Data Show Clinical Health Care Industry Representatives Face Higher Than Expected Radiation Dose, Require Monitoring

A position paper from LANDAUER, a National Voluntary Laboratory Accreditation Program approved organization, with data analysis from Chris Passmore, MS, CHP, Vice President of Dosimetry Services and Mirela Kirr, MS, Director Technical Services

Summary

Health care industry representatives (HCIRs) can be described as vendor employees who provide technical support and training for new products and procedures. Clinical HCIRs are frequently in hospital patient care areas, such as the operating room and catheterization lab.

Hospital leadership may need to take note of HCIR exposure to ionizing radiation as well as the health, safety and regulatory risks of not monitoring this population (particularly for clinical HCIRs entering the interventional radiology suite or the operating room). As this research suggests, hospitals should have a policy in place to assure that clinical HCIRs who may be exposed to ionizing radiation be monitored and that the data be maintained in a centralized database. In effect, HCIRs should adhere to the same level of radiation monitoring standards as hospital employees.

An estimated 120,000 people in the United States are clinical HCIRs who are exposed to radiation through their work in hospitals and elsewhere. With an increasing number of medical procedures using a higher dose of ionizing radiation for clinical care, it was presumed that clinical HCIRs may be exposed to more radiation than expected. LANDAUER is a leader in occupational radiation monitoring and keeps National Voluntary Laboratory Accreditation Program (NVLAP) accredited dosimetry results. LANDAUER researchers recently investigated this hypothesis. The data review suggests that clinical HCIRs working in U.S. hospitals may be exposed to more ionizing radiation than the required monitoring threshold as codified in the Nuclear Regulatory Commission (NRC) Title 10 CFR Part 20.

Study Method

A review of the LANDAUER radiation monitoring data program spanning three consecutive years was conducted to assess the amount of ionizing radiation received by regularly monitoring participants identified as HCIRs. LANDAUER occupational radiation exposure data were studied to determine the percentage of the monitoring population receiving a measurable dose and trends in whole body monitoring. Analysis of observed trends in dose data can reveal opportunities to improve radiological protection and highlight industry trends.

The analysis of the data falls into the following indicators:

— Number of monitored workers

— Number of dosimeters analyzed

— Dose distributions

What is a Health Care Industry Representative?

HCIRs are vendor employees who provide technical support and training for new products and procedures. Many of these individuals are in settings where they may be exposed to ionizing radiation. Clinical HCIRs are not typically included in most hospital radiation protection policies to support the requirement that all workers be held responsible for ensuring they do not exceed thresholds that could put their health and safety at risk.

Which HCIRs are Typically Exposed to High Levels of Ionizing Radiation?

— Clinical/medical device company representatives who visit the catheterization lab, interventional radiology, operating room or other areas with high exposure of ionizing radiation

— Those who work directly with a physician/clinician during a procedure

— Field-based technicians who service the equipment

— Individuals who are working with radiopharmaceuticals and radiation sources

While hospitals assure the monitoring of many groups in their facilities, HCIRs are not typically included in most hospital radiation protection policies. Those policies support requirements that all workers – while at that facility – be held responsible for ensuring they do not exceed thresholds that could put their health and safety at risk.

Effects of Chronic Radiation Exposure

The Environmental Protection Agency defines chronic exposure as the continuous or intermittent exposure to radiation over a long period of time. With chronic exposure there is often a delay between the exposure and the observed health effect. These effects can include cancer and other health outcomes such as benign tumors, cataracts and potentially harmful genetic changes.[1]

Regulatory Context

Study leaders recognized that organizations may have varying requirements that govern monitoring practices that may be more restrictive than the NRC or individual state regulations. For purposes of this paper, 10 CFR Part 20 and associated NRC Regulatory Guides (8.34 and 8.7) were primarily used when determining monitoring requirements.

It is important to understand the regulations that govern the standards for protecting against radiation. A close look at 10 CFR Part 20 reveals the following:

— Minimally, each licensee shall monitor occupational exposure to radiation for:

- Adults who may receive a dose in excess of 10% of the deep dose equivalent (DDE) limits, which is 500 mrem (5 mSv) annually
- Declared pregnant workers likely to receive a DDE during the gestation period:
  - In excess of 500 mrem (5 mSv)
  - In excess of 50 mrem/month (0.5 mSv/month)
- Individuals entering an area posted as high or very high radiation area, i.e., a health care worker operating a linear accelerator or sources used for therapeutic purposes

— Each licensee shall maintain records of doses received:

- NRC Regulatory Guide 8.7 further explains the instructions for the recording and reporting of occupational radiation dose data as outlined in 10 CFR Part 20. With regard to record keeping, the licensee is required to determine the total occupational dose in the current monitoring year for all persons who require monitoring. This is generally known as “previous history” and requires the licensee to obtain an up-to-date status of the worker’s cumulative total dose received from all employments in the current year and compare against the annual exposure limits prior to allowing the worker to perform work for the license.

