Telephone Conversation Record

Person Called:	Shannon L. Gleason, Ph.D., Radiation Safety Officer
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Licensee:	Bayer Healthcare, LLC Elkhart, IN
License No.:	13-02249-01
Docket No.:	030-04336
Callers:	George M. McCann, Senior Health Physicist NRC Region IIII, Division of Nuclear Materials Safety, Decommissioning Branch (DB) Andrew M. Bramnik, Health Physicist, DB
Date of Call:	January 10, 2007

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING LICENSE TERMINATION REQUEST DATED OCTOBER 23, 2006 (MAIL CONTROL NO. 315794)

REFERENCES:

NRC NUREG 1757, Vol. 1, Rev. 2, Consolidated Decommissioning Guidance, Decommissioning Process for Materials Licensees

NRC NUREG 1757, Vol. 2, Rev. 1, Characterization, Survey, and Determination of Radiological Criteria

NUREG 1575, Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)

NUREG 5849, Manual for Conducting Radiological Surveys in Support of License Termination.

NUREG 1748, Environmental Review Guidance for Licensing Actions Associated with NMSS P Programs

NRC Inspection Procedure 83890 Close out Inspection and Surveys

On the above date, NRC Decommissioning staff contacted Dr. Gleason to discuss the need for additional information to support their request for termination of Bayer Healthcare's license. The staff advised Dr. Gleason that the historical site assessment, and final status surveys are not adequate to demonstrate that Bayer's license can be terminated in accordance with NRC guidelines. As such, we advised Dr. Gleason that

we are voiding their current license termination action, until they are able to revise their termination request. Dr. Gleason was advised that we would reactivate their request upon receipt of their revised termination request. Dr. Gleason was advised that the above references are available from the NRC website.

The licensee was advised that their report satisfies the "Notification" provision of 10 CFR Part 30.36(d). However, without a satisfactory and complete final status survey, a decision whether or not a DP will be needed cannot be determined. The clock for completing the action has been initiated as of the date of their letter, and the termination action must be completed within the next twelve months. Additionally, this license termination will require NRC staff to prepare an Environmental Assessment, which will be used to determine if a Finding of No Significant Impact (FONSI) is applicable. If staff determines that an FONSI is applicable, the termination and NRC's staff assessment of the licensee's termination will be published in the Federal Register. Therefore, it is essential that the data provided for our review, and which will go into the NRC's electronic Agency Document Automated Management System (ADAMS), which is accessible to the public, be detailed, understandable and technically sound.

During the conversation, Staff discussed what information needed to be expanded and what additional information needed to be provided. Specifically, the general areas discussed with Dr. Gleason are outlined below:

1. **314 attached:** Form indicates that waste transferred Veolia Environmental Services, Menominee Falls, WI (262) 253-3350, No license number inferred. The 314 indicates ultimate disposal to be at Duratek, Inc. Oak Ridge, TN No license number for the Veolia Environmental indicated, they need to clarify how this transfer was affected and how it complied with 10 CFR Part 30.41?

2. The licensee's historical site assessment (HSA) of past licensed activities lacks sufficient detail and background information. Therefore, the licensee needs to expand their HSA to address the following areas:

A. The HSA must provide a comprehensive description of past locations of use, including buildings, outdoor areas (if any), and rooms in each building where materials were used. The revised HSA must address the type of activity performed in each area, quantities of materials possessed and used (flow through) for each area. The licensee's response must be a comprehensive document, which list sites of use, past buildings located at each site, rooms, and facilities where licensed radioactive materials were used, since the base license was issued on March 13, 1957. The staff reviewed past license amendments issued to your company and predecessor company. Information, not necessarily limited to the above (refer to NUREG 1757 vol.) must be provided regarding the following:

I. Amendment 4: specifies **an address as 1127 Myrtle Street,** Elkhart. Letter dated November 27, 1995, states the following": The location of material use and/or storage will continue to be limited to the principal campus at 1884 Miles Avenue, in Elkhart, Indiana. All previous address references were deleted in **May 17, 1993-letter, and March 4, 1995-letter detailing company name change with an address of the street renamed to 1884 Miles Avenue."**

ii. Amendment 3 first added incineration of animals. The incinerator location needs to be addressed. Were there other incinerators, at other locations? Building 9 appears to be where an incinerator was located. Was the incinerator demolished? Was it surveyed, records of survey and disposal?

