Spring Meeting, March 8, 2005

OSL, Optically Stimulated Luminescence Technology in Personnel Dosimetry and other Medical Applications

Guest Speaker: Inid Deneau

Aluminum oxide detector and optically stimulated luminescence technology for personnel monitoring offers many benefits and features over the current use of film and TLD. Both low and high energy photons along with betas can easily be detected with OSL; however, with recent new techniques, fast and thermal neutron energies can also be measured. Depending on the aluminum oxide material engineering, the OSL technology can be used in several dose measurement applications in medical dosimetry.

Inid Deneau is a radiation health physicist graduate of Purdue University who is currently the Director of Marketing for Landauer, Inc. The combination of a technical background with the marketing aspect affords the opportunity to understand the needs of customers and their requirements in radiation personnel monitoring. Prior to Landauer, Inc., Ms. Deneau was the RSO for Siemens Medical Systems, Nuclear Division along with the technical support responsibilities for the Siemens Dosimetry business unit. Experiences also include health physicist for Indiana University Medical Center involving support to the teaching institution’s departments of nuclear medicine, radiation therapy and research laboratories.

Treasury Dip Stick

Once again it is time to pay Chapter dues of $10 a year. Some people paid at the last meeting, so our paid membership is approximately at the 25% level. The paid affiliate membership is at 0%. Our income/spending Index level is at –15% so far this year (6 weeks of spending); therefore, your Treasurer requests your help eliminating our current deficit (and maybe creating a positive cash flow).

You can pay your dues at our March 8, 2005 Dinner Meeting or you can send your dues by mail to our NEW ADDRESS, Midwest Chapter Health Physics Society, PO Box 513, Westmont, IL 60559. Make your check payable to Midwest Chapter HPS.

I hope to see a lot of you (and guests are also welcome) at the March 8 Dinner Meeting.

Walt DeLise, Treasurer
Escalated Enforcement Actions
Two Medical Events
Submitted By: Darrel Wiedeman

NRC recently has taken escalated enforcement action against two hospitals as described below.

In the first case, several violations of NRC requirements were identified during an NRC inspection at a hospital. An Enforcement Conference was conducted with the licensee to discuss the violations. Subsequent to that conference and as a result of an investigation conducted by the NRC’s Office of Investigations, NRC established that four diagnostic misadministrations (now called “medical events”) had occurred before the NRC’s inspection and were not reported to the NRC. Two hospital employees stated to NRC investigators that the Radiation Safety Officer (RSO), who also was the Director of the Nuclear Medicine Department, instructed them to inform NRC inspectors that diagnostic misadministrations had not occurred. It also appeared that the RSO willfully concealed a film of a nuclear medicine misadministration scan and thus impeded NRC’s inspection into whether misadministrations had occurred. As a result, the NRC issued an Order to the hospital (1) to remove the RSO from that position and from all involvement in the performance or supervision of NRC-licensed nuclear medicine activities, and (2) to suspend all licensed activities at the hospital until the licensee demonstrates that a qualified individual has been appointed as the RSO and authorized by the NRC.

In the second case, an alleger stated that the Chief Nuclear Medicine Technologist (CNMT) of a hospital did not report a misadministration to either the NRC or the patient’s referring physician. During an interview conducted by the NRC’s Office of Investigations, the CNMT admitted performing a diagnostic misadministration and not being truthful with NRC inspectors. The CNMT explained that the hospital RSO, who is also the Medical Director of Radiology, instructed her via a hospital radiologist not to report the misadministration. During an interview with an NRC investigator, the RSO admitted that although he was aware of the NRC requirement, he did not report the misadministration because he did not think the incident was that serious. As a result, the NRC issued an Order to show cause why the license should not be modified to prohibit these individuals from any further involvement in the performance or supervision of licensed activities. Consideration was given to removing the CNMT from NRC-licensed activities by an immediately effective Order. However, this was not considered necessary because the CNMT had already left the hospital. In addition, although the violations occurred because of the deliberate, irresponsible actions of the two individuals, the NRC was concerned that hospital management did not aggressively pursue an investigation of the alleged misadministration when informed of it during the NRC inspection, but rather awaited the initiation of the NRC investigation. Thus, the NRC issued a proposed Imposition of a Civil Penalty in the amount of five thousand dollars ($5000).

