

APPENDIX A INDUSTRIAL/ACADEMIC/RESEARCH INSPECTION RECORD (IP 87110)									
REGION I									
Insp. Report #	02-001	License #	06-13053-04			Docket #	030-30292		
Licensee Name	Bayer Corporation								
Street Address	400 Morgan Lane								
City, State, Zip	West Haven Ct.								
Location (Authorized Site) Being Inspected	As above. Note: All visitors must enter the facility through Bayer Visitor Center. This visitor center is located on Frontage Road which runs to the right of the I-95 on ramp. You must take Exit 41 off I-95 the Marsh Hill Road Exit. Directions in Docket File								
Licensee Contact Name	William L. Galdenzu, CIH, CSP				Phone #	203-812-3132			
Priority	2	Program Code	03610		Description	Broad Scope R&D			
Date of Last Inspection:	3/10/99				Date of This Inspection	3/28/99			
Type of Insp.	Announced		Routine	x	Initial				
	Unannounced	x	Special						
Next Insp. Date	3/05	Normal		Reduced		Extended	x		
Justification for change in normal inspection frequency:	2 clear inspection 99-001 and 02-001								
Summary of Findings and Actions									
No violations, Clear 591 or letter issued				x	Non-cited violations				
Violation(s), 591 issued		Violation(s), letter issued							
Follow up on previous violations:									
Inspector - Printed Name	Jenny M. Johansen								
- Signature	/RA/				Date	4/5/02			
Approved - Printed Name	John D. Kinneman, Chief NMSB2								
- Signature	/RA/				Date	4/8/02			

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY		
1.	AMENDMENTS AND PROGRAM CHANGES	
License amendments issued since last inspection, or program changes noted in the license.		
Amendment No.	Date	Subject
9	12/26/00	Appoint management signer for correspondent, delete Fe-55 from license and add satellite waste storage locations.
8	10/3/00	Appoint new RSO and Chm RSC
7	5/2/00	Appoint Interim RSO
6	8/19/99	Relocate waste storage areas in B-24
2.	INSPECTION AND ENFORCEMENT HISTORY	
Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders.		
NONE.		
3.	INCIDENT/EVENT HISTORY	
List any incidents or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.		
NONE		
PART II - INSPECTION DOCUMENTATION		
NOTE: References that correspond to each inspection documentation topic are in Inspection Procedure 87110, Appendix B, "Industrial/Academic/Research Inspection References."		

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that not all areas indicated in this part are required to be addressed during each inspection. However, for those areas not covered during the inspection, a notation ("Not Reviewed" or "Not Applicable") should be made in each section, where applicable.

All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations.

1.	ORGANIZATION AND SCOPE OF PROGRAM
Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority.	
<p>Wolfgang Plischke, CEO ← Gary Toczylowski, Director Health Environment & Safety ← James Burns, Mgr Site Safety & Industrial Hygiene ← William Galdenzi, Superintendent, Laboratory Safety/RSO → Radiation Safety Committee.</p> <p>Licensee is authorized for At Nos 1-83 100mCi per radionuclide not to exceed 1 Curie and other specific radionuclides such as I-125 up to 1 Curie, however the research program has been downsized in the last 2 years and licensee is currently using only C-14, H-3, I-125, P-32,-33, and S-35. Research is performed daily each day of the week. They also have 2 Ni-63 gas chromatographs. Licensee has not amended its license to reflect sizing as potential for growth still exists. Licensee has 100 authorized laboratories in 4 research buildings and 300 authorized users. RSO is supported with 3 staff.</p>	
2.	MANAGEMENT OVERSIGHT
Management support to radiation safety; Radiation Safety Committee (RSC); Radiation Safety Officer (RSO); program audits, including annual reviews of program and as low as is reasonably achievable (ALARA) reviews; control by authorized users.	
<p>Management is very supportive of the radiation safety program. The Radiation Safety Committee(RSC) is very active at each quarterly meeting reviewing and approving research use of RAM and in about 15% of the reviews denying the request. The RSC met each quarter in 2000 and inspector reviewed the meeting minutes for 3/8/01, 6/12/01, 9/20/01 12/14/01and 3/12/02.</p> <p>Annual audits of the Program are performed. Reviewed audit records dated 11/21/2000 and March 12, 2002.</p>	
3.	FACILITIES

Facilities as described; uses; control of access; engineering controls; calibration facilities; shielding; air flow:

Bayer facilities cover a 110 acre site along I-95 in West Haven Connecticut which is fenced with a 10 ft chain link fence topped with barbed wire. Visitors and employees access gates are manned 24 hrs with Security guards. Visitors must register at the Visitor Center, be badged and are escorted at all times on site. Research is conducted in 4 large buildings on site B-24, B-31, B-36 and A-21. Package Receipt, Waste Disposal and the RSO offices are in the basement of Building B-24. Satellite locations for RAM waste storage are in B-26 and A-21. All entry into these buildings and the labs using RAM is key carded.

