

Telephone Conversation Record

Licensee: Bayer Healthcare, LLC, Elkhart, IN
License No.: 13-02249-01
Docket No.: 030-04336

CALL PARTICIPANTS:

BAYER: Shannon L. Gleason, Ph.D., Radiation Safety Officer
Telephone No. 574-262-~~6578~~ 256-3258
E-mail: shannon.gleason.b1@bayer.com

Tom Lenz, Bayer HE&S
Telephone No. (574) 262-6502

Bill Thomas, CHP, Integrated Environmental Management, Inc.
(IEM), licensee consultant

Date of Call: July 30, 2007

SUBJECT: DISCUSSION REGARDING LICENSEE'S May 16, 2007,
LETTER (ML071420287 (MAIL CONTROL NO. 316266

On the above date the licensee was contacted to discuss their May 16, 2007, letter. This letter was controlled in as an amendment, however, after staff review it was determined that it was not a final response to a previous NRC request for additional information. The licensee had previously submitted a license amendment (Mail Control No. 315794), which had been voided due to the need for additional information see NRC (Telephone Conversation Record dated January 10, 2007 (ML0701106540)).

Staff discussed with the licensee and their consultant, in general terms the following:

Bayer Healthcare, LLC, Elkhart, IN
July 30, 2007, Telephone Conversation Record

1. We discussed the provisions of 30.36(d), which indicates if all activities have ceased at a site, that the licensee has one year to close the issue and terminate their license. Dr..Gleason agreed to send a letter to the NRC requesting an extension to the decommissioning end date. We discussed that up til the end of March 2008 would be acceptable.
2. We briefly discussed the need to ensure that those sites, which were previously released, be adequately addressed in the Historical Site Assessment (HSA). Ensure, that previous release surveys were adequate and did not leave any open questions.
3. We briefly discussed the survey approach. It was indicated that MARSSIM 1775, Appendix B, Simplified survey approach would be used, The licensee's consultant indicated that NRC screening values will be used for the $DCGL_w$ and that the "hot spot ($DCGL_{emc}$)" limits will be three times the $DCGL_w$.
4. The overall plan proposed in the licensee letter appeared to be adequate.

The call closed with the licensee requesting a copy of the conversation record and a commitment to send a letter requesting the extension.

No further discussion.

ENCLOSURE
RESPONSE TO JANUARY 10, 2007 REQUEST FOR ADDITIONAL INFORMATION

Bayer HealthCare, LLC
USNRC License No. 13-02249-01

USNRC RAI No. 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?

Bayer Response: Veolia (formerly Onyx North America) has a company-owned low-level radioactive waste processing firm called Aleron Corporation that effected the transfer of waste from Bayer, with subsequent disposal by Duratek, Inc. Aleron, located at 2138 State route 18, Wampum, Pennsylvania, 16157, maintains USNRC License No. 37-20826-01 (expires December 31, 2008) that authorizes the possession, storage, maintenance, repair, decontamination, storage and transport of radioactive materials at temporary job sites. As such, the transfer of Bayer's waste to Veolia was done in compliance with 10 CFR 30.41.

Follow-up Action: Form NRC 314 will be revised to include the aforementioned information prior to re-submittal to the USNRC.

USNRC RAI No. 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:

USNRC RAI No. 2.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:

USNRC RAI No. 2.a.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."

Bayer Response: The addresses 1127 Myrtle Street, Elkhart and 1884 Miles Avenue, Elkhart both refer to the licensed site. The street address for the licensed site was changed in 1995 to 1884 Miles Avenue.

Follow-up Action: A final status survey report, to be attached to revised Form NRC 314, will include this information as part of the historical assessment.

USNRC RAI No. 2.a.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?

Bayer Response: Building 9 and the incinerator therein were demolished in 1999. A radiation survey that documented the building/incinerator could be released for unrestricted use was performed by the RSO for Bayer and by its environmental contractor, Baker Environmental. A letter demonstrating that the building and its contents were eligible for release was sent to the USNRC on August 24, 1999. The license was amended by the USNRC on November 18, 1999 in Amendment 47.

Follow-up Action: The Form NRC 314 will be revised to document the action previously approved by the USNRC.

USNRC RAI No. 2.a.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.

Bayer Response: Bayer ceased the use of licensed radioactive materials at the Tracor facility in 1983. All radioactive materials therein were removed and a final status survey performed before the building was vacated.

