March 7, 2001

JoAnn Barron
Office of Compliance
FDA/CDRH
2094 Gaither Road
Rockville, MD 20850

SUBJECT: INVITATION TO MEET WITH NRC REPRESENTATIVES

Dear Ms. Barron:

This refers to a telephone conversation between Ms. Linda Howell of the NRC's Region IV office and you on March 1, 2001 regarding an invitation to meet with selected NRC staff to discuss your agency's inspection programs. As discussed during the telephone conversation noted above, the Director, Office of Nuclear Materials Safety and Safeguards recently chartered a Task Group to review the NRC's materials licensing and inspection programs. The purpose of this review is, in part, to examine the programs and make recommendations on improving the efficiency and effectiveness of the programs and providing a more risk-informed basis to NRC's materials program. A detailed description of this project is provided in the enclosed Charter.

One of the activities assigned to the Task Group is benchmarking the NRC materials inspection program against those of other Federal regulatory agencies to identify approaches or techniques which might be considered by the Task Group in developing recommendations for NRC's materials inspection program. The purpose of our request to meet with you is to learn more about your agency's inspection program and to discuss specific techniques or approaches that your agency has used to improve the effectiveness of the program or to risk-inform the program. To facilitate our discussion, I have enclosed a list of questions that we desire to discuss during the meeting. This list is for your reference and was intended to identify the types of issues that we wish to review during the meeting. If you have other insights concerning your agency's inspection program that you believe may be of interest to us, we welcome your input.

I appreciate your willingness to meet with the Task Group members to discuss your agency's inspection program. Our meeting is scheduled for 10:00 a.m., Thursday, March 15, 2001, at NRC Headquarters, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. A member of the Task Group will meet you in the lobby of One White Flint North and escort you to our meeting room. Directions to our offices may be found at http://www.nrc.gov/NRC/WHATIS/directio.html#_1_3.

Should you have any questions concerning this letter or the material enclosed, please contact me at (610) 337-5281 or Ms. Linda Howell at (817) 860-8213.

Sincerely,

/RA/

George Pangburn, Director
Division of Nuclear Materials Safety

Enclosures:
1. Comparison of Inspection Programs, Discussion Questions
2. Phase II Task Group Charter

cc:
John McCrohan, Director
Division of Mammography Quality and Radiation Programs
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Comparison of Inspection Programs - Discussion Questions

The following questions concern issues that NRC's Phase II Task Group would like to discuss with other Federal regulatory agencies as part of the Task Group's benchmarking efforts for the materials inspection program.

1. What does your agency inspect?

2. Who performs the inspections?
   - Are the inspectors direct employees of the agency?
   - Is the program delegated?
   - Does the agency use consultants or the regulated community in portions or all of its inspection program?

3. What does the inspection program consist of?
   - What methods are used to perform inspections?
   - What is the frequency of inspections?
   - Is a routine inspection program in place or are inspections conducted for cause?

4. What guidance documents are available?
   - What style and format (level of detail) are used?
   - How available is the guidance (electronic, through internet) and to whom is it available?

5. Is the inspection program performance-based or prescriptive?

6. How is risk information incorporated in the program or used during inspections?

7. How are inspection results transmitted to those who are regulated and to the public?

8. What does the agency's Enforcement Program consist of?

9. What processes relating to licensing/registration and inspection have been streamlined recently? Why and what was done?

10. How does the agency measure effectiveness of its inspection program?

11. Are feedback mechanisms from stakeholders and customers developed? Are they used by stakeholders? How does the agency use the information?

Enclosure (1)

CHARTER

PHASE II REVIEW AND REVISION OF NUCLEAR BYPRODUCT MATERIALS PROGRAM

Beginning in January 2001 a task group with membership from the Regions, NMSS and other HQ offices and the Agreement States will conduct an independent review of NMSS' nuclear byproduct materials program. The purpose of the review is to make recommendations to: 1) improve efficiency and effectiveness; 2) where possible, apply a more rigorous risk basis to the program and 3) help control or reduce user fees charged to materials licensees. The recommendations may include in their scope, revisions to the existing materials licensing and inspection program, management and organizational recommendations, event evaluation recommendations, changes to the enforcement policy and recommendations for the rulemaking agenda. This review will be broad and programmatic in nature, and will address issues in the current configuration of the program as well as how it may come to look in the future as the national materials program moves toward a 50 Agreement State structure. The product of the review will be a letter report from the Team Leader to the Director, Office of Nuclear Materials Safety and Safeguards.

