

## Nuclear Materials & Medicine

From industrial gauges to cancer therapy, radioactive materials are used in many critical applications across the globe, by companies large and small.

We help industrial and medical users of radioactive materials – and their investors and stakeholders – navigate the accompanying complex global nuclear regulatory landscape.

The creation, use, possession, and distribution of radioactive materials are licensed in the United States by the U.S. Nuclear Regulatory Commission (NRC) and 38 NRC Agreement States. Similar agencies regulate radioactive materials uses in other countries.

Radioactive materials licenses are subject to strict regulatory requirements, including periodic inspections, decommissioning funding obligations, and prior approval before changing licensee ownership or control.

From applying for or amending licenses, transferring licenses to new owners, transporting or exporting radioactive materials abroad, and resolving enforcement actions, we have assisted clients in matters before many nuclear regulators. Our clients include producers of radiopharmaceuticals, large and small industrial users of radioactive materials, private equity investors whose portfolio companies hold radioactive materials, research facilities, hospitals, and universities.

### Contacts

**Amy C. Roma,**  
Washington, D.C.

**Daniel F. Stenger,**  
Washington, D.C.

---

### Practices

Nuclear Energy and  
Materials

Medical Device and  
Technology Regulatory

International Trade and  
Investment

Mergers and  
Acquisitions

---

We also work closely with our colleagues in our Life Sciences and Medical Device practices, as many medical users of radioactive materials find themselves under dual regulation by nuclear regulators and the U.S. Food and Drug Administration (FDA) (or international counterparts), and in our International Trade practice, including our Committee on Foreign Investment in the United States (CFIUS) specialists. Our lawyers have worked for the relevant regulatory agencies and have advanced degrees in relevant scientific backgrounds.

## Representative experience

Routinely advise clients on nuclear license transfer requirements and prepare associated applications.

Assisted medical innovator on licensing a novel cancer detection product that uses radioactive materials.

Advised licensees on license amendments to reflect new device designs, on amendments to sealed source and device registrations, and on various Agreement State matters.

Advised global radiopharmaceutical company on U.S. transportation requirements for radioactive materials, including unique requirements for cross-border shipments.

Supporting major U.S. radiopharmaceutical manufacturer in a challenge before the NRC of unfair government support of a foreign competitor who failed to transition to low-proliferation risk technologies.

Performed compliance audits and training for Fortune 500 technology companies' export control programs that involve export and import of small amounts of radioactive materials.

Conducted audits of Fortune 100 retail companies and advised on self-disclosure of violations of NRC requirements associated with the improper transfer and disposal of tritium exit signs.

Advised universities on decommissioning trust fund requirements, radioactive materials management, export controls, access authorizations, and joint university-commercial partnerships.

Assisted major medical companies and industrial users of radioactive materials with hundreds of radioactive material license transfer approvals from NRC Regional Offices and Agreement State regulators.

Advised a global radiopharmaceutical supplier on all nuclear aspects of acquisition of a major producer of medical isotopes.

Assisted device and radiopharmaceutical manufacturers to obtain licenses for the possession, use, and distribution of devices and medicines that contain radioactive material.

Advised foreign life science company being acquired by a U.S. company on NRC and Agreement State license transfer requirements, and how those requirements could impact the transaction structure.

Provided guidance for acquisition in the industrial goods industry on NRC and Agreement State license transfer requirements, and prepared associated license transfer applications.

Advised Fortune 500 companies on nuclear related licensing and regulatory issues associated with the transfer of manufacturing business overseas.

Advised licensees and investors with nuclear decommissioning funding requirements and appropriate means to demonstrate financial assurance to regulators.

Assisted with the creation, amendment, and replacement of financial assurance instruments required to demonstrate compliance with NRC decommissioning requirements.

Advised companies in obtaining FDA clearance for more than five separate proton beam therapy systems and a variety of accessories to the systems.

Advised companies on the FDA and NRC regulations associated with radiation therapy systems, including quality assurance and recordkeeping and registration requirements.