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December 2, 1996

Mr. John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Attn.: Chief of Docketing Service Branch
Washington, D.C. 20555-0001

Dear Mr. Hoyle:

Mallinckrodt, Inc. (MI) is submitting the enclosed comments on the NRC's Strategic Assessment of Regulatory Activities and Rebaselining and Direction Setting Issue Papers.

MI is a major manufacturer and distributor of radiopharmaceuticals – which include both the byproduct materials and accelerator (cyclotron) produced radionuclides. In addition to direct distribution to customers from our radiopharmaceutical manufacturing facility in St. Louis, Missouri, MI has 37 nuclear pharmacies located in major metropolitan areas of the U.S. Seventeen (17) of these nuclear pharmacies are licensed by the U.S. NRC and the remainder are administered through Agreement States.

MI supports the NRC initiative to determine which strategy and direction the agency should take to meet current and future challenges. As stakeholders, we appreciate having the opportunity to participate in the recent public meetings on Phase II of the NRC's Strategic Assessment Process in Washington, D.C., and Colorado Springs, as well as the opportunity to submit these written comments.

We have developed comments on several of the Direction Setting Issue (DSI) papers that impact our business and licenses under NRC and Agreement States. Our comments are provided in the following attachments:

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| Attachment I | Direction Setting Issue No. 4 - NRC's Relationship with Agreement States |
| Attachment II | Direction Setting Issue No. 5 - Low Level Radioactive Waste |
| Attachment III | Direction Setting Issue No. 7 - Material/Medical Oversight |
| Attachment IV | Direction Setting Issue No. 9 - Decommissioning Non-Reactor Facilities |
| Attachment V | Direction Setting Issue No. 12 - Risk-Informed, Performance-Based Regulation |
| Attachment VI | Direction Setting Issue No. 13 - The Role of Industry |
| Attachment VII | Direction Setting Issue No. 14- Public Communication Initiatives |
| Attachment VIII | Direction Setting Issue No. 21 - Fees |

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MI 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 these important issues. Please call me at (314) 895-2088 if we can be of further assistance, or if you need any clarifications.

Sincerely,



Ashok Dhar
Manager, Radiological Affairs

AD:jf
Attachments (8)

ATTACHMENT V

Mallinckrodt Inc. (MI)

Direction Setting Issue No. 12 - Risk-informed, Performance-based Regulation

General Comments:

MI supports this new NRC initiative. We believe that more effort should be made to establish a comprehensive national regulatory framework which is uniform and compatible with international standards. When the issue of uniform standards has been resolved, individual regulatory agencies will find it easier to determine which regulations should be risk-informed and performance-based and which should be prescriptive.

MI has attached detailed comments that indicate the concern that materials licensees have that current regulations are too prescriptive.

Specific Comments:

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

- The focus of this issue paper is on regulations appropriate to nuclear reactors. However, the NRC should be prepared to apply risk-informed, performance-based regulations to all licensees. The NRC should consider establishing a separate issue paper to address risk-informed, performance-based regulations, licensing, inspections and enforcement for materials licensees.
- The decision to apply risk-informed, performance-based regulations to a practice will depend on licensee conditions and the nature of the hazard. An important consideration is the level of training and experience that users must have to complete their tasks safely.
- The issue paper implies that higher risk activities call for more prescriptive regulations. MI does not agree with this assumption. Instead, we believe that the NRC will need to make a more sophisticated analysis when determining the appropriate regulatory basis for practices involving higher risk activities.
- There is insufficient consideration of cost effectiveness. Both regulatory practice and regulatory compliance must be cost effective.

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

- The issue paper has not properly addressed material licensees' concerns. In particular, medical licensees, manufacturers and the research community all have serious concerns that many NRC regulations are unnecessarily prescriptive.

- The issue paper mentions the influence of standard setting organizations and other regulators, but does not adequately discuss this. The decision on whether a prescriptive or performance-based regulation is appropriate depends on the complete regulatory framework. MI believes that there should be an independent radiation standard setting organization that is responsible for prescribing national standards. MI believes that agencies must then promulgate regulations compatible with these national standards, and that these regulations should be performance-based whenever practicable.

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

The Commissioner's preliminary views do not respond to the current environment and challenge of material licensees. Licensees have frequently commented on the unnecessary prescriptive nature of regulations including 10 CFR 35, reporting requirements, the absence of diminimis levels, burdensome security and control requirements and the redundancy of prescriptive emergency programs. A particular concern is dual regulations promulgated by the EPA and NRC which are conflicting. Examples include the EPA NESHAPS with a 10 and 3 mrem limit compared with NRC's 100 mrem, and EPA's separate 4 mrem groundwater standard.

4. Which option do you endorse?

- MI prefers elements of Option 3 and supports NRC effort to develop cost effective performance-based, risk-informed regulations. There is an urgent need to review those regulations that address practices with higher potential risk and those regulations that are most inappropriate first, such as dual regulations. However, the Probabilistic Risk Assessment (PRA) methods for nuclear materials and medical programs should be established prior to utilizing Option 3 for such licenses.
- The NRC should proactively and systematically review current regulations and not force licensees to obtain this review by petition and in a piecemeal manner.
- There is a need to reconsider the entire U.S. regulatory framework for ionizing radiation. The NRC should be proactive in this review. The objective should be to separate standard setting and regulatory activities and to eliminate duplicative and conflicting regulations. When this is achieved, it will be easier for each regulator to establish performance-based regulations.

Attachment V

Direction Setting Issue No. 12 - Risk-informed, Performance-based Regulation

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- MI recommends the need for a radiation standard setting agency that is not responsible for promulgating regulations. The EPA should not be such an agency, but should focus on regulating not standard setting. All regulatory agencies should be required to implement standards determined by the national standard setting agency.
- Once the position paper for risk-informed, performance-based regulations for materials and medical licenses is established, the stakeholders should be invited to participate in the meetings to discuss and understand the "cultural changes" that would be required for both NRC and licenses for the transition from prescriptive to risk-informed, performance-based regulations.