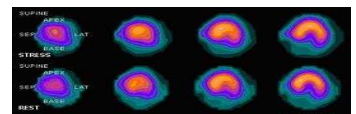


NRC Meeting – Briefing on Fee Process September 16, 2016

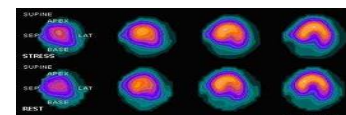
Future NRC Licensed Mo-99 Production Facilities

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CORAR

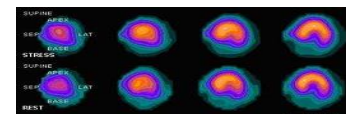
The Council on Radionuclides and Radiopharmaceuticals (CORAR) is an association comprised of companies in the United States and Canada who manufacture and distribute radiopharmaceuticals, sealed sources, radionuclides, and contrast agents primarily used in medicine and life science research. CORAR is tasked with advocating for regulations and legislation that facilitate the growth and viability of its member companies.



Mo-99 Background

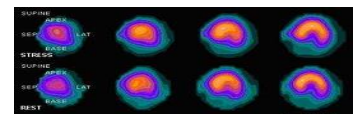
- Molybdenum-99 (Mo-99) is the parent isotope of Tc-99m
- 30 to 40 million Tc-99m procedures worldwide every year*
 - Approximately half of Tc-99m procedures done in US
 - Important for cancer and heart disease diagnosis
- Mo-99 provided through international supply chain
 - Currently, no Mo-99 producer in United States
- Severe Mo-99 shortages in 2009 and 2010
- Efforts to improve Mo-99/Tc-99m availability:
 - Nuclear pharmacies have increased efficiencies since 2009 and 2010
 - Current Mo-99 producers increasing capacity
 - New domestic Mo-99 producers

* OECD-NEA Report “2016 Medical Isotope Supply Review: 99Mo/99mTc Market Demand and Production Capacity Projection 2016-2021; March 2016



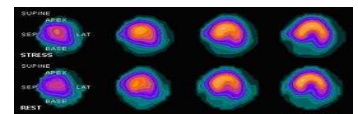
Part 170 User Fee Comments

- Part 170 User Fee comments from domestic radioisotope licensees - including future Mo-99 producers:
 - Licensees request increased invoice clarity and transparency
 - Provides licensees ability to better track and confirm charges
 - Track and confirm additional expenses “adders” issued by CFO’s office, subcontractors, etc.
 - Better manage applications reviews relative to projected review costs
 - Active communications between both NRC and radioisotope production facility licensee will support realistic expectations on invoiced user fees
 - Proactive project manager (PM) communication with licensee
- Part 170 User Fee hourly rate:
 - NRC calculates hourly rate on combined FTEs applied to all fee categories evenly
 - Radioisotope manufacturers (and future Mo-99 producers) represent a relatively small category versus others (e.g. power reactors)
 - Request NRC evaluate proportional hourly fee based on NRC category resource utilization



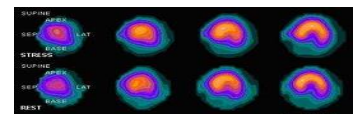
NRC Licensed Mo-99 Facilities

- Mo-99 production facilities are not currently assigned to an NRC fee category under 10 CFR Part 171
 - NRC is currently including 10 CFR Part 170 billings (from Mo-99 facility applications) in the determination of annual fees for research and test reactors
- CORAR supports NRC proposed NPUF rulemaking - SECY-16-0048:
 - Categorize research and test reactors and radioisotope production facilities under a single term, “*non-power production or utilization facility*” (NPUF)
 - Flexible and captures all non-power facilities licensed under § 50.22 or § 50.21(a) or (c)
- Recommend NPUF rulemaking include amending § 171.15(f) to apply to NPUFs licensed under 10 CFR Part 50, not just research or test (non-power) reactors licensed under 10 CFR Part 50
 - Cost to regulate a Mo-99 production facility is anticipated to be similar to a research and test reactor



NRC's Interoffice Special Committee

- CORAR appreciates NRC's Interoffice Special Committee evaluation of stakeholder's feedback on the annual fee process including:
 - The accelerated release schedule of the FY 2017 proposed rule
 - Please note – CORAR believes licensees would benefit if release schedule could be accelerated further
- CORAR believes the 14 administrative improvements to the NRC fee process (described in SECY-16-0097) is a good first-step towards improved:
 - Transparency
 - Timeliness
 - Equitability
- CORAR supports additional actions that further improve communication between NRC and licensees



Conclusions

- Domestic production of Mo-99 is important to ensure a reliable and sustainable supply for US patients
- Research and test reactors and Mo-99 production facilities should be categorized collectively as NPUFs
- Recommend NPUF rulemaking include amending § 171.15(f) to apply to NPUFs licensed under 10 CFR Part 50, not just research or test (non-power) reactors licensed under 10 CFR Part 50
- CORAR supports NRC's efforts to improve the NRC 10 CFR Part 170 user fee process, including:
 - Enhancing communication of billed services on invoices:
 - Sufficient detail to substantiate invoiced charges, such as NRC staff associated with hourly charges
 - Improved detail on contractor services
- Encourage NRC PM to proactively communicate with licensee

