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November 14, 2008

Michael T. Lesar, Chief
Rulemaking, Directives, and Editing Branch
Office of Administration
Mail Stop: T-6 D59
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: Comments on Proposed Revision of NRC Enforcement Policy

Dear Mr. Lesar:

Morgan, Lewis & Bockius, LLP respectfully offers the following comments regarding one of the proposed revisions to the U.S. Nuclear Regulatory Commission ("NRC" or "Commission") Enforcement Policy, as summarized in the Commission's recent request for comments. *See* NRC Enforcement Policy Revision, Notice of Availability of Draft and Request for Comments, 73 Fed. Reg. 53,286 (Sept. 15, 2008) ("Notice"). We commend the Commission for its efforts to update its Enforcement Policy to reflect changing requirements, experience and circumstances.

Among the changes proposed, however, is the elimination of the "Interim Enforcement Policy for Generally Licensed Devices Containing Byproduct Material (10 CFR 31.5)." *Id.* at 53,290-1. As described in the Notice:

This interim policy addressed violations that persons licensed pursuant to 10 CFR 31.5 discovered and reported before, as well as during, the initial cycle of a notice and response program related to the revision of 10 CFR 31.5. This interim policy was expected to remain in effect through completion of one cycle of the licensee notice and response program. Since one cycle is complete, this interim policy is no longer in effect.

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E-RIDS = ADM-03
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Id. at 53,291. For the reasons described below, we believe that the elimination of the above-referenced Interim Enforcement Policy (“IEP”) is problematic and that the IEP should continue to apply to general licensees who are not subject to the NRC registration program that covers certain generally licensed devices. Insofar as the Commission ultimately concludes that the total elimination of the IEP is in the interest of public health and safety, we recommend that the Commission revise its Enforcement Policy to clarify that the NRC remains able to exercise enforcement discretion, when appropriate, with respect to the general licensees that were previously covered by the IEP. This alternative recommendation is described below as well.

Starting in 1991, the Commission embarked on a rulemaking effort to address the accountability of generally licensed devices. *See* 56 Fed. Reg. 67,011 (Dec. 27, 1991). Although public comments on the proposed rule were received by the NRC, it did not go forward with a final rule because of resource constraints. *See* “Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material To Provide Requested Information,” 63 Fed. Reg. 66,492, 66,493 (Dec. 2, 1998). After further consideration of the issues and with assistance from the Organization of Agreement States, the NRC, in 1998, withdrew the 1991 rulemaking, but initiated a new rulemaking. The objective of the new rulemaking was to implement an annual registration program as proposed in the 1991 rulemaking, but limited to higher risk sources, as well as to add a requirement that licensees provide information in response to requests made by the NRC. *Id.* The 1998 rulemaking itself proposed to revise 10 C.F.R. § 31.5(c) to add a provision that would require general licensees to respond to written requests for information from the NRC.

In proposing revisions to 10 C.F.R. § 31.5 to require general licensees possessing “certain measuring, gauging, or controlling devices that contain byproduct material” to “provide . . . information concerning these devices,” the Commission concurrently proposed the IEP now at issue. *Id.* at 66,492. Under the IEP, the Commission stated that it would normally not take enforcement action “for violations identified [for example, for untested or leaking sources] by a licensee and reported to the NRC if appropriate corrective action is taken. For the period that the interim policy is in effect, it would also apply to general licensees not subject to the registration requirement if they identify and report violations and take appropriate corrective action.” *Id.* The statement of considerations accompanying the final rulemaking added, as a factor, that the licensee “[h]as undertaken good faith efforts to respond to NRC notices and provide requested information.” “Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information,” 64 Fed. Reg. 42,269, 42,270 (Aug. 4, 1999).

The objective of providing such discretion was laudatory—to “encourage general licensees to search their facilities to ensure sources are located, to determine if applicable requirements have been met, and to develop appropriate corrective action when deficiencies are found.” 63 Fed. Reg. at 66,494. In developing and implementing the IEP, the Commission highlighted the fact

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that many general licensees, of which there were estimated to be over 60,000 at the time, “[we]re *not* aware of the appropriate regulations.” *Id.* at 66,442. Notably, however, the primary method of ensuring that they became “aware of and underst[ood] the requirements” was the registration program described above, which, at the time, involved only about 6,000 of the general licensees responsible for devices containing byproduct material. *Id.* at 42,270. This relatively small number of general licensees were licensees for only certain kinds of such devices.

