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Application of risk analysis methods to radiation medicine, InSTEC approach

Among the most used methods of risk analysis for medical practices with ionizing radiations are the Risk Matrix and the Failures Modes and Effects Analysis. Two large projects represent these methods. The first corresponds to the Forum of Radiological and Nuclear Regulatory Agencies (FORO-IAEA) and the second to the TG-100, of the American Association of Medical Physicists (AAPM). The SECURE-MR-FMEA program, developed within the framework of the Bonn Call for Action, constitutes a prospective risk analysis system that includes the integrated and coupled management of both methods, with the traditional capabilities published in the representative bibliographies of the same, as well as a series of facilities that automate new types of applications, such as importance, sensitivity, results graphing, data entries, comprehensive documentation and risk monitoring of practices. For the development of these capacities, the experiences of safety analysis applications in nuclear power plants have also been used as a reference. Based on the recognition of the expertise needed to generate the risk patterns of both traditional radiation treatment variants and medical practices with a high degree of technological complexity, the system has included, as references, databases for more than 15 related practices with teletherapy, brachytherapy, diagnostic and therapeutic nuclear medicine, as well as models for the transport and production of radiopharmaceuticals. The system offers capabilities for a variety of applications, including those required in the regulatory arena and for the optimization of quality assurance. The example of risk analysis of stereotactic radiosurgery shows as illustration of the software capabilities.

Keywords: risk analysis, ionizing radiations, cancer treatment, Risk Matrix, SEVRRA, FMEA, TG-100, quality assurance, SECURE-MR.

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