EXECUTIVE SUMMARY

The Council on Radionuclides and Radiopharmaceuticals (CORAR) recognizes the need for comprehensive regulations to ensure the safety and security of radioactive materials and the protection of the public environment. There is an important need for federal and state regulations of radioactive materials and radiation protection standards to be uniform and compatible with international regulations and standards. In practice the best results will be obtained if the setting of radiation standards are separate from the promulgating of radiation regulations and these different functions carried out by separate agencies. To achieve these purposes, CORAR recommends that Congress establish an independent federal agency to be responsible for setting national radiation protection standards.

The current process, where the Environmental Protection Agency (EPA) is responsible for issuing federal guidance on radiation protection, continues to be unsatisfactory. This is due, in part, to the conflict arising from the EPAs standard setting responsibilities and its regulatory practices. To avoid this conflict of interest, in the future, CORAR recommends that an independent federal radiation standard setting agency should not also be responsible for regulating the uses of radioactive materials or other sources of ionizing radiation. An additional consideration is that Congress could grant the standard setting agency oversight authority to ensure that regulatory agencies uniformly adopt the national standards.
INTRODUCTION

Members of the Council on Radionuclides and Radiopharmaceuticals (CORAR) are the major manufacturers and distributors of radiopharmaceuticals, radioactive sources and research radionuclides used in the USA for therapeutic and diagnostic medical applications and for industrial, environmental and biomedical research and quality control. Since our products are distributed worldwide, CORAR members have a comprehensive understanding of the domestic and international regulatory framework involving radioactive materials and its strengths and weaknesses.

CORAR members have had long experience of the increasing number of regulations of radioactive materials that are duplicative, conflicting and otherwise counter productive. The primary cause is the overlapping jurisdiction of federal and state regulatory agencies and the inability of these agencies to coordinate the promulgation of uniform regulations.

Conflicting and duplicative regulations are a waste of governmental resources as well as industrial resources. They also imply to the public that government agencies lack consensus on radiation standards which in turn implies a lack of understanding, by such agencies, of the nature of ionizing radiation and measures needed to provide adequate protection.

CURRENT STATUS OF THE RADIATION REGULATORY FRAMEWORK AND REGULATIONS

The Environment Protection Agency (EPA) was mandated by Congress in 1970 to promulgate federal guidance on radiation protection standards. The EPA's representation with the Interagency Steering Committee on Radiation Standards (ISCORS) provides the EPA with the opportunity to collaborate with all relevant federal agencies in the preparation of federal guidance. Prior to the appointment of the EPA, the Federal Radiation Council provided advice to federal agencies on occupational exposure, non-occupational exposure and emergency protective action. During the past 38 years, the EPA has not yet issued the revision of this guidance. Consequently, federal guidance often lags far behind international standards.

The radiation protection guidance that the EPA has provided, during the past 38 years, has been harshly criticized by other federal and state agencies, the scientific community and professional societies. Issues include lack of consensus with other agencies, lack of justification, poor technical basis, errors in factual information and erroneous interpretations of recommendations from the National Council on Radiation Protection and Measurements (NCRP) and International Commission on Radiological Protection (ICRP).

Another practice, which exacerbates this situation, is the EPA's promulgation of regulations which conflict with EPA standards and duplicate or conflict with regulations of other federal agencies. Reports from the U.S. General Accounting Office illustrates the disagreement of EPA standards with those of the Nuclear Regulatory Commission (NRC) and other federal regulatory agencies.
These issues and conflicts have resulted in a multitude of practical difficulties including the following:

1. Federal and State radiation regulations, for the safe possession and use of radioactive materials, are more restrictive for certain categories of industry and in certain geopolitical locations causing competitive disadvantages and depriving communities of the employment opportunities and benefits of radioactive materials. Regulatory inequality is sometimes exploited for political purposes with no benefit in safety or protection for the public. Examples include access, cost and regulations of low level waste disposal sites, emergency preparedness requirements, incident notifications, defect notifications and rules concerning generally licensed devices. The diversity of regulatory requirements, from multiple federal and state agencies, severely complicate nationwide distribution of products and make it difficult for suppliers and manufacturers to advise their customers on safety and compliance.