FDA Proposes Draft Guidance on Medical Products to Treat Radiation Contamination
FDA Press Release P05-06
February 14, 2005

The Food and Drug Administration (FDA) today published a draft guidance document entitled "Guidance for Industry: Internal Radioactive Contamination—Development of Decorporation Agents" to help ensure that medical products called decorporation agents -- drugs that help eliminate radioactive materials from the body -- will be available

(Continued on page 4)

MESSAGE FROM OUR PRESIDENT

A lot has happened since the last newsletter. For everyone who could not make the last meeting, we have a new President-Elect, Eli Port, CHP. I would like to personally thank him for agreeing to do this and ask that you give him your support and help. Once again I would like to thank Joe Drago, who has done a great job of getting speakers for our meetings. We are coming to our second of three meetings; our third will be in late May. I would like to have a good showing at this meeting and ask that all members who will be attending ask a fellow worker to join us. Hopefully some of the our guests will enjoy the meeting enough to join.

Thanks,
Lee Sprouse, Jr.
Spring Meeting
Featured Speaker: Inid Deneau, Landauer

DATE: Tuesday, March 8, 2005

LOCATION: Greek Islands Restaurant
300 East 22nd Street
Lombard, IL 60148
630-932-4545

COST: $26.00 per person, guests are welcome.

RESERVATIONS: Please join us for the March Meeting featuring a presentation by Ms. Inid Deneau, Director of Marketing for Landauer. Phone or e-mail your reservations to Joe Drago, our Program Chairman. Joe’s e-mail address is joseph.drago@ch.doe.gov, and his phone number is 630-252-2673. Please contact Joe Drago with your reservation by noon Friday, March 4, 2005.

Menu
Family Style

Starters: Saganaki & Taramosalata
Salad: Greek Salad
Appetizer: Gyros (Flavorful beef and lamb slices)
Entrees: Chicken Riganati, Pastichio Dolmades, Meatballs
Side Dish: Rice pilaf & potato
Dessert: Baklava, galaktoburiko & karidopita
Beverages: Coffee/Soft Drinks

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to protect U.S. citizens from radiation contamination. The guidance provides advice on what studies sponsors need to perform to evaluate new decorporation agents in the hopes of getting these products approved by the FDA.

Decorporation agents reduce health risks by increasing the rate of elimination or excretion of radioactive contaminants that have been absorbed, inhaled or ingested.

"The guidance we are publishing today represents yet another step by the FDA to make medical countermeasures available to counteract potential acts of terrorism," said Acting FDA Commissioner Dr. Lester M. Crawford. "Protecting Americans from attacks is a fundamental part of FDA's public health mission."

The draft document provides guidance to industry on the development of those decorporation agents for which evidence is needed to demonstrate effectiveness but for which human efficacy studies are unethical or not feasible.

FDA convened a multidisciplinary group of scientists to discuss how provisions under the Animal Efficacy Rule, which took effect in 2002, could be used to facilitate development of new decorporation agents. This rule applies when adequate and well-controlled clinical studies in humans cannot be ethically conducted because the studies would involve administering a potentially lethal or permanently disabling toxic substance or organism to healthy human volunteers. It is a major part of FDA's effort to help make medical countermeasures available and thereby help improve the nation's ability to respond to emergencies, including terrorist events.

Other examples of approved decorporation agents are Prussian blue, potassium iodide (KI), Ca-DTPA and Zn-DTPA. These drugs, when manufactured under conditions specified in an approved NDA, have been found safe and effective for the treatment of internal contamination with radioactive cesium (Prussian Blue), iodine (KI), and plutonium, americium, or curium(Ca-DTPA and Zn-DTPA).

Written comments on the draft guidance may be submitted up to 60 days from the date it is published in the Federal Register. Comments should be sent to FDA's Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, Md. 20852.

NOTE: The guidance document can be found at http://www.fda.gov/cder/guidance/6394dft.pdf