December 3, 2013

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THRU: Robert K. Johnson, Chief
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SUBJECT: LESSONS LEARNED FROM THE NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY LICENSE RENEWAL

The following is a summary of lessons learned by the Office of Nuclear Material Safety and Safeguards (NMSS) in the ten year renewal of the Special Nuclear Material (SNM) License, SNM-362, for the Department of Commerce, National Institute of Standards and Technology (NIST).

The U.S. Nuclear Regulatory Commission (NRC) accepted the License Renewal Application (LRA) on June 29, 2007, and staff recently completed the license renewal on September 10, 2013. There are unique circumstances that are present in most every license renewal. The nature of this license and duration of the renewal require review and explanation to understand events that could not be avoided, as well as conditions within the Division that extended this action beyond the scope of normal licensing within Fuel Cycle.

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The report will discuss challenges encountered, what worked well, and recommendations:

1. Issues Identified.

a. Weak Project Management Leadership. The renewal took over 6 years to complete and there were 6 Project Managers (PMs) assigned during this time. The responsibility for this amount of turnover is a management issue. There were likely unavoidable staffing issues driving management to make these changes. There were also Fuel Cycle Safety and Safeguards (FCSS) management changes during the renewal period, as well as NIST staffing changes. FCSS experienced 4 Director and 2 Deputy changes during this period that contributed a great deal of churn within the Division. NIST experienced a Radiation Safety Officer (RSO) change midway through the renewal.

Some of the reasons for the lengthy renewal were entirely beyond Agency control, but leadership was certainly a responsibility to be managed. Numerous renewal issues fell into neglect that needed to be addressed in a renewal. Until 2011, not one PM had really been in place long enough to fully grasp what was complete or in-process, and provide focus to the direction of the renewal. The PM assuming responsibility in 2011 carried the renewal forward until his retirement at the end of 2012. His assignment to the position was extremely valuable in turning the corner toward an endpoint of renewal.

LESSON LEARNED: PMs should not normally be reassigned during renewal. The goal would be that PM continuity would be maintained, unless extenuating circumstances exist.

RECOMMENDATION: If a change to a PM is unavoidable, the reassignment should be documented with an internal memo to management, recording the basis for change and ensuring a thorough evaluation of the circumstance is carried out. This should ensure an adequate turnover of responsibility. Along with this, the licensee must be notified of any change in PM assignment. There was only one documented case found of licensee notification of PM change.

b. Poor Licensing Discipline. The frequent turnover in PM leadership led to a lack of ownership. Management turnover contributed to a lack of accountability for the PMs. This, in combination with regulatory issues NIST was attempting to manage concurrently, allowed them to lose focus and contributed to the LRA drift. The following are some of the symptoms or results of all this change:

1) There were approximately 40 documented exchanges in correspondence between the Agency and NIST. These consisted primarily of Requests for Additional Information (RAIs) and NIST responses, the most recent sent in on August 19, 2013. A certain amount of written communication in licensing space is necessary to ensure commitments are tied down. While little of this correspondence is redundant, it is representative of a piecemeal renewal developed in-process, without following a roadmap of necessary licensing dialogue. The complexity of the NIST license is addressed below, but the guidance for renewal is clear for both SNM and broad scope activity. Much of this written dialogue could have been reduced through using face-to-face meetings or even regular teleconferences, reviewing the way ahead to ensure arrival at a complete and satisfactory renewal.

LESSON LEARNED: The period preceding acceptance of any licensing request is as important as after acceptance. The requirements of 10 CFR 70.22 need to be reviewed by the PM and applicant going into renewal. Standard Review Plan-1520 is helpful, but does not address all the content of an application that is strictly fuel cycle, let alone one containing substantial broad scope

aspects.

RECOMMENDATION: The applicant and the PM should thoroughly discuss a license renewal ahead of submittal. Both parties need to understand, in general, the request and the content to be submitted. While all questions can't be answered at this point in regulatory interaction, a significant amount of time can be saved through opening up the lines of communication early.