4. EQUIPMENT AND INSTRUMENTATION

Operable and calibrated survey equipment; procedures; 10 CFR Part 21.

Licensee has a sufficient number of operable and calibrated survey equipment for the size of the program, including Ludlum Model 3 GMs, and ion chambers. Alarming ratemeters are used in hot labs, Ludlums in P-32 use labs and LEG probe survey meters are used in I-125 use labs. Liquid Scintillation counters are used in research counting labs. RSO has computerized records of instrument calibration. Survey meters are calibrated annually. Inspector reviewed calibration records for selected survey meters calibrated in 2001.

5. MATERIAL USE, CONTROL, AND TRANSFER

Materials and uses authorized; security and control of licenses materials; and procedures for receipt and transfer of licensed material.

Licensee has a computerized ordering and receiving record system. Packages are received at Receiving Department and taken to the RSO's receipt lab for surveys and wipe tests in Building B-24. Packages logged into computer system and then delivered to researcher's lab.
Licensee receives \approx 30-60 packages of RAM per month. Inspector reviewed package receipts and surveys for the periods March to June 2000 and June 2001 to March 2002. Inspector was informed that the licensee has not allowed iodinations at the site for over 2 years and requires researchers to order I-125 labeled materials that do not require such procedures to be performed on site.

6. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; contamination controls; records; and public doses.

Research staff performs daily weekly or monthly radiation surveys and wipes test of their individual laboratories. (Reviewed records in 5 labs visited; contamination found is decontaminated and resurvey of area perform until all contamination cleaned-up) The RSO does quarterly confirmatory surveys in labs and unrestricted areas (reviewed selected quarterly surveys for 2001 and March 2002 any contamination found is deconed). No air sampling for I-125 effluents is performed based on prior monitoring records, banning iodination and evaluation that effluents released are <10 % allowable air levels. Filters on fume hoods are surveyed after removal.

Leak test of GC were performed every 6 months, reviewed record of last leak test 1/17/02

Licensee maintains a computerized running inventory of materials on hand. Currently the licensee has 45.26mCi, C-14; 38.5 mCi, P-32; 31.97mCi, P-33; 311.24mCi, H-3; 12.27mCi, I125; and 20.29mCi, S-35.

7.	TRAINING AND INSTRUCTIONS TO WORKERS
Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Parts 19 and 20 requirements; emergency situations; and supervision by authorized users.	
License conducts monthly training for all new employees and contractors. Refresher training is given biannually to all badged employees. Last refresher in 2001.	

8.	RADIATION PROTECTION
Radiation protection program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose and survey records and reports; annual notifications to workers; bulletins and other generic communications.	
≈300 persons badged in 2000,2001andy currently with Landauer. RSO evaluates doses monthly. Highest exposure in last 2 years was 44 mRem/year. Majority of exposures are “M”. Routine thyroid monitoring has been eliminated since there are no more iodinations and licensee has made an evaluation that intakes would be <10%ALI	

9.	RADIOACTIVE WASTE MANAGEMENT
Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment; incinerators, hoods, vents and compactors; license conditions for special disposal method.	

Licensee's main waste facilities are in basement of B-24 near the RSO's office. Rooms are set up for handling of liquids, solids, short-lived for DIS and long lived solid wastes in different rooms within the facility. Satellite locations for RAM waste storage are in B-26 and A-21.

Licensee ships C-14 & H-3 scintillation wastes to NSSI Houston Tx for incineration and solid wastes to ATG Richland WA. There were 9 shipments in 2001. Reviewed records of waste shipments for 1/16, 2/15, 2/27, 4/17, 6/5, 7/16, 8/28, 10/16, and 12/10/0. All shipping papers and documentation met regulations.

10.	DECOMMISSIONING
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Records relevant to decommissioning; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements; changes in radiological conditions since decommissioning plan was submitted.

Licensee maintains relevant records.

11.	TRANSPORTATION
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Quantities and types of licensed material shipped; packaging design requirements; shipping papers; hazardous materials (HAZMAT) communication procedures; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports.

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12.	NOTIFICATIONS AND REPORTS
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Reporting and followup of theft; loss; incidents; overexposures; change in RSO; authorized user; and radiation exposure reports to individuals.

No reports or notifications to NRC required.

13.	POSTING AND LABELING
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Notices; license documents; regulations; bulletins and generic information; posting of radiation areas; and labeling of containers of licensed material.

All postings and labeling are current.

14.	INDEPENDENT AND CONFIRMATORY MEASUREMENTS
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Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date.

LUDLEM 14C NRC 033509 Cal 8/20/01 background levels of <0.02mR/hr in all areas visited

15.	VIOLATIONS, NON-CITED VIOLATIONS (NCVs), AND OTHER SAFETY ISSUES
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State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.