Background:

Over the last several years, NMSS has carried out a number of staff initiatives designed to improve efficiency and effectiveness and provide a more risk-informed basis to the materials program. These include the Business Process Redesign (BPR), byproduct materials risk review, working group on generally-licensed devices, and the Phase I–Mallinckrodt overexposures review. These various staff initiatives coming as they have at different points in time are in need of a focused review to determine how best to consider and integrate their work into the materials licensing and inspection program under its current configuration. The need for this integration has become particularly acute as resources in the program have become more constrained.

For example, NMSS embarked on a program of Business Process Redesign (BPR) for the nuclear materials licensing program beginning in 1995. The objectives of BPR were to maintain or raise public safety, increase the speed of the licensing process, integrate information technology into the process and reduce resources. A major component of BPR–development of a comprehensive series of guidance documents intended to assist licensees and NMSS staff–is nearly complete and is being used by the staff in review of license applications. This effort is expected to reap significant benefits in terms of timeliness, consistency and customer service for materials licensees. Other aspects of BPR , such as improving the Technical Assistance Request (TAR) process and electronic processing of license applications, remain to be fully integrated into the materials program.

NMSS has also sought to make the materials program more risk-informed and performance-based through formation of the Nuclear Byproduct Material Risk Review Group. This group prepared a technical basis document– NUREG/CR-6642–which was a first step in developing and implementing a formal and systematic approach to applying risk insights to the materials program. The Risk Task Group within NMSS is building on that effort in accordance with a plan laid out in SECY-99-100, "Framework for Risk-Informed Regulation in the Office of Nuclear

Materials Safety and Safeguards." This work needs to be evaluated to determine if we have enough risk information to make specific programmatic changes to improve efficiency and effectiveness (for example, revision of inspection frequencies) or if additional work needs to be done to provide that information.

In response to multiple occupational extremity exposures in excess of the NRC annual limits at Mallinckrodt's Maryland Heights, MO, and a reported overexposure to the extremities of a pharmacist at Mallinckrodt's Harrisburg, PA nuclear pharmacy, the Director, Office of Nuclear Materials Safety and Safeguards (NMSS) established a Lessons Learned Task Group. The Task Group's efforts were the first phase of a multi-phase review of the materials program. The Phase I group was charged with examining the specific regulatory issues surrounding NRC's licensing, inspection and rulemaking, and the jurisdiction of the NRC and other regulatory programs, associated with these overexposures. The Phase I group issued its report on November 14, 2000 and identified specific recommendations for rulemaking, licensing, and inspection along with the bases for those recommendations. These recommendations need to be evaluated for application to the entire materials program, as appropriate.

Other staff initiatives such as the National Materials Program, event evaluation working group, and the medical pilot program are ongoing. These programs and their potential for improved efficiencies and effectiveness of the NMSS nuclear byproduct materials program also need to be considered in a comprehensive manner.

The NMSS byproduct materials program could also benefit from an independent assessment of how the program might be improved through various management, organizational and information technology dimensions.

Objective: The objective of the Phase II effort is to review the NMSS byproduct materials licensing, inspection, enforcement, rulemaking and event reporting/evaluation programs in light of these various staff initiatives and to make recommendations to: 1) improve efficiency and effectiveness; 2) where possible, apply a more rigorous risk basis to the program and 3) help control or reduce user fees charged to materials licensees. The group's recommendations will be within the constraints of existing resources (i.e., resource-neutral), but it will also consider how the program would look if a significant resource reduction were imposed.

The working group described above will conduct the review according to the schedule described below. The group will be chaired by the Director, Division of Nuclear Materials Safety, Region I and will be augmented in its work by various subject matter experts.

