



Council on Radionuclides and Radiopharmaceuticals, Inc.

3911 Campolindo Drive
Moraga, CA 94556-1551
(925) 283-1850
Fax: (925) 283-1850
E-mail: corar@silcon.com

Henry H. Kramer, Ph.D., FACNP
Executive Director

September 18, 2006

The Honorable Arnold Schwarzenegger
Governor of California
State Capital
Sacramento, CA 95814

Dear Governor Schwarzenegger,

We are writing to you to express our view of the transfer of functions of the Radiological Health Branch from the California Department of Health Services to the California Environmental Protection Agency or another environmental, health or safety agency. As you are aware, this reorganization of agencies was recommended by the California Performance Review Commission.

The Council on Radionuclides and Radiopharmaceuticals (CORAR) is the North American Trade Association of manufacturers and distributors of diagnostic and therapeutic radiopharmaceuticals, life science research radiochemicals and sealed sources used in therapy, diagnostic imaging and calibration of instruments used in medical applications. All of the major nuclear medicine and medical radionuclides suppliers in North America are members of CORAR. We also work closely with nuclear pharmacists and nuclear medicine physicians who use our products. Many of our members are companies who make available radiopharmaceuticals and other medical isotopes for the diagnosis and treatment of citizens in California. We do this by operating a highly efficient supply chain that achieves the timely delivery of these products, many of which have a very short half-life, by way of a network of nuclear pharmacies and other distribution centers throughout the State.

While we are pleased that no action to date has been taken to transfer the resources and programs of the Radiological Health Branch (RHB), we are concerned with the state of affairs within that agency with its collaboration with the County of Los Angeles Department of Health Services (DHS), and the obstacles the current regulatory landscape present to the radiopharmaceutical supply chain in the State of California. Our facilities are among the most highly regulated operations in the State and despite the complex framework in which they are operated, the record of delivery on compliance is exemplary. However, we find ourselves dealing with an agency that, partially due to no fault of theirs, cannot maintain a service level to more than 2,000 licensees that is commensurate with the high level of compliance performance that is expected of the regulated community. Some examples of the difficulties we face are as follows:

- Partially due to State legislation that has an inadequate technical basis and which fails to follow convention of other Agreement State or Nuclear Regulatory Commission (NRC) regulations,

standards and guidelines, there are no clearly established regulations for radiological decommissioning or transfer of clean sites to unlicensed status or unrestricted use. At the same time, the NRC has repeatedly and most recently determined¹ that the Agreement State program in California is not adopting NRC regulations in accordance with their policy on adequacy and compatibility. The NRC has determined that California is overdue in the adoption of 18 regulations including Radiological Criteria for License Termination². As a result, RHB personnel are frustrated by their own inability to understand the decommissioning regulatory framework and interpret the requirements. This is exacerbated by the lack of continuity within RHB in interpretation of regulation and the expectations placed upon those regulated.

- Small sites that handle radiopharmaceuticals that are essentially non-radioactive after 30 days are being subject by RHB and LA County DHS to State decommissioning requirements in a variety of unwarranted situations, ranging from something as simple as the remodeling of a room within a site to the termination of a license for a site that has no residual radioactivity and for which an approved decommissioning plan is not required under California law. The interpretation of regulation, particularly by LA County DHS officials, has been in our view arbitrary and inconsistent between officials within the same agency.
- RHB staff have communicated that they are understaffed and therefore cannot complete licensing transactions within a reasonable amount of time. This concurs with NRC's recommendation³ that the State needs to ensure that adequate resources, including staffing, need to be devoted to the radiation control program to sustain satisfactory performance. Many of the radioactive materials licenses in the State have expired. The experience of CORAR members is that licensees have met the regulatory obligation to apply for renewal well in advance of expiration but it is not uncommon for licensees to be in a status of timely renewal for 2 or 3 years. A simple license amendment usually takes at least 3 and as many as 9 months. As a result, a licensee may be subject to conditions that no longer reflect the nature of operations or its hazards. This is not in the best interests of the licensee, the agency or the citizens of California.

Our sites have operated for years with reasonable agreement with officials on site closure and license transfer expectations. More recently, the same site operators are now diligently trying to hit a moving target of compliance. Termination of a license in California can take anywhere between 6 to more than 18 months. As a result, sites whose operations are moved to another location now sit inactive, sometimes in violation of lease agreements and then subject to litigation with owners who are entitled to a return of their property. Sites have also been cited for violations for taking actions consistent with those previously approved by agency representatives.

CORAR companies operate in all 50 states and 4 NRC Regions. The difficulties experienced in California are unique and the extent unprecedented. It is in our mutual best interests to establish a regulatory framework in your State that is both efficient and effective in its oversight of the regulated community. In light of this concern and the examples presented above that we respectfully urge you to do the following:

¹ U.S. Nuclear Regulatory Commission. Final Report – Integrated Materials Performance Evaluation Program Follow-Up Review of California Agreement State Program. March 27 – 30, 2006. Section 3.1.

² U.S. Nuclear Regulatory Commission. Radiological Criteria for License Termination. 10 CFR 20, 30, 40 and 70. Federal Register, Vol. 62, page 39057.

³ U.S. Nuclear Regulatory Commission. Final Report – Integrated Materials Performance Evaluation Program Follow-Up Review of California Agreement State Program. March 27 – 30, 2006. Section 2.1.

- Take into account the recommendations made by NRC as a result of their on-going heightened oversight of the California Agreement State Program. Any changes made to reorganize the program should be done in recognition of the need for adoption of compatible NRC regulations and to ensure that adequate resources are available to maintain a satisfactory service level.
- Before any consideration of the need to transfer the Radiological Health Branch of the California Department of Health Services to another agency or jurisdiction, address the immediate need to improve the current status of the agency. A comprehensive and likely independent review should be initiated to identify deficiencies in this bureaucracy so that they can be addressed to enable the agency to be effective in meeting its obligation to protect the citizens of the State without undue hardship on the providers of critical diagnostic and therapeutic tools to the healthcare community in California.
- Establish better oversight of subordinate agencies, such as the County of Los Angeles Department of Health Services, to ensure that their regulatory oversight of licensees meets expectations with regard to interpretation of regulations, consistency of regulation and enforcement, appropriate transactional service level and consistency with State law.
- Challenge the legislative bodies in California to 1) promulgate laws that are based on established scientific standards and consistent with best practices of Federal agencies and other Agreement States, 2) be accountable to the agencies that will regulate and enforce laws to ensure they are sufficiently resourced to take on the burden, and 3) consider input from stakeholders affected by new regulations or otherwise risk the consequences of a regulatory framework that makes it impossible to conduct business in compliance.

If, in consideration of these recommendations, you or your staff need additional information from CORAR or have any question concerning this letter, please contact me at (314) 795-6166. In the meantime, thank you for any attention paid to these important matters.

Sincerely,



Roy W. Brown
Senior Director, Federal Affairs
CORAR