

No. S-19-92  
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Remarks by  
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Commission

at the

Nuclear Materials Licensees Regulation  
Briefing

Washington, D.C.  
June 8, 1992

It is indeed a pleasure for me to be here this morning to kick off this two-day conference on the regulation of nuclear materials licensees. As many of you know, the issues associated with the licensing and regulation of materials licensees have taken on growing importance at the Nuclear Regulatory Commission, particularly over the past five years or so, and with every indication that these various issues will continue to occupy the Commission's attention for the foreseeable future. Consequently, this conference comes at a most timely point.

I should also say that with the great diversity of activities that we find in the materials area -- ranging from waste disposal and decommissioning, to radiopharmaceutical manufacturing, fuel fabrication, radiography, and medical and academic activities -- the challenges that the materials area presents for the regulator, as well as for the regulated community, are oftentimes as complex as those that we encounter for power reactors.

Indeed, that diversity is reflected in the wide range of topics that you are scheduled to cover these next two days.

Fortunately, I haven't drawn the task of covering every one of those topics here in my opening remarks. Instead, the organizers of this conference have assembled a truly first-rate group of speakers, some of which I am pleased to note come from the NRC,

to address each of the many topics in detail, and so with your indulgence, I will defer to your later speakers for more detailed discussions of these various topics.

Instead, what I would like to do is to provide a general overview of the agency's materials licensing and regulatory program from the perspective of a Commissioner, touching in general terms on some of the more important issues that have occupied the Commission in this area, and then concluding with some observations about what the future might hold for materials licensing and regulation.

### **Introduction**

At the risk of overwhelming you with statistics right at the outset, let me start with a few numbers, to give you a flavor of the general dimensions of our materials licensing program and the diverse character of the activities encompassed by that program:

- o First, we have approximately 23,000 NRC licenses currently in effect for medical, academic, and industrial uses of nuclear material -- roughly 7,800 of which are administered directly by the NRC, with the remaining 15,000 administered by the 29 States that participate in our Agreement State Program. Additionally, the NRC licenses and inspects all commercial nuclear fuel facilities involved in the processing and fabrication of uranium ore into reactor fuel. This includes two uranium hexafluoride production facilities and nine uranium fuel fabrication facilities.
- o We will also be responsible for licensing the proposed uranium enrichment facility in Homer, Louisiana, and perhaps have a regulatory role with regard to the existing gaseous diffusion plants, depending upon the final outcome of the energy legislation currently pending in Congress.
- o Second, NRC issues approximately 5,600 new or renewed licenses, or amendments to those licenses, annually for materials activities, with our Agreement States processing more than 13,000 such actions annually.
- o Third, when it comes to inspections, NRC conducts approximately 3,100 health and

safety inspections of nuclear materials licensees annually, with an additional 4,800 conducted by the Agreement States.

- o Fourth, insofar as enforcement activities are concerned, over the past four years we have had, on average, about seventy escalated enforcement actions per year involving materials licensees (which includes orders), roughly 2/3 of which have been accompanied by the imposition of a civil penalty. In this regard, I would note that the number of enforcement actions, as well as the amount of the civil penalties collected during this period (1988-1991) has remained relatively constant.
- o And finally, perhaps much to the chagrin of many of you here in this room, we are required by Congress to collect 100 percent of the cost of our activities in this area from those that we license and regulate -- a subject to which I will return later in my remarks.

Against this backdrop, and recognizing that the wide diversity of our activities in this area is reflected in the diversity of the audience and of your individual interests here this morning, there are a number of issues that have recently come, or are currently pending, before the Commission that I would like to discuss. In particular, there are four areas where there has been a good deal of recent activity: (i) license fees under the new user fee rule; (ii) our recent activities in the decommissioning area and, in particular, the recently-approved Site Decommissioning Management Plan; (iii) the status of the agency's ongoing reevaluation of how we regulate major materials licensees; and (iv) the issue of State Compatibility for Agreement States.

### License Fees

Let me begin with the issue that has had an impact on virtually every NRC licensee, regardless of the type of activity in which you engage -- the issue of license fees. As you all, no doubt, are aware, Congress has mandated that the Commission recover 100 percent of our budget through fees imposed on the licensees that we regulate. That requirement, which was adopted in the Omnibus Budget Reconciliation Act of 1990 and which extends for a five-year period beginning in fiscal year 1991, has been implemented through the imposition of annual fees under 10 CFR Part 171. To give you an idea of the magnitude of the fees in the materials area, these fees range from --

- o \$700,000 to \$1.6 million for fuel facility licensees;
- o \$67,000, to \$100,000 for uranium recovery facility licensees; and
- o \$390 to nearly \$11,000 for all other categories of materials users.

