Undisclosed Radioactivity in Specimens: How Much of a Problem?

To the Editor:

Our institution, a clinical reference laboratory, receives specimens from a wide geographic location. In September 1996, a waste-disposal contractor alerted us to the presence of residual radioactivity in a 30-gallon (~135-L) drum of what was supposed to be nonradioactive laboratory waste. Because clinical laboratories are regulated regarding the receipt, use, and disposal of radioactive material, we sought the source. Investigation revealed that the radiation originated from a urine specimen container, specifically from a specimen sent for catecholamine testing. During an evaluation for a possible pheochromocytoma, the patient involved had undergone nuclear imaging with radiolabeled m-iodobenzyl guanidine (MIBG) before urine collection. The subject of radioactive specimens forwarded to the clinical laboratory is not commonly addressed in the literature. Particularly specimens containing undisclosed radiation and shipped to distant laboratories. Regulations concerning laboratories vary widely by state and by type of licensure. Many states are licensed directly through the NRC. In our case, the laboratory has a “radioactive material license” from the State of Utah, which allows the presence of several radionuclides on site, including $^{131}$I, up to a total of 3 mCi. Licenses do not necessarily include $^{131}$I, and each laboratory experiencing problems similar to that described here needs to determine what is allowed under its specific licensing regulations. Analysis of low-level radioactive specimens is permissible as long as the amounts are in compliance with licensing regulations. Liquid specimens containing low-level radioactivity can be discarded into the sewer, but the containers should be considered solid radioactive waste and treated accordingly (10 CFR 20.2003). Decay in storage is an authorized method for radioactive waste disposal.

After considering the implications of this case, we began to screen for radioactivity specimens received for catecholamine analysis, because this group included patients who were likely to be evaluated with nuclear imaging procedures. Initial screening was performed with a hand-held radiation monitor (TBM-6SP; Technical Associates, Canoga Park, CA), and those specimens identified as radioactive were quantified with a gamma counter (Genesy 6000; Laboratory Technologies, Roselle, IL). Between October and January, ~1% of the specimens screened (8 of 928) were found to be radioactive. These specimens had been received from multiple locations and contained between 0.2 and 1160 μCi/L. Total radioactivity in a single 24-h collection was as much as 0.4 mCi. The health risks to laboratory personnel from inadvertent exposure to the low amounts of radiation described here are minimal. However, associated regulatory and licensing issues are of considerable concern.

Low-level radioactive waste issues are discussed in references such as Hill [2]. Nuclear Regulatory Commission (NRC) regulation 10 CFR 20.2003(b) states that excreta from individuals undergoing medical diagnosis or therapy with radioactive materials are exempt from regulation if discharged directly into the sanitary sewer. However, the subject of radioactive specimens forwarded to the clinical laboratory is not commonly addressed in the literature. Particularly specimens containing undisclosed radiation and shipped to distant laboratories. Regulations concerning laboratories vary widely by state and by type of licensure. Many states are licensed directly through the NRC. In our case, the laboratory has a “radioactive material license” from the State of Utah, which allows the presence of several radionuclides on site, including $^{131}$I, up to a total of 3 mCi. Licenses do not necessarily include $^{131}$I, and each laboratory experiencing problems similar to that described here needs to determine what is allowed under its specific licensing regulations. Analysis of low-level radioactive specimens is permissible as long as the amounts are in compliance with licensing regulations. Liquid specimens containing low-level radioactivity can be discarded into the sewer, but the containers should be considered solid radioactive waste and treated accordingly (10 CFR 20.2003). Decay in storage is an authorized method for radioactive waste disposal.

A separate issue involves Department of Transportation (DOT) regulations concerning shipment of radioactive materials. If patients’ specimens are included under DOT regulations concerning shipment of “limited quantities” of radioactive materials (specifically 49 CFR 173.421 and related paragraphs), then certain conditions must be met, including appropriate packaging and minimal labeling requirements [3]. Above specified radiation values, more-stringent packaging and labeling requirements apply.

A number of questions remain, although, clearly, undisclosed radiation has the potential to be a significant problem for the clinical laboratory. When a radioactive specimen is discovered, the laboratory needs to verify that it is licensed to have radioactive material of that nature on-site. Clinical laboratories should be aware that specimens are shipped from patients who have undergone nuclear medicine procedures; these specimens may contain undisclosed low-level radiation, which may cause problems with waste disposal and related regulatory policies.

References


Mark E. Astill 1
Kern L. Nuttall 1,2*

1 ARUP Labs.
500 Chipeta Way
Salt Lake City, UT 84108
2 Dept. of Pathol.
Univ. of Utah School of Med.
50 North Medical Dr.
Salt Lake City, UT 84132

*Address correspondence to this author, at ARUP Labs.

Rapid Qualitative TSH Test to Screen for Primary Hypothyroidism

To the Editor:

We evaluated a qualitative, solid-phase two-site immunochromato-