2) Four different LARs were submitted during the renewal period, the most recent of these submitted in June 2013. These were not necessarily requested by the Agency. It appears in two instances that NIST attempted to resolve licensing issues through revised applications. Part of this was the result of staff willingness to accept additional requests and endeavoring to manage these, rather than rejecting the submittal in favor of the appropriate format, thus having to accept the delay that would be required to accommodate the administrative change. If the renewal process had been thoroughly discussed and understood early on, the required responses in appropriate format would likely have been received. Related to the submission of four LARs, three exemption requests were received in March 2013 and included in the renewal. In June of 2013, NIST requested two other exemptions, one of which ultimately was rejected and later determined to not be necessary.

LESSON LEARNED: As a rule, there should be no add-ons or resubmissions to a renewal following acceptance. Any additional requests a licensee may make should generally be handled as separate licensing actions. Submittals of revised LARs should almost never occur. A non-acceptance would be appropriate if the submittal falls substantially short of all pre-licensing discussion. Additional requests to add to a renewal should be reviewed and approved by the Branch Chief.

RECOMMENDATION: Site visits should be scheduled prior to LAR submittal so both the applicant and the PM can thoroughly discuss the standing license and any upcoming changes. A thorough face-to-face discussion of the upcoming action, the requirements and schedule for renewal should be conducted.

3) The lack of direction for renewal resulted in an unclear picture of progress and endpoint. There was a failure to understand the resources needed to complete the renewal. These items are all related to the lesson learned identified in paragraph 1.b., understanding the upcoming licensing request, the requirements, and the content of the submittal. The following are instances of a failure to understand early on what would be needed to complete the action:

(a) Early in the renewal, it was determined that NIST had not previously submitted a Decommissioning Cost Estimate (DCE) for their facilities, nor were they prepared to submit such a document at renewal. In response to an RAI in early 2008, NIST requested additional time to provide a DCE for their facility. DCE updates had also not been submitted by NIST every three years, as required by 10 CFR Part 70.25. Completing the DCE proved to be a formidable task for NIST and lengthened the renewal, taking almost 3 years to formally complete and answer associated RAIs. While discovering the issue early was valuable to the renewal, the fact that the licensee came into the renewal with no Decommissioning Funding Plan presents separate concerns. This should have been in-process before beginning renewal and any early planning meeting should have identified this deficiency. This item was a major contributor to the extended renewal.

(b) Early on, there was no awareness that NIST possessed greater than a critical mass of SNM. It was not understood that NIST did not have either a criticality accident alarm

system (CAAS), or an exemption from the requirements to have one installed until NIST responded to an RAI in 2008. This should probably all have been dealt with under Amendment 3 (standing license), before this renewal began. NIST ultimately requested exemption in 2011 and this was approved and published in the *Federal Register* Notice (FRN) in April 2012.

(c) The previous renewal (1997) preceded the implementation of Increased Controls Order EA-05-090 and, though this area has been regularly inspected since the issuance of the order, a thorough review of procedures would necessarily be a part of a license renewal for such a complex program. Review of NIST's Increased Controls Program, as a part of renewal, was not initiated until 2013.

(d) The Part 73 requirements for Physical Security and Transportation required evaluation as a part of renewal. However, the NSIR office was not engaged to complete this portion of the review until 2013. The submittal of the Safety Evaluation Report (SER) from NSIR encountered its own delays and challenged the completion of the renewal before the end of the fiscal year.

LESSON LEARNED: A thorough understanding of the request and content of a submittal is necessary for both the PM and the applicant. These examples above are all symptomatic of an inadequate acceptance review. These problems were compounded by a lack of communication along the way.

RECOMMENDATION: 1) Regular Teleconferences with the applicant, following submittal of the LAR, should be scheduled if licensing activity is stalling or falling behind; and 2) If a renewal will exceed the Operating Plan Metrics for a Complex Licensing Action (540 days), the PM should produce a monthly report of renewal status to FCSS Management. The report should address completed actions, outstanding actions and any basis for delay

a. NIST, Boulder, Colorado (Co), Regulatory Issues. This section and the next are cited here because of their contribution to the lengthy renewal. There is little to address in terms of lessons learned, because they are factual and were unavoidable circumstances that contributed significantly to stops and delays in the license renewal.

A physical complication to the completion of the renewal was a contamination spill that occurred at a satellite facility of NIST's at Boulder, Co. On June 9, 2008, a plutonium spill occurred at the NIST facility in Boulder, Co resulting in personnel contamination of two laboratory workers, as well as facility contamination. This event sidelined NIST Gaithersburg from a focused involvement in their renewal with attention directed in the Boulder facility recovery. This event occurred within 1 year of submittal of the LRA. At this point in the renewal, the Agency had already changed PMs and was in the midst of completing a lengthy DCE.

