NIH/NIAID Radiation and Nuclear Countermeasures Program Portfolio-Wide Radiation Dosimetry Harmonization Program

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In 2004, the US Department of Health and Human Services directed NIH/NIAID to establish the RNCP to increase the Government's capability to provide an effective public health response in case of a radiological or nuclear incident. Since that time, the RNCP has supported development of medical countermeasures (MCMs) to mitigate and/or treat injuries resulting from a radiation public health emergency. The program also supports identification of biomarkers for radiation injuries, and development of non-invasive biodosimetry tools to rapidly triage potentially exposed individuals. The RNCP's research portfolio is aimed to understand, diagnose, mitigate, and treat acute radiation syndromes and delayed effects of acute radiation exposure, through award of grants, cooperative agreements, contracts, and interagency agreements spanning a wide range of research topics.

Since most research necessary to accomplish these goals is not feasible or ethical to conduct in humans, development is typically conducted in accordance with the "FDA Animal Rule"[1] using well-defined preclinical animal models that recapitulate the natural history of radiation exposures. Consequently, the RNCP portfolio supports animal models ranging from mice to nonhuman primates across many institutions, which employ a broad array of irradiators and irradiation conditions. Furthermore, although investigators make every effort to use best practices in standardizing their dosimetry methods, most institutions conducting radiation biology research in animal models do not have sufficient resources to employ a dedicated health physicist or metrologist to oversee and provide dosimetry support for these studies. The need to increase and improve dosimetry standards, traceability to National Institute of Standards and Technology (NIST) standard beamlines, and to provide dosimetry harmonization within the radiation biology community has been noted for over a decade. To address this requirement, the RNCP initiated a centralized portfolio-wide dosimetry assessment and harmonization effort through a contract awarded in 2020 to the MRRC, which uses its associated Accredited Dosimetry Calibration Laboratory. This contract provides a resource for expert NIST-traceable dosimetry evaluation, consultation, and inter-institution harmonization across the entire RNCP-funded portfolio. To date, this effort has evaluated and provided support for 15 radionuclide-based irradiators (^{137}Cs and ^{60}Co) and 18 cabinet-type orthovoltage X-ray irradiators at more than 20 institutions.

[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-development-under-animal-rule