Because of the concern over the impact of these fees on small businesses, particularly in the area of materials activities, the Commission has adopted a "small entity fee limitation" of \$1,800 for licensees who qualify. Specifically, this limitation applies to --

- o small businesses with annual receipts of \$3.5 million or less;
- o private practice physicians with annual receipts of \$1 million or less;
- o small governmental entities with populations of less than 50,000; and
- o small educational institutions which are supported by qualifying small governmental entities or have fewer than 500 employees.

As a result of the impact on small licensees, particularly materials licensees, the Commission amended Part 171 just this past month to lower the cap to \$400 for those licensees who qualify as --

- o small businesses or non-profit organizations with gross annual receipts of less than \$250,000; or
- o small governmental jurisdictions with populations of less than 20,000.

Needless to say, even with the small business limitation, the fee structure has not been wildly popular. Indeed, during the five-month period from July to December of last year, we terminated

nearly 2,000 materials licenses, largely for the reason that the holders of those licenses reached the conclusion that it was no longer cost-effective to continue to engage in the licensed activity, given the new fee structure.

Nevertheless, we are obligated under the law passed by Congress to collect 100 percent of our budget through these user fees. Recognizing that this is having a tremendous impact on our licensees -- and particularly the materials licensees -- there is unfortunately very little that the Commission can do to alleviate what I am sure is a most difficult situation for many of you. I would note that if you believe your own individual situation is particularly egregious, for some reason, and you do not qualify under the small entity fee limitation, there is a procedure for seeking an exemption from the fee. But I should emphasize that to date, exemptions have been quite rare, largely for the reason that what we don't collect from one licensee, must in turn come from some other licensee -- and invariably, that other licensee will complain just as loud. So the exemption process is available to you, but understand the difficulty that you face in demonstrating that you should be granted an exemption from your fee.

### **Site Decommissioning Management Plan**

Let me turn my attention now to a subject that has been a matter of high priority for the Commission over the past year, the program for cleaning up and stabilizing various nuclear materials sites around the country, pursuant to the so-called "Site Decommissioning Management Plan", or SDMP.

Over the past several years, we have identified on the order of about 40 sites around the country with buildings, former waste disposal areas, large pilings of tailings, groundwater, and soil contaminated with low levels of uranium or thorium or other radionuclides. Some of these sites are under the control of active NRC licenses, while the licenses for other sites have been terminated or may never have been issued.

While the Commission adopted a program in 1990 to bring about the timely cleanup of these sites, progress has been slower in coming than the Commission and our staff would like to see. Accordingly, in April of this year, the Commission moved to accelerate the cleanup of these sites, through a number of revisions to the Site Decommissioning Management Plan. In particular, the Commission took the following steps:

First, the Commission laid out the cleanup criteria that will be used in determining whether sites have been sufficiently decontaminated so that they may be

released for unrestricted use. These criteria, which are set forth in various existing agency guidance documents, will be used pending the development of generic cleanup criteria.

Second, if a licensee cleans up its site in accordance with these criteria, the NRC will not require the licensee to conduct additional cleanup in response to generic NRC standards that might be established at some future point. This is the so-called "finality" policy.

Third, the revised SDMP sets forth generic schedules, with the timing to be addressed on a case-by-case basis, for completing cleanup. In general, the Commission expects cleanup to be completed within four years after operations cease, or within three years after issuance of an initial cleanup order.

Fourth, while the Commission obviously is desirous of obtaining voluntary cooperation, the agency is prepared to take additional steps to secure the necessary commitments, including the issuance of Demands for Information to establish licensee commitments to perform decommissioning, as well as the issuance of Orders, including immediately effective orders, to compel cleanup by licensees or other responsible parties, and the establishment of an escrow account where a licensee fails to comply with an order.

I should note that the agency has issued its first Order pursuant to this policy, and, depending upon the circumstances of individual cases, may find itself issuing additional such Orders.

Accordingly, for those of you who find yourself on the SDMP list, I would encourage you to familiarize yourself with the recent steps taken by the Commission in this area. I would observe that, while progress has been slow in coming at many sites, there are some where the cooperation has been salutary, and I would certainly encourage that approach, in lieu of our resorting to the legal mechanisms that I have described.

