

C.1 **Renewal** - Performance Evaluation Checklist

**PERFORMANCE EVALUATION OF RENEWAL APPLICANT**  
 Official Agency Record

Licensee: Lawrence Pharma, Inc.

License or Docket No: 29-21169-01

Control No: 136378

Records for the 5 years preceding this renewal application were reviewed and/or appropriate staff were interviewed with respect to the following performance indicators:

Performance Indicator	Conclusion	If YES, explain:
Escalated enforcement, or OI or OIG investigation occurred or ongoing	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
Lost control of licensed material presumed in public domain that is reportable or resulted in a violation	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
Unauthorized disposal or release of material that is reportable or resulted in a violation	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
An overexposure that resulted in a violation	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	

If any of the above items are checked "YES," perform a Comprehensive Review using the applicable guidance contained in NUREG-1556. If all boxes are checked "NO," perform a Limited Review. An exception must be approved by a supervisor, documented on this form, or a copy of the documentation must be attached to this document for placement in the docket file.

Additional Information or Explanation of Exception

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The review should be  comprehensive  limited.

DB. Am 6/15/05  
 Reviewer / Date

\_\_\_\_\_  
 Supervisor / Date  
 (if exception granted)

# IDENTIFICATION OF SIGNIFICANT LICENSING ACTION POSSIBLE NEED FOR ONSITE INSPECTION PRIOR TO ROUTINE INSPECTION

Licensee: Laureate Pharma, Inc.

License No. 29-21169-01 Docket No. 03019868 Control No. 136378

An onsite inspection of the licensee identified above must be considered due to a recent significant licensing action involving one or more of the criteria described below. Additional information is attached (if needed).

Check all that apply:

- Increased types and uses
- Physical move or temporary job site
- Authorization of satellite facilities
- Increased disposal authorization
- Significant increase in number of authorized users
- Change in Radiation Safety Officer

Date of Last Inspection: 12/13/00 Results (Clear, #NOVs): Clear

Date of Next Scheduled Inspection: 12/2005

Reviewer Recommendation and Justification:

- Change \_\_\_\_\_
- No Change \_\_\_\_\_

License Reviewer: [Signature]

Date: 6/15/05

Change date of Next Inspection?

- No
- Yes New Inspection date: \_\_\_\_\_

Branch Chief: [Signature]

Date: 6/16/05

**C.2 Renewal – Limited Review Checklist**

**RENEWAL-LIMITED REVIEW CHECKLIST**

Use either a check mark to designate a satisfactory response, "NA" to designate not applicable or "D" to designate deficiency, as appropriate. Document areas receiving a focused or thorough review at the end of the checklist.

Licensee: <u>Laureate Pharma, Inc</u>	License No. <u>29-21169-01</u>
	Docket No. <u>03019868</u>
	Control No. <u>136378</u>

- NRC-313 or appropriate equivalent signed and dated by senior licensee representative.
- Check the possession limits and confirm that any decommissioning financial assurance remains adequate.
- Licensee name and address match the current license.
- Place of use is a physical location (i.e., not P.O. Box, etc.)
- RSO and key personnel are appropriately qualified.
- Facilities and equipment are adequate.
- All uses qualify for a categorical exclusion in 10 CFR Part 51.
- Organizational structure conforms with applicable regulations and NUREG-1556 guidance. Reviewers are reminded licensees have the flexibility to provide information equivalent to that requested in NUREG-1556. (Appropriate individuals are present and are assigned necessary authority & responsibility.)
- New authorizations requested by the licensee and any major program elements that require change as a result of the new authorization structure conform with applicable regulations and NUREG-1556 guidance.
- Inspection records reviewed for issues to be resolved during licensing.

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**RENEWAL-LIMITED REVIEW CHECKLIST**

(continued)

Major program changes, new high risk technology programs, and changes in control (ownership) normally require only a focused review of the specific changes. If these changes are so extensive that a Comprehensive Review of the entire application is needed, obtain Branch Chief approval before proceeding. Each of the following three items must be marked with NA or a check and the change briefly identified.

N/A

Major program change conforms with applicable regulations and NUREG-1556 guidance.

N/A

New high risk technology program conforms with regulations for similar technologies, guidance provided for similar technologies in NUREG-1556 guidance, and specific licensing conditions for the new technology.

N/A

Change in Control (Ownership) conforms with applicable regulations and NUREG-1556 guidance. NOTE: Financial assurance documents can be affected by change of ownership.

A brief overview of the remainder of the application found that the major areas discussed in the guidance on the contents of the application from the appropriate NUREG-1556 series are present.

An obvious failure or a deficiency in a significant area resulted in a thorough review of that area. Document below.

Additional information was requested, and an adequate response was received. (circle request as appropriate: phone log / e-mail / fax / letter letter)

A Comprehensive Review was conducted, and the reason for changing from a Limited Review to a Comprehensive Review is documented on the "Performance and Limited Review Check List."

**Area(s) of Focused or Thorough Review:**

Date: 6/15/05

Change date of Next Inspection?

No

Yes New Inspection date: \_\_\_\_\_

Branch Chief: [Signature]

Date: 6/16/05