

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Genencor International, Inc. 925 Page Mill Road Palo Alto, California 94304		2. NRC/REGIONAL OFFICE USNRC Region IV 611 Ryan Plaza Drive, Suite 400 Arlington, Texas 76011-4005	
REPORT NUMBER(S) 2004-001			
3. DOCKET NUMBER(S) 030-36487	4. LICENSEE NUMBER(S) 04-27770-01	5. DATE(S) OF INSPECTION December 13, 2004	

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

- 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

(Violations and Corrective Actions)

Licensee's Statement of Corrective Actions for Item 4, above.

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Randy R. Erickson	/RA/	12/13/04

Docket File Information
SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION

1. LICENSEE Genencor International, Inc. REPORT NUMBER(S) 2004-001		2. NRC/REGIONAL OFFICE <p style="text-align: center;">USNRC Region IV</p>	
3. DOCKET NUMBER(S) 030-36487	4. LICENSE NUMBER(S) 04-27770-01	5. DATE(S) OF INSPECTION December 13, 2004	
6. INSPECTION PROCEDURES USED 87126	7. INSPECTION FOCUS AREAS 03.01 through 03.07 <p style="text-align: right;">Email: spepper@genencor.com</p>		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03510	2. PRIORITY 03	3. LICENSEE CONTACT Susan Pepper	4. TELEPHONE NUMBER (650) 846-5863 (Palo Alto)
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<input checked="" type="checkbox"/>	Main Office Inspection	Next Inspection Date: <u>January 2006</u>
<input type="checkbox"/>	Field Office <u>N/A</u>	
<input type="checkbox"/>	Temporary Job Site <u>N/A</u>	

PROGRAM SCOPE

This is a large biotech company manufacturing industrial enzymes used as additives to cleaning agents, and food and feed for livestock. They have a California license to possess and use a JL Shepherd irradiator at a California location near their Palo Alto, California, corporate office. They use the irradiator to suppress the immune systems in laboratory mice so they can test allergic reactions to their enzymes.

Approximately 1 year ago, they secured space at NASA located at the Ames Research Center at Moffett Field, California, an area of exclusive federal jurisdiction. They planned to move the irradiator to that facility, however they had scheduling difficulties with JL Shepherd and as of the date of the inspection, they had not moved the irradiator. In an email message dated 12/20/04, the RSO stated that the irradiator was scheduled to be moved on January 5, 2005.

This was an initial inspection which was initially attempted approximately 6 months earlier. This inspection was conducted to comply with IMC 2800 which requires that even if the licensee does not possess byproduct material within one year of license issuance, an inspection should be conducted. In accordance with IMC 2800, the inspection frequency should be reduced from its current frequency to one year following the January 5, 2005, irradiator move where possession under the NRC license was established.

The RSO is officed at the 925 Page Mill Road, Palo Alto, California, 94304, location and is not at Moffett Field on a daily basis. Inspectors should take this into consideration when performing future inspections.