iii. Amendment No. 27, Condition 10 indicates that materials may be used at the Item 2 address. But it also mentions approval to use I-125, H-3 (120 mCi) and H-3 (650 mCi) at **Tracor Inc. 641 Growth Avenue, Ft. Wayne, Indiana.** This site needs to be addressed in the HSA, and FSS survey data needs to be provided

iv. Amendment No 28. Condition 10, adds the use area located at **3400 Middlebury Street, Elkart, IN** This site needs to be addressed in the HSA, and FSS survey data needs to be provided

v. Amendment 30, November 25, 1975, Condition 10 adds **1301 Napanee Court, Elkart, IN.** This site needs to be addressed in the HSA, and FSS survey data needs to be provided

vi. Amendment 32, 1997, Condition 10 adds **4315 South LaFayette Street, South Bend, Indiana.** This site needs to be addressed in the HSA, and FSS survey data needs to be provided

vii. Letter dated November 26, 1978, and dated February 6, 1980, indicates these locations of use: **4718 Yender Avenue, Lisle, IL and 30 West 475 North Aurora Road, Naperville, IL** This site needs to be addressed in the HSA, and FSS survey data needs to be provided

viii. Amendment 39, July 25, 1985, modified the licensee's location of use condition added two additional sites as follows: 1. **430 South Beiger, Mishawaka, IN, 2. 4315 South Lafayette, South Bend, IN,** This site needs to be addressed in the HSA, and FSS survey data needs to be provided

ix. Amendment 41, 1990, added the sites to the licensee's approved locations of use as follows: 1. 1127 Myrtle Street, Elkhart, IN; 2. 3400 Middlebury Street, Elkhart, IN; 3. 1301 North Nappanee Court, Elkhart, IN, 4. 430 South Beiger, Mishawaka, IN; 5. 4315 South Lafayette, South Bend, IN; 6. 4718 Yender Avenue, Lisle, IL; 7. **1000 Randolph Street, Elkhart, IN** This site needs to be

addressed in the HSA, and FSS survey data needs to be provided

x. Attached to a June 4, 1990, license renewal is a discussion regarding animal facilities described as follows: "The Miles Corporate Animal Facility consists of a main animal facility located in the **C.S. Beardsley Research Building** in Elkhart, Indiana. This is a conventional facility that consists of 29 animal rooms that are fully air-conditioned and heated totaling 8,850 sq.ft. The facility occupies portions of 3 floors **(Building 9:** basement; Wing 1, both 1st and 2nd floors; and Wing 2, both 1st and 2nd floors. **There is also a large animal facility consisting of 2 barns located 7 miles northwest of the main facility. The total footage of animal space in these barns is 1936 sq.ft. The quarantine barn is heated and neither barn is air-conditioned."**

The licensee needs to clarify if radioactive materials were used in these barns and if close out surveys were performed. Also, does the current survey report include the animal rooms in the C.S. Beardsley Research Building? The building description for the animal facility is the general information, which will be needed for the EA. These sites need to be addressed in the HSA, and FSS survey data needs to be provided

xi. Amendments 19 through 21, indicate that plated sources containing americium 241, curium 242 in the form of plated sources were approved for prototype testing of devices. Where were these materials used? Condition of use, any leak test records, which infer leakage? Did any leaks or incidents occur, which required records pursuant to 10 CFR 30.35(g)? What was the results of the licensee reviews of past accountability, inventory, leak test, spill, and incident records?

xii. Review of past license amendments indicate that the licensee ran a production facility involving byproduct material. The licensee needs to discuss this production activity, as far as the types of materials used, the processes involved, where the materials were used, how much was used, and were there spills, incidents, records pursuant to 10 CFR 30.35(g)?

B. The licensee needs to discuss in greater detail the types, quantities of radioactive material used at each location, in each specific use area, and implications for associated hazards, survey, and disposal for all radioactive materials used and possessed under the license. The licensee's license approved a wider range of materials than that inferred in the licensee's current report. A general review of past license amendments revealed the following:

I. Amendments 1 and 2 approved the use of C-14 and H-3 in 10 millicurie quantities for animal studies in 1957.

ii. Amendment 6, boosted **H-3 to 1 curie**, C-14 (50 mCi), I-131 (10 mCi), S-35 (100 mCi), Chromium 51

iii. Amendments 10 and 11 added **cobalt 60 (any form 5 mCi) cesium 137 (any form 5 mCi), respectively**. The HSA doesn't address the use of these materials, where, what forms, and what quantities?

iv. Amendment 12, renewal basically same boosted H-3 to 2 curies, also discussed **distribution**. Also added **iodine 129 (16 million years @ 5 mCi**). The HSA needs to talk to this, where was the production done, and where was the I-129 used?

v. Amendment 17 added **barium 133 (10.7 years @ 5 mCi)**. Where and what was this material used for?

vi. Amendment 21, boosted H-3 to 3 curies. What required this increase, where and what was it used for?