NRC sent a special inspection team to independently assess the on-site radiological conditions at the Boulder facility and verify the adequacy of NIST corrective actions. The inspection team identified ten apparent violations of NRC requirements, involving the licensee's failure to conduct the radiation safety program at NIST-Boulder in accordance with NRC requirements as specified in the license, failure to follow security requirements, and the deliberate failure of the facility's RSO to provide complete and accurate information in a license application to the NRC. Executive Management at NIST Gaithersburg was a part of the review and response to this action. The RSO at the Gaithersburg was identified in the findings of the Investigation Report. The intent of this level of documentation here is to convey the gravity of the event and the consequences to NIST and the renewal. In an Alternative Dispute Resolution (ADR) mediation

on January 5, 2010, nearly three years into the license review, NIST agreed to take numerous corrective actions relating to the apparent violations, including paying a civil penalty of $10,000. The NRC agreed to refrain from pursuing further enforcement actions against NIST for this event. Since the proposed corrective actions were accepted, the apparent violations were not assigned severity levels or escalated as violations under the traditional enforcement process. NRC issued NIST Confirmatory Order (CO), EA-09-142, on March 1, 2010, and documented the commitments made by NIST, which are still ongoing and continue into 2014.

One of the actions coming out of the CO was to replace the RSOs at both facilities. The replacement for the RSO at Gaithersburg came in July of 2009 and was in place by the time the CO was issued. This item was necessarily a significant setback in renewal, now two years along. There is no record of turnover between the previous RSO and the replacement. It is known that the replacement RSO had worked previously at NIST as a Health Physicist (HP) and this is addressed below. Considering the content of the CO issued, the new RSO immediately had his hands full with carrying forward the corrective actions required of the CO. This may have been the most substantial of setbacks to renewal. Technical continuity was lost for NIST.

d. Weak NIST RSO Turnover. The new RSO was hired approximately 2 years after the LRA had been submitted. The trail of correspondence shows that little was occurring in the area of renewal at this time. NIST provided an updated DCE in August of 2009, but there were continuing issues with this as addressed earlier in this report. There are two issues resulting from the RSO change:

1) An unavoidable result was that becoming familiar with all of the tasks as RSO was time-consuming. This ‘new’ RSO had worked as a HP at NIST previously, but had left the facility for two years, taking employment as an RSO elsewhere during the time the Boulder event occurred. There is a great deal of value in hiring someone who had familiarity with the NIST mission and facilities, but the scope of responsibilities for the RSO are significantly greater, and required a substantial learning curve. The NIST license is complex, with a variety of sources, materials, safety requirements, procedures and personnel that required time to get familiar with. Combined with the support required of the Gaithersburg facility in Boulder recovery, the RSO was otherwise occupied. There is very little correspondence exchanged between the Agency and NIST until Spring of 2011. There is a revised LRA that was submitted in June 2010, but that was driven primarily by changes to the DCE. By the time broader licensing review activity has restarted, the Agency assigned the fourth PM to the renewal.

2) The new RSO was unfamiliar with the content of the LRA and was not involved in the original submittal. There appeared to be a lack of understanding of the exemptions NIST had received and needed to continue operations. Ongoing Agency staff changes were not helpful in assisting this RSO in current events in the licensing area. Amendment 3, the standing license standing since 1997 and under renewal, documented 8 exemptions requested of the Agency. Most all of these exemptions came in one request submitted in 1998 and approved in 1999. When the LRA came in in 2007, only 2 of these exemptions were requested to be continued. There is no record of discussion of LRA content, nor was it necessarily the business of the Agency to do this. This comparison should have been completed during acceptance. It would appear to be reasonable that a comparison between the standing license and the LRA to note these differences would be conducted, but there is no record of this. And the RSO who assumed responsibility failed to note the differences until 2013. In March 2013 a request for continuing 3 of these exemptions was received. In June 2013, an email request was received requesting continuance of 2 more of the exemptions from Amendment 3. The lack of applicant identified changes in the exemptions and the failure to identify changes early on challenged the NRC’s

ability to complete the LAR as late as June 2013.