How the IEP applied to the other tens of thousands licensees of *other* kinds of devices—licensees who did not participate in the registration program—was left unclear. The duration of the IEP, for instance, was linked solely to general licensees participating in the registration process. As the final rule provided, the IEP would remain in effect for “one complete cycle of the registration program.” *Id.* The period of “one full cycle” is defined as “the issuance of one round of registration requests to all affected general licensees.” *Id.* This obviously is problematic for the many general licenses who are not subject to the registration program and, therefore, did not participate in the registration process, because the timing of the NRC’s registration requests are largely unknown to them.

The Notice proposing the elimination of the IEP is equally unclear in that it is only accompanied by the stark declaration that “[s]ince one cycle is complete, [the IEP] is no longer in effect.” 73 Fed. Reg. at 53,291. The abrupt termination of the IEP that is now being considered could result in fundamental unfairness to at least some licensees who, although otherwise uninvolved in the registration process, in good faith and in at least partial reliance on the fact that the NRC would forego enforcement action, initiated comprehensive and robust programs, at great expense, to ensure compliance with all applicable NRC requirements. As the NRC Staff surely appreciates, these programs likely include communication with the regulators—NRC and, where appropriate, Agreement States—to ensure timely notification and involvement, extensive and costly efforts to ensure the accountability and proper disposition of the particular generally licensed device, and even corrective action programs to avoid recurrence of any underlying systemic deficiencies. In some instances, these programs may be well underway by the time of the announced end of the IEP. Hypothetically, if a general licensee had, in good faith, started but not yet completed its efforts, it may be caught “mid-air,” and subject to enforcement actions that do not appear to be justified. A suitable extension of the discretion allowed by the IEP should be made available in these circumstances.

The abrupt termination of the IEP also represents a significant “lost opportunity” for other general licensees who also were not covered by the registration program and who, despite good faith efforts to comply with all known health and safety regulations applicable to their lines of business and practices, only recently became aware of their regulatory obligations as general licensees of the NRC and/or the “safe harbor” offered by the IEP. Realistically, many licensees who do not need to register with the NRC—even today—do not know that they are general licensees or that they are covered by the IEP. This is understandable given that past NRC

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rulemakings have focused on general licensees subject to the registration program. The titles of these rulemakings alone reveal the NRC's nearly exclusive focus on licensees of "*certain* generally licensed industrial devices containing byproduct material." The substantive terms of these rulemakings are even more revealing in that they, above all else, establish an information sharing program—the registration program—which, as noted above, targeted only a very small portion of the total number of general licensees at the time (6,000 out of 44,000). The disproportionate emphasis placed on licensees participating in the registration program and now the proposed elimination of the IEP has prevented other licensees from receiving a full and fair opportunity to ensure compliance with applicable NRC regulations, which, in and of itself, justifies preserving the status quo for those licensees with the respect to the IEP.

Even general licensees who might have been aware of applicable NRC regulations might not have been aware of the fact that the IEP applied to them and offered them a "safe harbor." Significantly, one of the criteria for determining whether enforcement action would be taken against a licensee under the IEP asked whether the licensee in question undertook "good faith efforts to respond to NRC notices and provide requested information." Given that this criterion would only apply to a licensee that is subject to the registration program, it stands to reason that many general licensees took this to mean that the IEP did not apply to them and that it applied only to registered licensees. In sum, there are various reasons to conclude that general licensees who have not participated in the registration process have not received the benefit of the IEP to the same extent of those licensees who have participated in the process. As a result, the IEP should be extended for general licensees under specified circumstances so that all general licensees are accorded the same opportunity.

Alternatively, the proposed revision of the Enforcement Policy does leave intact the exercise of enforcement discretion in certain contexts that may offer some relief, short of continuing the IEP. In large measure, though, the areas in which discretion may be exercised in the future and which are explicitly identified are related to nuclear power reactors. *See* Draft "NRC Enforcement Policy," Section 3.0 (NRC ADAMS Accession No. ML082800381). Potentially applicable to violations that may be associated with generally licensed devices, however, is discretion involving special circumstances. *Id.*, Sec. 3.5. Without specific regard to whether the underlying activity is reactor- or materials-related, this provision appears to recognize that there may be situations in which "normal guidance in the policy is unwarranted," *id.*, and the NRC should refrain from initiating an enforcement action. While sensibly nonspecific in describing circumstances in which it may be applied, we believe that it would be sound policy and a prudent exercise of agency discretion to continue to forego enforcement for general licensees who have embarked on broad and comprehensive programs to self-identify violations, remediate those situations identified to promptly protect public health and safety, and have initiated efforts to achieve lasting corrective actions to avoid recurrence—hallmarks of the NRC's enforcement program.

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Accordingly, in the event that the Commission is not inclined to continue the specific form of discretion related to general licensee, discussed above, we would recommend that Section 3.5 be revised to expressly acknowledge its applicability to all NRC licensees when the appropriate prerequisites are found.

Sincerely,



Lawrence J. Chandler