C. The licensee needs to discuss evaluations of potential environmental contamination resulting from liquid discharges and or burials of material (10 CFR 20.304 (rescinded in 1981), 20.2002 etc. The licensee must determine and indicate whether there were any potential for hold-up tanks, leach or septic fields, sewer lines, in-house plumbing

D. The licensee must discuss, and provide if required (See NUREG 1757 Vol 1) Records which demonstrate that the licensee has performed a thorough inventory review, to account for license materials, both sealed and unsealed, including copies of leak tests for sealed sources possessed and used by the licensee.

3. Surveys The current release surveys and past end-users release surveys are not adequate to demonstrate or support the release of past use areas and facilities. Acceptable guidance on surveys is found in Figure 8.1 and Section 15.4 of NUREG 1757 vol 1, rev 2 as well as Appendices A and B of Volume 2 of this NUREG. Areas noted which need to be addressed are discussed as follows:

A. For the final status survey of past locations of use, each building must be described, that is address, general size (number of floors, rooms, and number of rooms where isotopes were used and stored. Each location of use (e.g., laboratories, process areas, storage areas, animal laboratories and kennels for dosed animals, incinerators, compactors, waste collection points, hold-up takes, septic fields, etc. must be specified with enough detail to understand size, equipment and associated ventilation and sanitary/sewer discharge systems.

B. The areas do not appear to have been classified according to potential residual contamination, MARSSIM Classes or NUREG 5849 impacted or non-impacted areas? Describe the systematic survey scheme used by your surveyor for conduct of FSS in past use areas. Areas which were impacted as a result of the

use of licensed radioactive materials should be identified using knowledge of past site operations together with site characterization surveys. Additionally, consideration for surveys in suspect or non-impacted areas, which could have had potential for contamination should also be considered.

C. Describe the method used to identify individual measurement/sampling points on each surface in the indoor area that was involved in licensed material use. Describe basis for frequency of wipes based on area classification, determination of fixed versus removable. Was a grid used for systematic sampling?

D. Indicate if confirmatory surveys by the licensee's RSO or radiation safety staff were conducted at the time the areas were released to supplement the end-user surveys The current surveys were referred to as scoping surveys, neither the en-user surveys or the current surveys appear to satisfy final status survey requirements as far as rigor and quality control.

E. Final status survey data must be tabulated in a report form, which correlates area dose measurements, direct survey meter results and test for removable contamination keyed to an attached detailed diagram for each area. The survey report should indicate findings in individual sections according to location, buildings and areas. The report should also have a section, which discusses instrumentation, analytical procedures (MDC, MDCsr), calibration and instrument efficiencies, conversion factors, and QA.

F. Clarify if a one hundred percent scan of all impacted surfaces in each use area was performed, using an appropriate radiation detection instrument, that is appropriate for specific gamma energies, alpha and beta radiation. The type instruments used should be specified with their associated scan sensitivities, discussion of calibration, and certified calibration sources used. If it is not possible to ascertain materials used in each area, then the survey must be capable of detecting all potential radioactive materials, and their associated radiations, which were authorized under the licensee's license. Review of your scoping survey results are indicated in cpm. Results must specify instrumentation used, be corrected for efficiency, area factor and provided in dpm.

G. Provide details of evaluations and or surveys, analysis of samples collected from drains, hold-up tanks, leaks via sewer lines, vacuum collection systems, re-concentration of radio nuclides release to the sanitary or septic fields (if any), air vents, or other fixtures or equipment that may have become contaminated during licensed material use. This is especially significant in situations where renovations have occurred and potentially contaminated areas may be inaccessible under current conditions.

H. Specify release criteria for all past authorised materials. Also, for areas with

multiple contaminates, the sum of ratios need to be applied. NUREG 1757 vol 1., Rev 2. Appendix B cites acceptable surface and soil release criteria.

I. Review of surveyor's current record indicates that wastes were stored in Room B37 and the garage, from 1999 to 2006 and 1970 to 1990s, respectively. Where were wastes stored before that?

End of conversation record. No further discussion.