Clear 591 issued.

16. PERSONNEL CONTACTED

Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone).

Use # to indicate individual present at entrance meeting.

Use * to indicate individual present at exit meeting.

Name	Title	Phone No.	In Person or By phone
*James Burns	Manager, Site Safety & Industrial Hygiene	203-812-3132	in person
*#William L Galdenzi	RSO		in person
Peter Babin	H&S Staff		in person
Bob Roach	H&S Staff		in person
Sandy DiMatteo	H&S Staff		in person
Peter Rae	CHM RSC		in person
R Hong	Researcher		in person
T Rossomando	Researcher		in person
Various Research Assistants in 5 labs	RAs		in person

17. PERFORMANCE EVALUATION FACTORS

A.	Lack of senior management involvement with the radiation safety program and/or RSO oversight.		Y		N	x
B.	RSO too busy with other assignments.		Y		N	x
C.	Insufficient staffing.		Y		N	x
D.	RSC fails to meet or functions inadequately.	N/A	Y		N	x
E.	Inadequate consulting services or inadequate audits conducted.	N/A	Y		N	x

REMARKS :(Consider the above assessment and/or other pertinent Performance Evaluation Factors (PEFs) with regard to the licensee's oversight of the radiation safety program)

N/A

18. SPECIAL CONDITIONS OR ISSUES

NONE	x	Special license conditions
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PART III - POST- INSPECTION ACTIVITIES

1.	REGIONAL FOLLOWUP ON PEFs
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N/A	
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2.	DEBRIEF WITH REGIONAL STAFF
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Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer; and/or State Liaison Officer.	
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Briefed Branch Chief	
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TO ADVANCE TO NEXT SECTION OF FORM - PRESS **PAGE DOWN** KEY

APPENDIX A - ATTACHMENT A DECOMMISSIONING TIMELINESS INSPECTION										
Licensee:		Bayer Corp				Date of Inspection:		3/28/02		
1.	COMPLIANCE WITH DECOMMISSIONING TIMELINESS RULE									
(NOTE: Repeat the answers given in Section 12 of the main body of the inspection record. The issues in subsequent sections are dependent on the answers to these questions.)										
	A.	License to conduct a <i>principal activity</i> <u>has</u> expired or been revoked:				Y		N	x	
	B.	Licensee <u>has</u> made a decision to permanently cease <i>principal activities</i> at the entire site, or any separate buildings, or any outdoor areas, including inactive burial grounds:				Y		N	x	
	C.	A 24-month duration has passed in which no <i>principal activities</i> have been conducted under the license at the site, or at any separate buildings, or any outdoor areas, including inactive burial grounds:				Y		N	x	
	D.	If "Yes" to either A or B or C above:								
	(1)	Identify Site/Bldg./Area:								
	(2)	Date of occurrence of A, B, or C:								
2.	NOTIFICATION REQUIREMENTS									
	A.	Licensee has provided written notification to U.S. NRC within 60 days of the occurrence of 1.A., 1.B., or 1.C. above.				Y		N	x	
	If "Yes," date of notification:									
	B.	If the licensee is requesting to delay initiation of the decommissioning process, the licensee <u>has</u> provided written notification to NRC within 30 days of occurrence of 1.A., 1.B., or 1.C. above:				N/A	x	Y		N
	If "Yes," date of notification:									
Basis for Findings:										
3.	DECOMMISSIONING PLAN/SCHEDULE REQUIREMENTS									
	A.	Licensee is required to submit a decommissioning plan per 10 CFR 30.36(g), 40.42(g), 70.38(g), or 10 CFR Part 72?				N/A	x	Y		N

If "No" to 3.A., answer the following items B - F:							
B.	The decommissioning work scope is covered by current license conditions.	Y			N		
C.	Decommissioning has been initiated within 60 days of notification to NRC, or NRC has granted a delay.	Y			N		
D.	If licensee has initiated decommissioning, give date the decommissioning was initiated:						
E.	If decommissioning has been completed, it was completed within 24 months of notification to NRC.	N/A	x	Y		N	
F.	If decommissioning is still scheduled to be completed, it is on schedule to be completed within 24 months of notification to NRC.						
		N/A	x	Y		N	
Basis for Findings:							
If "Yes" to 3.A., answer the following items G - J:							
G.	The decommissioning plan has been submitted to NRC within 12 months of notification.	Y	X		N		
If "Yes," date of submittal:							
If NRC approved, date of NRC approval:							
H.	Has the licensee submitted an alternative schedule request?	Y			N		
If "Yes," date of submittal:							
I.	If decommissioning has been completed, it was completed within 24 months after approval of the decommissioning plan.	N/A	x	Y		N	
J.	If decommissioning is still scheduled to be completed, it is on schedule to be completed within 24 months after approval of the decommissioning plan.						
		N/A	x	Y		N	
Basis for Findings:							
Violations identified, if any:							

END