The working group will use as a guiding principle the four agency performance goals: maintaining safety; reducing unnecessary regulatory burden; enhancing public confidence; and efficiency, effectiveness, and realism. The working group will make use of the following in its efforts:

- NUREG-6642, Nuclear Byproduct Materials Risk Study
- Specific recommendations from Phase I
- Initial results of TI for medical pilot
- Human factors considerations,
- Results of IMNS audit on use of Form 591
- Inspection Manual Chapter 2800

- NUREG-1556 series
- Event reporting/assesment group

SPECIFIC TASKS:

1. Evaluate the specific findings and recommendations of Phase I to identify those that are candidates for broader application to the materials licensing and inspection program.

2. Benchmark the NRC materials inspection program against those of other Federal regulatory agencies to identify approaches or techniques which might: 1) improve efficiency and effectiveness of the program, 2) improve public confidence; and 3) reduce unnecessary regulatory burden, while maintaining safety. Candidate agencies could include OSHA, FDA, EPA, USDA, Coast Guard, and FAA.

3. Evaluate inspection frequencies and approaches in IMC 2800 and associated Inspection Procedures in light of the results of the Nuclear Materials Risk Review and the Phase I study to determine if programmatic changes are warranted to improve efficiency and effectiveness while maintaining safety. Make recommendations for specific changes based on the risks posed by specific uses and classes of uses.

4. Evaluate licensee classes (specific, general, exempt, registrants) in light of the results of the Nuclear Materials Risk Review and the Phase I study to determine if licensees have the right level of agency control for the risk posed by their specific use of material. Make recommendations for changes to the materials licensing program, as appropriate.

5. Evaluate results of audit of Form 591 and preliminary results from medical pilot Temporary Instruction to determine if changes to the inspection process in IMC 2800 are warranted.

6. Examine major aspects of the inspection and licensing program to determine where greater use of technology could improve efficiency and effectiveness.

7. Examine current organizational structures and work arrangements (i.e., flexiplace) to determine if changes could improve efficiency and effectiveness of the byproduct materials program. Maintain awareness of the ongoing work of the National Materials Program working group and how that effort may impact the NRC byproduct materials program.

8. Evaluate current headquarters licensing and inspection activities (exempt distribution licensing, sealed source and device reviews, etc.) to determine if these functions could be performed more efficiently in the Regions.

9. Evaluate the ongoing work of the events reporting group and the role played by Operational Events Briefings, regional coordination and the Generic Assessment Panel to determine if efficiencies or effectiveness in events reporting and analysis can be improved.

10. Examine the Technical Assistance Request process for materials licensing to determine if changes are warranted to improve the timeliness of licensing actions.

11. Estimate short term costs and long term resource savings associated with recommendations.

12. Working in concert with OCFO and PMDA evaluate implications of recommendations for materials users fees.

Methodology: The group will conduct its work through review of relevant documents; interviews with subject matter experts, NMSS managers, and others; discussion sessions with representatives of other Federal regulatory agencies, and brainstorming sessions.

Working Group Members:

George Pangburn, Director, DNMS, Region I, Chair
John Kinneman, RI
Tom Decker, RII
John Madera, RIII
Linda Howell, RIV
Brian Smith–NMSS
Thomas Young–NMSS
Lawrence Kokajko–NMSS/RTG
Jim Lieberman—OGC
Jocelyn Mitchell—RES
Richard Blanton-OSTP
TBD— Organization of Agreement States Representative

Subject Matter Experts:

George Deegan, IMNS—Materials Budget Process
Claudia Seelig/OCFO Representative—Materials Fees Issues
John Lubinski/Sally Merchant—OE

Timeline:

1st working group meeting	January 2001
Working group recommendations	September 2001

The final product will be a report from the Chair of the working group to the Director, NMSS. The report will describe the current condition of the program; the approach followed by the group in evaluating that condition; the short-term and long-term recommendations of the group (including the bases for those recommendations) and the resource implications of its recommendations for the nuclear byproduct materials program budget.