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Preface

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Medical imaging and radiation therapy are indispensable in healthcare. Medical imaging is central to the diagnosis, monitoring, and treatment of a variety of clinical conditions; in 2016, roughly 700 million radiologic, computed tomography (CT), dental, and nuclear medicine examinations were performed in the US.[1] Radiation therapy is an important part of cancer treatment, received by over half of cancer patients as part of their treatment.[2] Yet despite the number of lives touched by radiological health and the critical role that radiological health plays in healthcare, few patients or care providers understand how these devices actually reach the commercial market in the US – a process in which regulatory affairs plays a major role. Even regulatory affairs experts coming from other device areas are unlikely to have an in-depth understanding of regulatory considerations specific to radiological health devices, which deal