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Mr. John C. Hoyle
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CORAR will be pleased to work with the NRC on further development of the Strategic Assessment and Rebaselining Initiative.

We appreciate the opportunity to provide comments on this important issues. Please call me at (314) 895-2913 if we can be of further assistance, or if any clarification is necessary.

Sincerely,



Roy W. Brown
Chairman,
Council on Radionuclides and Radiopharmaceuticals

ATTACHMENT VI

Council on Radionuclides and Radiopharmaceuticals (CORAR) **Direction Setting Issue No. 13 - The Role of Industry**

General Comments:

Industry can offer a great deal of expertise in setting up an oversight program as proposed in DSI 13. This is evident in the success of the NVLAP program for dosimetry. Professional and industrial groups are also good sources of expertise. CORAR supports the concept of accreditation by industry groups, and certification of industrial representatives as outlined in DSI 13.

The Council on Radionuclides and Radiopharmaceuticals (CORAR), representing radionuclide and radiopharmaceutical manufacturers and distributors, works with the NRC to promote improved standards, regulations and guidelines. CORAR's main concern is that federal and state regulations should be stable and compatible with international consensus and that duplicative or redundant regulations should be avoided. CORAR members are proactive in providing safety instructions and compliance assistance to industrial and institutional customers that include most of the NRC and Agreement State licensees. CORAR provides feedback to the NRC on the practical effect of proposed regulatory changes on material licensees. CORAR also provides the NRC with information on the benefits to society of the numerous biomedical, environmental and quality control applications of radionuclides to enable the public to appreciate the cost benefit analysis necessary to justify regulations.

Specific Comments:

1. What if any important considerations may have been omitted from this issue paper?

It appears that all pertinent issues have been addressed in this issue paper.

2. How accurate are the NRC's assumptions and projections for internal and external factors discussed in the issues papers?

- CORAR believes the issues identified in the DSI are accurate and cover all external and internal factors.
- The DSI points out that the public had not "voiced significant concerns" in the Strategic Assessment process. The public was involved in the public hearings on the Strategic Assessment, and CORAR feels they will continue to play an active role in this process.

3. Do the Commissioner's preliminary views associated with each issue paper respond to the current environment and challenge?

CORAR agrees with the Commission's preliminary views to move expeditiously to more industry activities. There are a great deal of industry resources available, and these should be used to improve licensees' resolving programs. Examples of industry initiatives include the sharing of best practices as is done now with CORAR members; the NEI/NIST program in which the industry pays for round-robin calibration standards that are manufactured by the NIST and are used for radioisotope calibrations; and the NVLAP program for dosimetry in which standards have been developed by industry and a stand-alone certification program has been developed.

4. Which option do you endorse?

- A combination of the options appears to provide the best utilization of industry expertise. Option 2 suggests an expanded role for industry, which CORAR fully supports.
- Accreditation by industry groups and certification of industrial representatives as outlined in Option 3 would help provide technical expertise, and should be adopted.
- We also support industry groups developing and endorsing codes, standards, and guidelines as outlined in Option 4.
- We agree with option 2 in support of the concept of increasing industry's role by allowing more self-assessment in the regulatory process. NRC makes the point that they are experiencing a decline in agency resources. Increasing the opportunity for industry self-assessment could result in the lifting of the burden on NRC resources.