

Lisa Cole Dimmick

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Work Experience:

U.S Nuclear Regulatory Commission

Two White Flint North, 11545 Rockville Pike

North Bethesda, MD 20852 United States

Team Leader, Medical Radiation Safety Team

03/2009 – Present

Supervisor: Doug Bollock (301-415-6609)

Series: 1301 **Pay Plan:** GG **Grade:** 15

Hours per week: 40

Duties, Accomplishments and Related Skills:

Medical Safety and Events Assessment Branch, Team Leader: May 2017—present:

Assign, coordinate, and monitor regulatory activities in the areas of radiation protection, technical assistance, and safety evaluation associated with the implementation of 10 CFR Part 35, Medical Use of Byproduct Material. Perform reviews of medical events, medical consultant reports, and proposed responses to Part 35 regulatory implementation issues; prepare requests for additional information, safety evaluation reports, and other medical licensing actions; perform concurrence reviews of documents generated by the Medical Radiation Team staff; provide technical and programmatic leadership during interactions with the Advisory Committee on the Medical Uses of Isotopes (ACMUI); provide and coordinate technical assistance to the NRC regional staff; perform assessment and analyses of medical events to identify generic issues; and provide technical information regarding to inquiries from members of the public, the regulated community, professional societies, and Agreement States. Interact with ACMUI on various technical and policy issues with the purpose of achieving an effective implementation of Part 35 in the Agreement States. Coordinate the development and maintenance of medical licensing guidance on NRC's website. Serve as medical consultant coordinator for the Division of Material, State, Tribal and Rulemaking Programs.

Agreement State Program Branch, Senior Health Physicist: March 2011—April 2017:

Coordinated all aspects of the agency's Integrated Materials Performance Evaluation Program (IMPEP). Provided IMPEP training to team leaders and team members. Conducted IMPEP reviews as team leader. Briefed management on IMPEP and Agreement State issues. Prepared the annual report to the

Commission on the status of Agreement State material program performance. Conduct trend analysis of materials programs performance. Served as Co-Chair on NRC /Agreement State working group updating the policy statement on “Principles and Policy of Agreement State Programs” and associated guidance documents. Served as Co-Chair on NRC /Agreement State working group for developing recommendations for performance-based compatibility and revise IMPEP metrics. Supported oversight of those Agreement State programs on Monitoring, Heightened Oversight, and Probation. Supported the Agreement State Program Branch improvement initiatives as requested by management.

Licensing Branch, Health Physicist: March 2009—February 2011:

Coordinated, developed, and maintained licensing guidance documents (NUREG 1556 series). Provided and coordinated technical assistance to NRC regional staff and Agreement States. Performed reviews and coordinated responses to exempt distribution implementation issues. Provided technical information regarding exempt distribution inquiries from members of the public, Agreement States, and internal stakeholders. Supported technical assistance requests for issues related to commercial and academic uses of radioactive materials. Prepared and concurred on correspondences for internal and external communications. Served as the technical contact for irradiated gemstones. Prepared and provided weekly reports to branch chief on activities related to licensing policy and guidance.

Nucletron Corporation

8671 Robert Fulton Drive
Columbia, MD 21046 United States

Regulatory Affairs and Quality Assurance, RSO

05/2001 - 02/2009

Hours per week: 45

Duties, Accomplishments and Related Skills:

Quality Assurance

Served as the Quality Assurance Manager. Directed the company’s QA program for compliance with FDA regulations (21CFR Part 820) and conformity to ISO standards (9000, 9001, and 13485). Planned and performed internal (activity and process) and supplier audits. Reviewed and developed standard operating procedures and process maps used throughout organization. Coordinated management reviews and recommended corrective and preventive actions and controls to Executive Management.

Safety

Served as the Corporate Safety Officer and Radiation Safety Officer. Directed the radiation safety program including personnel dosimetry, maintenance and calibration of radiation monitoring equipment, radiation safety training, source procurement schedules, ALARA program, hazmat shipping, and radiation safety protection practices. Prepared domestic and international radioactive materials license applications, renewals, and amendments. Provided regulatory responses, regulatory interpretation, and regulatory correspondence. Assisted clients with preparing radioactive materials licenses. Oversaw the OSHA program. Conducted self-checks of the Radiation Safety and Occupational Safety Programs.

Regulatory

Oversaw and submit medical device pre-market notification applications to the US FDA (i.e. 510(k) submissions). Prepared and submit medical device license applications to Health Canada. Prepared and submitted Sealed Source and Device Registry applications to the State of Maryland and the Canadian Nuclear Safety Commission. Assisted the company's Latin American agents with medical device registrations in countries throughout South America. Maintained device and establishment listings, registrations, product reports for the FDA and Health Canada. Oversaw medical device reporting and prepare required reports. Monitored organizational Promotion/Advertising activities for FDA and Health Canada compliance. Directed the HIPAA compliance program. Served as the company's Privacy and Security Officer Oversaw HIPAA contracts. Corresponded with regulatory agencies as needed. Consulted with physicists and physicians as requested. Served as the official correspondent/US agent for foreign medical device manufacturers.