Follow-up Action: A final status survey report, to be attached to revised Form NRC 314, will summarize this information as part of the historical assessment. The survey report will use the existing survey data generated by the RSO in January, 1983.

USNRC RAI No. 2.a.iv: Amendment No 28. Condition 10, adds the use area located at 3400 Middlebury Street, Elkhart, IN This site needs to be addressed in the HSA, and FSS survey data needs to be provided.

Bayer Response: Work with radioactive materials at this location ceased in 1992. On May 17, 1993, after confirming that the site could be released for unrestricted use, Bayer submitted an application to remove this location from the listing of permanent restricted areas on Amendment 43 of its license. By issue of Amendment 44 on June 29, 1993, the USNRC approved this application.

Follow-up Action: The Form NRC 314 will be revised to document the action previously approved by the USNRC.

USNRC RAI No. 2.a.v: Amendment 30, November 25, 1975, Condition 10 adds 1301 Napanee Court, Elkhart, IN. This site needs to be addressed in the HSA, and FSS survey data needs to be provided

Bayer Response: Work with radioactive materials at this location ceased in 1992. On May 17, 1993, after confirming that the site could be released for unrestricted use, Bayer submitted an application to remove this location from the listing of permanent restricted areas on Amendment 43 of its license. By issue of Amendment 44 on June 29, 1993, the USNRC approved this application.

Follow-up Action: The Form NRC 314 will be revised to document the action previously approved by the USNRC.

USNRC RAI No. 2.a.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.

Bayer Response: Work with radioactive materials at this location ceased in 1992. On May 17, 1993, after confirming that the site could be released for unrestricted use, Bayer submitted an application to remove this location from the listing of permanent restricted areas on Amendment 43 of its license. By issue of Amendment 44 on June 29, 1993, the USNRC approved this application.

Follow-up Action: The Form NRC 314 will be revised to document the action previously approved by the USNRC.

USNRC RAI No. 2.a.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

Bayer Response: Work with radioactive materials at these locations ceased. After all licensed radioactivity was removed, final surveys were performed to demonstrate that the sites could be released for unrestricted use.

Follow-up Action: A final status survey report, to be attached to revised Form NRC 314, will summarize this information as part of the historical assessment. The survey report will use the existing survey data generated by the RSO at the time the facilities were released.

USNRC RAI No. 2.a.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.

Bayer Response: Work with radioactive materials at these locations ceased in 1992. On May 17, 1993, after confirming that the sites could be released for unrestricted use, Bayer submitted an application to remove these locations from the listing of permanent restricted areas on Amendment 43 of its license. By issue of Amendment 44 on June 29, 1993, the USNRC approved this application.

Follow-up Action: The Form NRC 314 will be revised to document the action previously approved by the USNRC.

USNRC RAI No. 2.a.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.

Bayer Response: The addresses 1127 Myrtle Street, Elkhart, 1884 Miles Avenue, Elkhart and 1000 Randolph Street, Elkhart, all refer to the licensed site. The street address for the receiving area for the site remained 1000 Randolph Street. The mailing address for the facility was changed in 1995 to 1884 Miles Avenue.

Work with radioactive materials at 3400 Middlebury Street, 1301 North Nappanee Court, 430 South Beiger, and 4315 South Lafayette ceased in 1992. On May 17, 1993, after confirming that the sites could be released for unrestricted use, Bayer submitted an application to remove these locations from the listing of permanent restricted areas on Amendment 43 of its license. By issue of Amendment 44 on June 29, 1993, the USNRC approved this application.

Work with radioactive material at the Yender Avenue location ceased. After all licensed radioactivity was removed, final surveys were performed to demonstrate that the sites could be released for unrestricted use.

Follow-up Action: A final status survey report, to be attached to revised Form NRC 314, will summarize this information as part of the historical assessment. The survey report will use the existing survey data generated by the RSO at the time the facility was released. The Form NRC 314 will be revised to document the actions previously approved by the USNRC.

USNRC RAI No. 2.a.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."

Bayer Response: The C.S. Beardsley Research Building is also called Building 9 which was demolished in 1999. A radiation survey that documented the building could be released for unrestricted use was performed by the RSO for Bayer and by its environmental contractor, Baker Environmental. A letter demonstrating that the building and its contents were eligible for release was sent to the USNRC on August 24, 1999. The license was amended by the USNRC on November 18, 1999 in Amendment 47.