2. Duplicate regulations increase the cost of regulatory compliance for the supplier, user, regulator and taxpayer.

3. Conflicting governmental regulations increase the cost of compliance and are sometimes technically impossible to comply with, creating unnecessary liability to users. It is, for example, impossible to comply with a regulation that uses inappropriate terminology transferred from an inapplicable technical field. This deficiency causes the public to perceive that government agencies do not agree on or understand radiation protection needs.

4. Frequent regulatory changes implemented at widely different times in different geopolitical places make it very difficult for suppliers to determine which standards apply at any given time. This adds significant cost to the process and increases the potential for errors in distribution.

5. The regulators' promulgation of erroneous information and erroneous interpretation of NCRP and ICRP recommendations confuses the public and frustrate efforts for public participation in establishing an appropriate technical basis for the regulations.

6. Regulators typically exaggerate the risks and understate the benefits of radioactive materials to promote unnecessary regulations. Misinformation of this nature can contribute to public panic over trivial radiation events and cause the opposition of siting needed facilities.

7. The proliferation of different radiation units, definitions, and terminology is confusing to the public, complicates communications and can cause misunderstandings that lead to errors, unnecessary radiation exposure and a loss of worker and public confidence in the regulatory process.

8. Regulatory practices that extend beyond the intent of Congress have eroded user management controls and interfered with the practice of medicine.
9. The high costs of licensing, inspections and compliance documentation increases the costs of health care, biomedical research, environmental protection, safety, quality control, nuclear power and consumer products causing society to pay more for these services or lose access to them.

10. Differences in federal and state licensing regulations and practices make it difficult for national suppliers to verify that the recipient is adequately licensed.

11. Differences in regulations for a radionuclide, because it is produced in a nuclear reactor or accelerator or is naturally occurring, cause users and the public to question the credibility of regulatory agencies.

12. Differences in state agency practices and resources causes differences in the time taken to review devices and sealed source registrations which can cause unfair competitive advantages to some suppliers.

13. State regulatory agencies that do not accept device and source evaluations of another State or do not provide reciprocal qualifications for operations at temporary job sites also cause unnecessary competitive disadvantages.

**CORAR RECOMMENDATIONS**

In the U. S., we need to have one set of radiation standards and uniform regulations concerning all interstate activities and all activities where uniform regulations can reduce cost and increase safety and security.

To avoid dual regulations there must be either one regulatory agency or clear demarcation of regulatory authority. As a temporary expediency, Congress should mandate that users subject to the regulations of one agency are automatically exempt from similar regulations from another agency. Alternatively the regulators should agree to promulgate identical regulations.

To achieve these objectives, the regulatory framework must be restructured. The regulatory development process must be drastically simplified to be less wasteful of resources and to promote public and user understanding and participation.
CORAR recommends that federal agencies be separately empowered to either set radiation standards or promulgate radiation regulations in the following organization structure:

1. **NCRP**: Conducts and reviews scientific studies, etc., and makes radiation protection recommendations compatible with international standards.

2. **FEDERAL RADIATION STANDARD SETTING AGENCY**: Commissions and funds NCRP etc. projects. Reviews NCRP and other recommendations, establishes federal radiation standards compatible with international standards and provides guidance to regulatory agencies.

3. **FEDERAL REGULATORY AGENCIES**: Promulgates regulations to implement federal standards. Licenses and inspects users and enforces regulations.

4. **STATE REGULATORY AGENCIES**: Implements federal regulations in all interstate commerce.

The federal radiation standard setting agency could be a new agency responsible for technical and policy issues. This would be similar to the previous Federal Radiation Council and Committee on Interagency Radiation Research and Policy Coordination who were both successful agencies established from 1959 to 1970 and from 1984 to 1985, respectively. These agencies invited delegates from federal and state regulatory agencies and individual experts to participate in resolving issues and establishing standards.

Alternatively the NRC could be mandated by Congress to serve as the radiation standard setting agency. NRC already has authority for establishing standards for and regulating the nuclear fuel cycle industry and this appears to work very well and should not be changed. The NRC recently expanded its jurisdiction to include certain Naturally Occurring and Accelerator Produced Radioactive Materials (NARM) \(^4\). NRC regulations are comprehensive, providing both safety and security of radioactive materials to ensure both occupational and public environmental protection. The separation between standard setting and regulatory functions could be achieved for material licensees by completing the transfer of regulatory authority from the NRC to Agreement States.
REFERENCES:

1. Reorganization Plan No. 3 of 1970.