Insofar as the significant issues before us in this area, let me note three issues in particular:

First, as I alluded to earlier, we are in the process of establishing generic standards for the cleanup of these sites, pursuant to a process recently approved by the Commission -- and referred to as the "enhanced participatory rulemaking process" for establishing residual radioactivity standards. Many of you may recognize this as the process that supplanted the so-

called "BRC" -- or Below Regulatory Concern -- process. It would be our hope that through this process, we will be able to address, in a generic fashion, the question of "how clean is clean enough" for these sites. Until that time, however, the existing guidance that I referred to earlier will constitute the operative standards, with, as I indicated, sites cleaned up in accordance with that guidance not having to be reopened when the generic criteria are established.

Second, there are about 20 sites on the SDMP list which have large volumes of soil or tailings, generally containing low levels of uranium or thorium contamination, with five sites on the list having more than 1 million cubic feet of such wastes. Options for disposal of such high-volume waste are limited. Obviously, the cost of disposal at the existing commercial low-level waste sites makes this option prohibitively expensive. Alternatively, in some situations, disposal of such material at existing uranium mill tailings impoundments may be permissible, and the Commission is in the process of formulating guidance on this option. Finally, there is the general authority of section 20.302 of our regulations, pursuant to which a licensee may request permission to dispose of this material in some other manner, including on-site disposal. Again, of course, this approach would be highly case-specific.

Third and finally, prior to 1981, there were a number of cases where licensees disposed of material pursuant to Section 20.304 of our regulations, in a manner that did not require Commission approval. Some of these burials included long-lived uranium and thorium wastes. Where this has occurred, the agency intends to evaluate such cases to determine the suitability of the approach taken, with the possibility that exhumation of such wastes may be required to meet the agency's unrestricted use criterion. Three sites have been identified to date and are currently being evaluated to determine whether the burial satisfies the relevant Commission criteria; and the staff is reviewing existing records in an effort to identify any additional cases.

#### **NUREG 1324 -- Regulation of Major Materials Licensees**

Let me turn my attention now to the third general topic that I'd like to discuss, the ongoing agency reevaluation of how we

regulate our major materials licensees. Recognizing that this is a topic that I understand you will be discussing in more detail later in this conference, I'll make my remarks here brief and general.

By way of background, over the past five years or so, we have seen several significant events at a number of facilities -- beginning with an event at the Sequoyah Fuels facility in Oklahoma in 1986 involving a ruptured uranium hexafluoride container, and including two events at NFS Erwin and an event at GE-Wilmington in 1991, and recurrent problems at Sequoyah Fuels this past year.

As a result of these various events, and based upon the detailed evaluations that were undertaken to address the root causes of these events -- particularly the Incident Investigation Team that examined the GE-Wilmington event -- Bob Bernero, the director of our Office of Nuclear Material Safety and Safeguards, established a task force in August of last year to focus on the licensing and regulatory process for large material facilities. Quoting from the Charter,

"This effort is to start with an examination of the full range of safety, safeguards, and environmental issues that should be considered in the regulation of large material licensees. The task force should systematically identify and classify those issues in a regulatory system that can be addressed by licensees in their license applications and engineering documents and then reviewed and acted upon by the staff. The task force effort should include the outlines of documents such as a Standard Format and Content for License Applications, a Standard Review Plan, a Standard License Format and Content, and an Inspection Manual Chapter and accompanying procedures."

The Task Force, which was headed up by Charlie Haughney, set about that task and, in February of 1992, published for public comment the results of its efforts in NUREG-1324, "Proposed Method for Regulating Major Materials Licensees."

I won't go into detail on the findings of the Task Force, nor the detailed recommendations -- but I certainly commend this report to those of you who have an interest in this matter. In particular, section 5.3 of the report sets forth the recommendations of the Task Force on those areas where additional regulatory attention, in the form of modifications or additions to our current regulations, should be considered. In particular, the proposal to require the performance of a "Hazards Analysis" strikes me as a particularly important area for your and our attention. I would also note that, while many of the recommendations involve internal agency issues, the

recommendations in section 5.4 of the report on agency staffing include a recommendation that NMSS establish an organization to conduct team inspections at fuel cycle and large materials plants.

Based upon the comments that have been filed to date -- and I should note that the comment period just closed at the end of May -- it appears that these two issues -- the preparation of a hazards analysis and the proposal concerning team inspections in the materials arena -- have garnered much of the attention. Of particular note, in my view, are the comments that we have received that express the concern that the team inspections may actually detract from safe operations, because of the significant licensee commitment involved in such inspections and the potential for diverting limited licensee resources from ensuring safe operations at the facility. This is a concern that we should examine carefully, because the last thing that any of us wants to do is to have an adverse impact on safety.