Other common practices that are required by some state regulations include:

— Consulting physicists/clinicians and representatives who work in proximity to radiation-producing equipment

— Workers handling radiation material

A summary of additional pertinent accrediting body regulations can be found in Table 1.

Table 1: Summary of Additional Relevant Regulations

Accrediting Body Regulation	Brief Summary
Centers for Medicare and Medicaid Services (CMS): CMS 482.26(b)(3)	Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure. This requirement applies to radiology personnel, as well as other hospital employees who may be regularly exposed to radiation due to working near radiation sources. The personnel should be knowledgeable about radiation exposure for month, year, and cumulative/entire working life.
The Joint Commission (TJC): Standard EC.02.02.01	The results of staff dosimetry monitoring are reviewed at least quarterly by the radiation safety officer, diagnostic medical physicist, or health physicist to assess whether staff radiation exposure levels are "As Low As Reasonably Achievable" (ALARA) and below regulatory limits.

Data Analysis

To assess the magnitude of the exposure, a review of the LANDAUER occupational dose results and associated data was conducted. This study looked at a random sample of 17,000 participants known to be HCIRs. The total data set equated to 51,000 results over a consecutive three-year period.

By way of background, the monitoring and analysis program works by issuing dosimeters to the HCIR participants and requiring that their dosimeters be worn when they are in proximity to radiation producing equipment. At assigned intervals, the dosimeters with a control dosimeter are sent to the NVLAP-accredited laboratory to be read and analyzed. A summary report is sent to the participant upon completion of the analysis.

As outlined in Table 2 below, the data showed that:

— 40% of HCIRs studied who worked in U.S. hospitals received a measurable DDE within a calendar year

— 5% of HCIRs exceeded 100 mrem (1 mSv) DDE, which is the monitoring requirement in some states

— 1% of HCIRs received more ionizing radiation than the required monitoring threshold of 500 mrem (5 mSv) of DDE as codified in 10 CFR 20

The number of HCIRs who are exceeding the monitoring threshold of 500 mrem (5 mSv) is increasing at an overall rate of 1.8% from 2014 to 2016. Further, there were 14 occurrences of HCIRs exceeding the annual monitoring limit for DDE, greater than 5,000 mrem (50 mSv) in the three-year period reviewed.

These data points are critically important -- regardless of where the historical dose was accumulated, the facility in which the dose goes beyond the outlined limit is the one that assumes regulatory responsibility.

Table 2: Workers with Measurable Dose

% measurable	% above 100mrem (1 mSv)	% above 500mrem (5 mSv)	Number of doses over 5,000mrem (50 mSv) over the 3-year period
40%	5%	1%	14

The distribution of doses among the 40% of HCIRs who received measurable doses over the three-year period are observed to have a wide variation in the annual radiation exposure with doses ranging from minimal up to just over the federal limit of 5,000 mrem (50 mSv) per year.

Issues with Monitoring

Based on the data analysis, there is a compelling case to develop a monitoring assurance program for HCIRs who have a higher likelihood of exposure to ionizing radiation. However, this effort presents some challenges:

— Multiple hospitals
  - HCIRs often visit several different hospitals making it difficult to maintain a common monitoring process for each location

— Company/territory change
  - HCIRs could change companies or geographical territories within a company making it difficult to maintain dose data in the midst of change

— Unreturned dosimeters
  - An average of 23% of dosimeters issued to HCIRs are never returned and therefore not analyzed. LANDAUER benchmark data indicate that an average of 8% of dosimeters issued throughout the country are not returned. This means that HCIRs are nearly three times less likely to return their dosimeters and are therefore not receiving their assigned doses for those instances. While there may be a monitoring program in place, there may not be good adherence to monitoring protocol.

Conclusion – How to Minimize Health and Safety Risks

To minimize risk to the HCIR and the hospital, it is imperative that hospitals consider developing and enforcing a policy to assure the monitoring and dose tracking of HCIRs that have a higher likelihood of exposure to ionizing radiation. Radiation Safety Officers and hospital management of hospitals are in an ideal situation to create and implement a policy and program to improve the safety and risk for HCIRs and hospitals.

It is further advisable that the facility consider utilizing a third-party monitoring program to overcome critical issues that are encountered with traditional monitoring. A centralized dose database would eliminate obstacles created when HCIRs changes geographical territory or hospital locations. Additionally, an enforcing system or policy would assure higher compliance and improve the likelihood that dosimeters are returned and read as they were intended to be used to reflect accurate dose data. Vendor credentialing service providers should consider adding radiation monitoring as part of their offering.

Although there are radiation safety programs in place at hospitals, HCIRs are often overlooked, which may introduce a health and safety risk for the facility. Recognizing this problem and putting measures in place to monitor and track through a credentialing service will help provide a comprehensive radiation safety program for the full spectrum of employees in the facility. It is recommended that hospitals ask treat HCIRs as they do their own employees.

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[1] United States Environmental Protection Agency. Radiation Protection: Radiation Health Effects [online]. Available at: https://www.epa.gov/radiation/radiation-health-effects. Accessed 2 February 2017