notified Body, China NMPA, and Japan MHLW. Multiple direct FDA QSIT and Subchapter J audit "front room" and "backroom" leadership positions at global GEHC facilities. Represent GE as 21CFR Subchapter J, radiation safety,and dose expert.

Post Market Complaint Handling and Medical Device Reporting

Evaluate, perform risk analysis, and determine appropriate actions for safety and regulatory related product complaints. Perform Medical Device and 21CFR Subchapter J Reporting and evaluation for global products. Ensure adequate preventative and corrective action is performed. Perform correction and removal evaluation for field actions

New Product Approvals – International

Responsible for obtaining global regulatory approvals. Experienced and knowledgeable in global approval criteria and processes including EU CE marking, China NMPA, Japan MHLW, Health Canada, Taiwan DoH, Korea KFDA, ANZ TGA.

Marketing Material Review

Review and approve advertising and promotional material. Provide interactive solution-based reviews to maintain both compliance and marketing effectiveness.

December 1997 to January 2000
Integrated Production Team - Team Leader,
Wisconsin Electric Power Company, Milwaukee, Wisconsin

Responsible for the safe, efficient, environmentally compliant, and cost-effective operation of a five-unit fossil plant. Supervised a diverse workforce. Performed employee performance reviews, coaching, development, and training. Determined and implemented staffing and scheduling. Worked with system control and market planners to enhance economic dispatch of Port Washington Power Plant.

April 1992 to December 1997
Sr. Nuclear Engineer, Wisconsin Electric Power Company
Nuclear Safety Analysis Group / Continuous Safety and Performance Assessment Group
Milwaukee, Wisconsin

Safety and Performance Assessment

Lead and participated on assessment teams providing integrated assessments for a variety of projects including low-pressure turbine replacement, steam generator replacement, and dry fuel storage.

Point Beach Uprating:

Lead a team to develop and document the feasibility and subsequent implementation of uprating the Point Beach Units from 1518 MW_{th} to 1650 MW_{th}. Was the project overall technical lead and project co-manager, integrated analysis and evaluation of all major reactor, plant and transmission systems and components. Developed the project plan, cost, schedule, financial analysis, and regulatory (state and federal) strategy for the project.

Safety/Licensing/Regulatory Analysis and Evaluation:

Performed a wide variety of nuclear safety, thermodynamic, and NRC licensing evaluations and safety system performance calculations for Point Beach including installation of a dry fuel storage system. Was the lead on numerous regulatory/licensing issues and interfaced with the NRC. Performed outage planning, scheduling, and safety reviews. Developed Shutdown Emergency Procedures. Performed project management for a variety of technical projects.

Duty Technical Advisor:

Served as a Duty Technical Advisor for Point Beach. Received SRO-based operations training and provided consul to the shift superintendent during off normal and emergency situations. NRC certified ability to make critical decisions in high-stress nuclear power accident environment.

August 1990 to March 1992
Nuclear Engineer, Westinghouse Electric Corporation
Commercial Nuclear Fuel Division
Monroeville, Pennsylvania

PWR Core Design and Analysis:

Performed reactor core reload and thermodynamic design, nuclear safety, and licensing/regulatory analysis. Included three-dimensional neutron modeling, enrichment setting, loading pattern determination, evaluation of neutronic safety parameters and reload safety analysis, licensing, and authoring of Nuclear Design reports.

October 1987 to July 1990
Research and Development Engineer, Battelle - Pacific Northwest National Laboratory
Nuclear Systems and Concepts Department
Richland, Washington

New Production Reactor Design:

Performed physics, hydraulic, regulatory, and financial analysis for several proposed light and enhanced heavy water new production reactors. Included fuel, target, and control design. Developed explicit two and three-dimensional integral transport theory, diffusion, and monte-carlo neutronic models and analysis. Worked with Department of Energy and NRC on regulatory and licensing issues for the various NPR proposals. Held a DOE “Q” security clearance.

Thermal Hydraulic Analysis

Performed single and two-phase thermal hydraulic modeling, design, and analysis for light water and enhanced heavy water new production reactors and enhanced liquid metal reactors.

Tritium Distribution Modeling

Wrote and developed the “TDM” computer program for the time dependent transport, concentration, and environmental releases of tritium or other soluble fission products in a PWR throughout the plant's operating life.

June 1986 to August 1987
Teaching Assistant – Nuclear Engineering Department
University of Wisconsin, Madison, Wisconsin

Assisted in the teaching and student mentoring of undergraduate and graduate level courses in Nuclear Reactor Engineering and Power Plant Technology.

PROFESSIONAL AFFILIATIONS:

Convenor of IEC MT-30. This Maintenance Team has the responsibility for authoring and updating all IEC CT standards including IEC 60601-2-44 for CT safety, and IEC 61223-3-5 / 61223-2-6 for CT Acceptance and Consistency Testing.

Convenor of IEC PT62985. This Project Team developed a new standard for implementation of Size Specific Dose Estimates on CT systems.

Chair/Co-Chair of MITA's CT Group. This group focuses on current issues in the CT industry such as CT dose, user group activities, and new regulatory initiatives. The group provides one industry voice to regulators and others in the CT community and works closely with FDA, AAPM, ARC, ASRT, and other global industry groups such as COCIR and JIRA. Lead the creation and development of NEMA XR-25, XR-26, XR-28, and XR-29 standards. Also lead MITA's CT IQ/Dose task force working with FDA to develop advanced phantom and testing methods for CT image quality and dose performance evaluation.

AAPM Alliance for Quality Computed Tomography working group. This group has membership from AAPM, ACR, ASRT, FDA, and an invited person from each manufacture. Group developed and posts dose-appropriate reference protocols, creates user training materials, and reference notification values for Dose Check. It also works with FDA to help review new NEMA CT standards.

United States Access Board Advisory Committee leader. Lead the diagnostic imaging portion and created standards for access to diagnostic images devices by citizens who are mobility impaired.

EDUCATION:

UNIVERSITY OF WISCONSIN - MADISON, Madison, Wisconsin
M.S. Nuclear Engineering and Engineering Physics – 1987
Concentration in thermodynamics, heat transfer, neutronics.
Institute of Nuclear Power Operations Fellowship

UNIVERSITY OF WISCONSIN - MADISON, Madison, Wisconsin
B.S. Nuclear Engineering – 1986
Concentration in reactor physics, thermodynamics, and power plant technology.

Wauwatosa East High School, Wauwatosa, Wisconsin – 1981, Valedictorian, class of ~400.

PUBLICATIONS:

Gesh C. J., Jaeckle J. W., Jenquin U. P., Love E. F., Pauley K. A., Prichard, A. W., Schmitt B. E.; *"FY90 WNP-1 Reference Core Design Document for the Light Water New Production Reactor"*; PNL-7552, Pacific Northwest Laboratory, Richland, Washington, 1991.

Jaeckle J. W.; *"Tritium Distribution Modeling in a Light Water New Production Reactor"*; PNL-6877/UC-731, Pacific Northwest Laboratory, Richland, Washington, 1989.

Bickford W. E., Jaeckle J. W., Webb B. J.; *"Enhanced LMR Core Cooling Utilizing Passive Vortex Devices"*; PNL-SA 15314, Pacific Northwest Laboratory, Richland, Washington, 1988.

Jaeckle J. W.; *"The Moving Capacitance Approximation for Transient, One-Dimensional, High Biot Number Heat Conduction Problems"*; Master's Thesis, University of Wisconsin, Department of Nuclear Engineering and Engineering Physics, Madison, Wisconsin, 1987.