2. Renewal Successes. In the face of these challenges, there were features of the renewal that worked well, were beneficial to a better license, and were notable in completing the renewal by the end of fiscal year 2013:

a. Office of General Counsel (OGC). Prior to the completion of any renewal, OGC will complete a review of requirements and commitments to assist licensing staff in ensuring the legal aspects of the application are met. The PM contacted the staff attorney assigned to the NIST renewal while Fuel Manufacturing Branch (FMB) was still in the process of completing and finalizing all the documentation in preparation for submission to OGC for final review. There was a general discussion of the renewal history, including many of the same events noted in this document. The intent was to convey to the staff attorney the state of the renewal and the process getting to that point. Also discussed was the FCSS goal of completing the renewal by the end of the fiscal year. This goal had been discussed within FCSS in late Spring and the end of the fiscal year was deemed an achievable goal. The Safety Evaluation Report (SER) and draft licenses (both public and non-public) were turned over to the staff attorney on July 29, 2013. Comments from the initial review were provided in a marked up SER. These were addressed and returned to the staff attorney in a revised SER. A final set of comments were received from the staff attorney, followed by a review of Office of the General Counsel (OGC) management with comments. The entire OGC review and granting of No Legal Objection (NLO) was received by September 5, 2013. There was a great deal of constructive communication between the FMB PM and the OGC staff attorney, as well as the FCSS Director and OGC management that facilitated the thorough and rapid turnaround of the SER. This particular working relationship was an essential element in the completion of the renewal by the end of the fiscal year.

b. Administrative Support. FCSS Licensing Assistant (LA) support was essential in facilitating the completion of the renewed license. The renewed license consists of public and non-public SERs and licenses, as well as cover and internal administrative documentation. Once comments had been received from OGC, these required incorporation into all affected documents. LA staff provided outstanding support in providing editing and reformatting support to keep the renewal on track for on-time completion of the renewal.

c. Updated Dose Evaluation. On September 10, 2012, staff requested that NIST re-evaluate the potential for offsite dose to ensure that no requirement for an Emergency Plan still exists. The standing license possessed a similar evaluation, over 20 years old, performed in 1992. In its RAI response dated October 25, 2012, NIST submitted an updated evaluation using the possession limits in the current application, consistent with the NUREG-1140 Methodology, and included demographic changes in the Gaithersburg area surrounding the NIST facility. The updated evaluation showed that the maximum dose to a person offsite due to a release would not exceed 1 Rem effective dose equivalent or 5 Rem to the thyroid. Staff verified that an emergency management plan is not required, on the basis that the 2012 submittal was adequate.

3. Recommendations. There is one primary recommendation forwarded in this report:

a. Re-evaluate the Approach to Renewal. NIST has been operating under licenses from the Nuclear Regulatory Commission (NRC) since 1974, when the Agency assumed responsibility from the Atomic Energy Commission (AEC). At one time NIST possessed separate licenses for Part 30 byproduct material, Part 40 source material, and Part 70 special nuclear materials. In the 1970's, these were consolidated into a single SNM License, SNM-362. Combining the licenses into a single 'broad scope' type of license that included SNM was intended to simplify the overall

licensing approach and reduce costs. Anecdotally, the NIST RSO at that time found that the requirements for the Part 70 license, due to criticality and security issues, were more stringent than the requirements for the other licenses and decided that all could be universally maintained under one license and one set of requirements. And at that time in licensing history, the Regions were not administering licenses, so that function of the Agency was managed by NMSS. The historical record is that oversight of a license that is 95% broad scope is still managed by Headquarters, primarily due to the fact that NIST meets the criteria for a Greater Than Critical Mass license. Region I staff state there have been suggestions to split the license and managed accordingly. There is no written detail on those initiatives, though it is probably worth discussion with FCSS Management and the Region on the merits of that action prior to the next renewal. This is an item of Lessons Learned, but from a greater perspective in terms of going forward and aligning Agency Business Processes with licensing today. Technical Assistance Reviews were not sent to Region I materials licensing for their review and input on the byproduct, irradiators, and source material portions of the license. The impact to this renewal is not entirely clear, but the true expertise in Part 30 licensing resides in the Regions. Licensing could remain with NMSS, under the same terms it exists now. However, a more inclusive effort should be made in the future to include Region I staff early on as a part of planning meetings and site visits. Region I staff have extensive site inspection experience that would be beneficial as a part of renewal.

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