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**Subject: CORAR Comments on NRC Safety and Security Policy.
Docket ID NRC-2009-0485**

**Reference: Federal Register Vol.74, No 214, November 6, 2009. Pages 57525-57529.
Draft Safety Culture Policy Statement: Request for Public Comments.**

These comments are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR)¹. CORAR members have well established safety and security cultures and fully support the NRC's policy to ensure that both safety and security are given appropriate priority. CORAR appreciates the opportunity to comment on this important subject and would be glad to provide clarification or additional information.

Yours Sincerely,

Leonard R. Smith, CHP
Co-chair CORAR Committee on Manufacturing Quality and Safety.

1. CORAR members include the major manufacturers and distributors of radioactive chemicals, radioactive sources, radiopharmaceuticals and research radionuclides used in the U.S. for therapeutic and diagnostic medical applications and for industrial, environmental and biomedical research and quality control.

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CORAR COMMENTS ON NRC SAFETY AND SECURITY CULTURE POLICY

General Comments

CORAR understands that the NRC purpose is to protect personnel and the environment. It appears that terrorist activities during the last decade require that licensees need to make security a higher priority than before, and this has caused conflict between Safety and Security priorities. Hence the NRC strategy is to confirm that both Safety and Security are important and licensees must pay more attention to the interface between Safety and Security to ensure that both are appropriately addressed and unintended consequences are avoided. If the NRC restatement of Safety Culture is intended to promote and implement this new strategy, the culture should be renamed "Safety and Security Culture", and this term used throughout the statement.

The eight S&SC Characteristics that NRC presents appear appropriate for material radiopharmaceutical/medical isotope/source licensees but might also include methods to demonstrate compliance such determining the significance of a concern and setting performance goals and metrics.

Licensees could be better prepared for this change in emphasis if the NRC explained how they would implement this policy, what metrics will they use for enforcement purposes and what level of Agreement State compatibility will be established.

Specific Comments (each number refers to the specific NRC question)

1. What other specific characteristics are there?
 - Safety and Security (S and S) is a condition of employment and employees must be empowered to stop any operations that become unsafe.
 - S and S is required of other interfacing entities including suppliers, carriers, customers and visitors.
 - Performance reviews should include assessment of performance against S and S goals and objectives which are established by management.
 - Organizations should have a written S and S policy that defines minimum expectations as well as responsibilities. Signed and promulgated by senior manager.
 - Employees at all levels of the organization should be encouraged to actively participate in S and S related programs and activities.
 - Leaders of the organization should be involved in investigation of incidents and regularly review S and S program performance.
 - All S and S concerns can be prevented.
 - Employees should be expected to report all incidents, accidents, emergencies and unsafe/insecure conditions and practices using reporting procedures provided by the licensee.
 - Standard Operating Procedures should include emergency procedures.
 - A process or procedure should be established and implemented to ensure S and S in the event of changes in personnel, facilities and operations.

2. Which characteristics should be deleted?
 - None.
3. Should safety characteristics be included in policy statement?
 - Yes or referenced to a checklist of characteristics.
4. Safety Culture Definition
 - Is OK but would be clearer if it included the required characteristics and examples of different levels of significance to facilitate the development of appropriate administrative controls.
5. Does the fostering of Safety Culture characteristics according to significance need clarification?
 - Yes, examples of significance are needed.
6. Does the policy enhance licensee understanding that Safety Culture includes security?
 - Yes but could be more explicit if the policy was called “Safety and Security Culture”.
7. What else could the NRC do to increase attention?
 - Provide examples of S and S Culture best practices in published guidance.
8. How can NRC better involve stakeholders?
 - Explain how the policy affects inspections and how licensees can prepare for this. Share with stakeholders any plans and operating mechanisms NRC may use to measure licensee performance and provide the opportunity for input prior to implementation.