



Meredith Stein, Director, Division of Risk Management and Audit Liaison, National Institutes of Health

BOTTOM UP TO TOP DOWN

By Russ Banham



RIMS

For more than a century, scientists at the National Institutes of Health (NIH) have paved the way for vital scientific discoveries that improve health and save lives. Part of the U.S. Department of Health and Human Services (HHS), the NIH is the Nation's premier medical research agency. The organization traces its roots to 1887, when a one-room laboratory was created within what is

today the U.S. Public Health Service. Since then, 153 Nobel Prize winners have received support from the NIH.

In July 2016, the federal government's Office of Management and Budget (OMB) updated [Circular No. A-123](#) to ensure federal agencies effectively manage the risks that confront their strategic objectives, operations and activities on an enterprise-wide basis. Meredith Stein, director, NIH division of risk management and audit liaison, is entrusted with implementing the aims of the new rule. RIMS sat down recently with Stein, who joined the NIH in June 2007 and is maturing its risk management program, to discuss her experiences.

RIMS: Tell us a bit about your background before joining the NIH.

Stein: Previously, I worked for a Big Four accounting firm, giving me public accounting experience and knowledge on how to conduct a risk assessment. NIH brought me in to set up its risk management program, following a mandate by the director at the time to identify, assess and prioritize risks, and create a risk management culture. I worked with about eight or so program executives to develop the goals, vision and strategy for the NIH risk management program.

RIMS: Was this a difficult process?

Stein: NIH is a very decentralized organization, with 28 component units of which 27 are the various Institutes and Centers. Each component has a specific research agenda, which is typically focused on a specific disease like HIV/AIDS, drug addiction, or cancer or a specific part of the body such the heart or lungs. The remaining component is the Office of the Director, the central office for setting policy, planning, managing and coordinating the program activities of all 27 of NIH's Institutes and Centers. All but three of the institutes receive funding directly from Congress.

RIMS: When you arrived at the NIH in 2007, what was the state of risk management?

Stein: It was focused on internal control. Following the Sarbanes-Oxley Act of 2002, the OMB issued an earlier revision to Circular No. A-123 (in 2004). It emphasized more rigorous internal controls and documentation. Then, in 2007, the NIH director at the time said "let's not just do internal controls; let's think about our risks and the internal controls in place to mitigate them. Let's think about this from a risk perspective." That's when I was hired. In my first few years we established a bottom-up approach to identify risks, working with each of the NIH components. Our goal was to build and pilot a risk management framework, and determine the steps that would be included in this framework. From this pilot, we implemented the risk management framework across the NIH. We also developed a risk management guidebook and policy, and in 2010 implemented a data repository where institutes and centers could enter, store and report on their risks.

RIMS: And then the OMB issued its latest revision to the circular, ushering in ERM.

Stein: Exactly. OMB's new circular was our mandate to think about risk from an enterprise perspective, through a top-down approach of looking at the risks that may promote or derail us from achieving our mission. We needed to better understand what each Institute's director and the office of the director considered to be their most important risks. Each leader needed to think about their top three to five enterprise risks and document them in terms of their impact on that organization's strategic goals and objectives. That's what I mean by a top-down process.

RIMS: Given the decentralized structure of the NIH, was this a difficult exercise?

Stein: It wasn't easy. Luckily the risk management framework we had in place provided a solid foundation to implement ERM across NIH. Leadership agreed to develop an initial NIH ERM Risk Profile.

RIMS: Once you had their buy-in, were these risks aggregated in some way to provide an enterprise view?

Stein: Yes. My team took a look across all the risk data we had and did an environmental scan to aggregate information, draw conclusions and propose key takeaways for NIH leadership to consider. For instance, a risk identified as "frequent" last year may be less frequent in the coming year for some reason. New risks may emerge or particular risks may increase in severity. We aggregated this information and provided a report to the CFO of NIH, in addition to the CFO-equivalents of each Institute and Center.

RIMS: Now that you're a full year into the ERM implementation, what is different at NIH and in your role?

Stein: In December 2015, NIH developed the NIH-Wide Strategic Plan. In the NIH-wide plan, the director emphasized the importance of engaging in proactive risk management practices. (The report is available at <https://www.nih.gov/about-nih/nih-wide-strategic-plan>.) He underlined that risk management is each person's responsibility at NIH. Consequently, risk management has really spread across the enterprise, with ERM

becoming the apparatus to elevate risk to leadership. As for my role, we were one of the first government agencies to implement a program and are focused on designing a sustainable ERM program framework. We receive a lot of calls from our colleagues at other agencies looking at what we've accomplished. At the same time, we're learning from their experiences. Altogether, we've talked to about 40 agencies about their innovative approaches to managing risk through the implementation of ERM practices.

RIMS: It must feel good to have come so far so quickly.

Stein: Risk management is not new to the NIH; we manage risks every day. We tackle important and scientific challenges in our research. Incorporating ERM practices in our daily work helps achieve the NIH mission to enhance health, lengthen life, and reduce illness and disability. ■