Additionally, beyond these two general areas, the issue of how prescriptive the regulations should be has also been the subject of considerable comment, with many commenters urging the Commission to emphasize performance-based regulations in lieu of prescriptive requirements, where we conclude new regulations are necessary.

Where do we go from here? The staff is currently in the process of evaluating the comments that have been received -- of which there have been about a dozen -- and will be formulating final recommendations on the actions to be taken. I would anticipate that when the staff reaches that point, the Commission itself will desire to be briefed on the effort, reviewing the findings and recommendations with some care, and then proceed to reach some final conclusions about the steps that should be taken in this area.

### **Agreement State Compatibility**

With the time remaining, the final topic that I'd like to cover this morning is the issue of Agreement State Compatibility, and the recent discussions that the Commission has had in this area. I assume that all of you are familiar with the Agreement State Program and the general concept of compatibility. Just briefly, therefore, you are aware that the NRC may relinquish its authority to regulate certain activities to individual States, so long as those States maintain what are referred to as "compatible" programs. This authority includes many materials activities, but does not permit States to engage in the regulation of reactor licensees. We currently have 29 Agreement States.

It is in the area of compatibility that the question has arisen, "How much flexibility should the States have to set their own requirements, particularly more stringent requirements in the area of radiation protection standards?" And the question has arisen most prominently in the area of low-level waste disposal, where the States have been given the responsibility by Congress for developing new disposal capacity under the compact scheme enacted by Congress in 1985. More precisely, the issue, as I see it, is whether those States that have been tapped to host new low-level waste disposal facilities should be permitted to establish radiation protection standards for those facilities that exceed the standards established by the NRC (i.e., that are more stringent than NRC standards).

In view of the interest in the compatibility issue, the Commission decided last year to solicit comments and recommendations on our general approach to compatibility and, on December 23rd, published a Federal Register Notice outlining the nature of the issue and the questions on which the Commission was interested in receiving public comment.

The comment period has now closed and we have received over one-hundred comments, which, in turn, cover the entire spectrum from maintaining uniform federal standards to allowing States to establish more stringent standards.

Let me say that while this initiative may not affect many of you directly, for those of you with a role in the low-level waste disposal program, this is an initiative that may have an important impact. In addition, there may be some -- indeed, there are some -- who argue for relaxing the compatibility procedures to permit greater flexibility for States in areas beyond low-level waste disposal.

Accordingly, with the comment period now closed and the staff in the process of evaluating the comments that have been submitted, the staff will be coming to the Commission later this summer with its recommendations on how to proceed in this area -- and I urge those of you who have an interest in this area or who may be affected by the decisions reached to follow the process closely.

### **Conclusion**

Those four issues -- license fees, the SDMP Program, NUREG-1324, and Agreement State Compatibility -- are just four of the many issues affecting materials licensees that are currently pending before the Commission, or that have been addressed in recent Commission decisions. I apologize for covering those issues in such a general manner, as well as for all of the other issues that I did not discuss, but you have an excellent group of

speakers assembled here for this conference, and I trust that your subsequent speakers will make up for my oversights.

With that, let me bring my remarks to a close with one final observation. Without a doubt, the NRC's materials licensing program is undergoing a significant evolution. In some respects, this is occurring as a result of the additional responsibilities that Congress has directed us to undertake, with the areas of low- and high-level waste disposal coming to mind as the two most obvious areas. But beyond that, the evolution is more importantly a direct consequence of the fact that, over the past five or so years, we have experienced a number of significant events at materials facilities, beginning with an event at the Sequoyah fuel cycle facility in 1986 and including several events in the intervening years at facilities such as NFS Erwin, GE Wilmington, Amershamm, Radiation Sterilizers of Georgia, and Cintichem.

The elevated level of regulatory attention that we are now seeing being devoted to materials licensees is, in some respects, analogous to the situation that we faced in the mid-1980s on the reactor side, when several significant reactor events, including events at the Davis-Besse, San Onofre, Rancho Seco, and Salem nuclear plants, led to a number of important changes in the agency's regulatory oversight of reactors, including the institution of the so-called "problem plant" process, as well as the formation of our incident investigation program.

Because of the obvious differences between reactor and materials licensees, I suspect that we'll never reach the day when our regulatory programs are virtually identical in these two fields. But I do believe it is fair to say that the recent escalation of interest in the materials area and the changes that are currently under discussion reflects a desire to bring about improvements in the way that materials licensing and regulation is conducted. The challenge that we face is to approach this task in a balanced and reasonable fashion, taking into account the obvious differences between reactor and materials licensees, and come up with sensible changes that will move us toward the objective of a disciplined and efficient regulatory process. Thank you.