An animal facility was indeed added to the license, however no radioactive materials were ever used within that facility. Therefore, no routine or final survey records exist for the facility.

Follow-up Action: The Form NRC 314 will be revised to document the action previously approved by the USNRC.

USNRC RAI No. 2.a.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?

Bayer Response: Bayer used these sealed radiation sources as part of the research effort at the Elkhart, Indiana site. Pursuant to license requirements, leak tests and physical inventories were performed as required. The sources were subsequently returned to the manufacturer.

Follow-up Action: A final status survey report, to be attached to revised Form NRC 314, will summarize this information as part of the historical assessment. Included as well will be a review of past accountability actions, and any spills or incidents.

USNRC RAI No. 2.a.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)?

Bayer Response: Building 9 housed the referenced production facility before its demolition in 1999. A radiation survey that documented the building could be released for unrestricted use was performed by the RSO for Bayer and by its environmental contractor, Baker Environmental. A letter demonstrating that the building and its contents were eligible for release was sent to the USNRC on August 24, 1999. The license was amended by the USNRC on November 18, 1999 in Amendment 47.

Follow-up Action: The Form NRC 314 will be revised to document the action previously approved by the USNRC.

USNRC RAI No. 2.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:

USNRC RAI 2.b.i: Amendments 1 and 2 approved the use of C-14 and H-3 in 10 millicurie quantities for animal studies in 1957.

Bayer Response: Concur.

Follow-up Action: A final status survey report, to be attached to revised Form NRC 314, will summarize the available information on Building 9 as part of the historical assessment. A final status survey in the Rad Lab (Room 18.C.B.013) and the storage room in the basement of Building 18 will be performed pursuant to the recommendations of MARSSIM by individuals experienced in its implementation.¹ The final status survey report will include a statement as to the radiological status of these locations in light of the applicable release criteria.

USNRC RAI No. 2.b.ii: Amendment 6, boosted H-3 to 1 curie, C-14 (50 mCi), I-131 (10 mCi), S-35 (100 mCi), Chromium 51.

Bayer Response: Concur.

¹ U. S. Nuclear Regulatory Commission, et al, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)", NUREG-1575, EPA 402-R-97-016 and DOE/EH-0624, Rev. 1, August, 2000.

Follow-up Action: A final status survey report, to be attached to revised Form NRC 314, will summarize the available information on Building 9 as part of the historical assessment and approved by the USNRC. A final status survey in the Rad Lab (Room 18.C.B.013) and the storage room in the basement of Building 18 will be performed pursuant to the recommendations of MARSSIM. The final status survey report will include a statement as to the radiological status of these locations in light of the applicable release criteria.

USNRC RAI No. 2.b.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?

Bayer Response: Concur.

Follow-up Action: A final status survey report, to be attached to revised Form NRC 314, will summarize this information as part of the historical assessment. The survey report will use the existing survey data generated by the RSO at the time the sources were employed.

USNRC RAI No. 2.b.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?

Bayer Response: Concur.

Follow-up Action: A final status survey report, to be attached to revised Form NRC 314, will summarize the available information on Building 9 as part of the historical assessment. A final status survey in the Rad Lab (Room 18.C.B.013) and the storage room in the basement of Building 18 will be performed pursuant to the recommendations of MARSSIM. The final status survey report will include a statement as to the radiological status of these locations in light of the applicable release criteria.

USNRC RAI No. 2.b.v: Amendment 17 added barium 133 (10.7 years @ 5 mCi). Where and what was this material used for?

Bayer Response: Bayer purchased a source of Barium-133, sealed within a vial, for use in calibration and daily source checks of a liquid scintillation counter. As described in our response to RAI No. 1, this source was disposed of by a licensed contractor.

Follow-up Action: Form NRC 314 will be revised to include the aforementioned information prior to re-submittal to the USNRC.

USNRC RAI No. 2.b.vi: Amendment 21, boosted H-3 to 3 curies. What required this increase, where and what was it used for?

Bayer Response: See Response to RAI No. 2.b.1.

Follow-up Action: A final status survey report, to be attached to revised Form NRC 314, will summarize the available information on Building 9 as part of the historical assessment. A final status survey in the Rad Lab (Room 18.C.B.013) and the storage room in the basement of Building 18 will be performed pursuant to the recommendations of MARSSIM. The final status