Administration

Oversaw consultant contracts. Oversaw business partner policy and vendor program requirements. Instructed staff on standard operating procedures. Provided employee training such topics as, but not limited to, ISO, GMP, Occupational Safety, HIPAA, Advertising & Promotion, Radiation Safety & Protection, Hazardous Materials Shipping, and Ethics. Provided customers with Radiation Safety Officer training for afterloaders. Consulted internally on product training course development.

Krueger-Gilbert Health Physics

3601 East Joppa Road
Baltimore, MD 21234 United States

Health Physicist

03/1992 - 04/2001

Hours per week: 50

Duties, Accomplishments and Related Skills:

Reviewed and coordinated radiation safety programs for radioactive materials licenses. Prepared NRC/State license applications, renewals, and amendments. Provided regulatory responses and regulatory interpretation. Developed radiation safety training in-service programs and materials. Conducted radiation safety training lectures (up to 50 persons/session) with subject matter addressing radiation safety and protection, radiation physics, radiation biology, instrumentation, NRC/State regulations, and DOT shipping requirements. Performed instrument calibrations (gamma cameras, dose calibrators, survey meters, and well/uptake probe detectors). Performed radiation safety audits for nuclear medicine and brachytherapy programs. Conducted sealed source leak testing and inventories. Determined ventilation requirements for the use of Xenon-133 in Nuclear Medicine Departments. Prepared X-ray room shielding and design recommendations for diagnostic x-ray machine, CT, cath/angio, mammography and PET installations. Inspected X-ray machines for federal/state compliance standards. Performed machine/image quality assurance surveys in mammography and computerized tomography. Provided film processing analysis. Monitored occupational exposure. Computed and monitored patient exposures from diagnostic x-ray, mammography, and CT exams. Evaluated exposure from environmental/area monitoring. Reviewed policy and procedure manuals. Developed radiation safety procedures and protocols. Supervised and trained staff Health Physicists.

Union Memorial

201 E. University Parkway
Baltimore, MD 21218 United States

Nuclear Medicine Technologist

08/1989 - 02/1992

Hours per week: 45

Duties, Accomplishments and Related Skills:

Performed SPECT and planar imaging. Prepared and administered radiopharmaceuticals. Participated in clinical research. The clinical research resulted in one publication on reflex sympathetic dystrophy and two exhibits concerning wrist pain and reflex sympathetic dystrophy, respectively. Performed instrument and radiopharmaceutical quality control procedures. Responsible for the logging, shipping, disposal of the hospital's radioactive waste. Monitored staff infection control performance.

Education:

Hood College Frederick, MD
Technical or Occupational Certificate 12/2008

Major: Regulatory Affairs

Georgetown University Washington, DC
Master's Degree 12/2003

Major: Health Physics

Johns Hopkins University Baltimore, MD
Master's Degree 05/1993

Major: Administrative Sciences

Old Dominion University Norfolk, VA
Bachelor's Degree 05/1989

Major: Nuclear Medicine Technology

Old Dominion University Norfolk, VA
Bachelor's Degree 12/1987

Major: Biology

Affiliations:

Health Physics Society - Member

Professional Publications:

1. "Estimation of Radiation Dose Received During Treatment of In-Stent Restenosis Using Ionizing Radiation," L.C. Dimmick, B. Bass, R. Waksman MD, M. Moscovitch PhD, Cardiovascular Revascularization, June, 2005
2. "Reflex Sympathetic Dystrophy in the Foot: Clinical and Scintigraphic Criteria," L.E. Holder MD, L.A. Cole, BS, M.S. Myerson, MD, Journal of Radiology, August, 1992.
3. Exhibit: "Evaluation of Wrist Pain through Three Phase Radionuclide Bone Imaging," P.A. Sheehan, L.A. Cole, L.E. Holder MD, June 1992.
4. Exhibit: "Reflex Sympathetic Dystrophy in the Foot: Clinical and Scintigraphic Criteria," L.A. Cole BS, L.E. Holder MD, M.S. Myerson MD, June, 1991.

Additional Information:

NRC: Performance award 2009, 2010, 2011, 2012, 2013, 2014, 2015; Special Act Group Award 2011, 2014; Special Act Award 2015; Certification of Appreciation Fukushima 2011, and Lapse in Appropriations 2013.

Nucletron: Developed and implemented the corporate OSHA Program. Developed and implemented the corporate HIPAA Privacy and Security Programs. Successfully upgraded the corporate ISO certification from the ISO 9000:1994 standard to ISO 9001:2000. Successfully achieved the ISO 13485:2003 standard certification. Developed corporate vendor and business policy program. Updated the corporate Ethics Program.