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Mirion to Elevate Radiopharmaceutical Production Quality with Advanced Apex-Guard Software

Apex-Guard™ Software Version 1.2 Introduces Robust Impurity Analysis for Enhanced Radioisotope Quality

ATLANTA--(BUSINESS WIRE)-- [Mirion Technologies](#) (NYSE: MIR), a global provider of advanced radiation safety solutions, today announced the latest release of its [Apex-Guard gamma spectroscopy software](#). Tailored to meet the stringent regulatory demands of commercial radioisotope producers, Apex-Guard software V1.2 significantly enhances the Mirion solutions suite within the radiopharmaceutical supply chain with a robust impurity analysis for radioisotope producers. This software release reinforces the Mirion commitment to improving quality in cancer care, through focused innovation across its Mirion Technologies and Mirion Medical groups.

The radiopharmaceutical field is experiencing rapid expansion, with over 100 drugs currently in Phase I or further clinical development stages¹ poised to revolutionize patient-centric diagnosis and treatment in cancer care and other medical specialties. To manage the growth, radioisotope producers require robust quality management and impurity analysis to ensure compliance and patient safety.

Building on the established Mirion Technologies Genie™ and Apex-Gamma™ gamma spectroscopy software platforms, Apex-Guard software offers advanced controls, security, audit features, and data integrity. These features support compliance with regulations such as U.S. FDA 21 CFR Part 11². The latest version introduces a solution for Radionuclidic purity gamma spectroscopy measurements through a broadly applicable, ready-to-use patent-pending algorithm. This advancement streamlines quality management processes, increases confidence in quality and facilitates efficient regulatory compliance.

Apex-Guard software further enhances the radiopharmaceutical lifecycle through streamlined workflows via interoperability with industry-leader BioTrax QMS®, an electronic quality management tool encompassing inventory management, document management, and production batch records from ec² Software, a Mirion Medical Company.

“Mirion is deeply committed to providing the most advanced and reliable technologies for the radiopharmaceutical field, which plays a critical role in modern cancer care,” said Tom Logan, Mirion CEO. “The rapid growth in the radiopharmaceutical sector has increased demand for radioisotopes used in cancer care. This new Apex-Guard release demonstrates our investment in aiding the acceleration of these life-changing advancements in precision medicine by ensuring the highest quality and safety standards.”

Mirion's Role in Radiopharmaceuticals

The Mirion mission is to harness its unrivaled knowledge of ionizing radiation for the greater good of humanity. The mission is embodied by focused innovation across the Mirion Technologies and Mirion Medical groups as evidenced in support of the radiopharmaceutical supply chain. From research and production to practitioner protection and patient care, Mirion provides a comprehensive portfolio of proven solutions from its Mirion Technologies, Capintec, and ec² Software brands.

For more information about Apex-Guard software, implementation support services, and how it can benefit commercial radioisotope producers, [visit mirion.com](https://www.mirion.com).

About Mirion

Mirion (NYSE: MIR) is a global leader in radiation safety, science and medicine, empowering innovations that deliver vital protection while harnessing the transformative potential of ionizing radiation across a diversity of end markets. Focused on nuclear and safety, the Mirion Technologies group is committed to powering advancements in nuclear energy through proven radiation safety technologies and expertise. Dedicated to driving better patient outcomes, the Mirion Medical group is focused on improving quality in cancer care through its broad range of solutions that enhance the delivery and ensure safety across the medical landscape. Headquartered in Atlanta (GA – USA), Mirion employs approximately 2,800 people and operates in 12 countries. Learn more at [mirion.com](https://www.mirion.com).

¹ClinicalTrials.gov; An official website of the [U.S. Department of Health and Human Services](https://www.hhs.gov), [National Institutes of Health](https://www.hhs.gov/nih), [National Library of Medicine](https://www.nlm.nih.gov), and [National Center for Biotechnology Information](https://www.ncbi.nlm.nih.gov)

²21 CFR Part 11 is the United States Food and Drug Administration (FDA) regulation that sets forth the requirements for electronic records and electronic signatures in the pharmaceutical industry.

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