

C.1 Renewal – Performance Evaluation Checklist**PERFORMANCE EVALUATION OF RENEWAL APPLICANT**

Official Agency Record

Licensee: Alexion Pharmaceutical, Inc.License or Docket No: 06-28799-01Control No: 132920

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

The review should be ☐ comprehensive ☒ limited.

Edward H. Li
Reviewer / Date

4/10/03

Supervisor / Date
(if exception granted)

C.2 Renewal – Limited Review Checklist**RENEWAL-LIMITED REVIEW CHECKLIST**

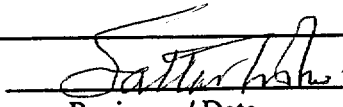
Use either a check mark to designate a satisfactory response, "NA" to designate not applicable or "D" to designate deficiency, as appropriate. Document areas receiving a focused or thorough review at the end of the checklist.

Licensee: <i>Alexion Pharmaceuticals, Inc.</i>	License No. <u>06-28799-01</u> Docket No. <u>030-32976</u> Control No. <u>132920</u>
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- ☒ 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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C.3 New and Renewal – License Term Checklist

LICENSE TERMS OF LESS THAN 10 YEARS Official Agency Record																											
Licensee: <u>Alexion Pharmaceuticals, Inc.</u>	License: <u>06-28795-01</u> Docket No: <u>030-32976</u> Control No: <u>132920</u>																										
The application and license records were reviewed against the following criteria to determine if a reduced license term is appropriate:																											
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;">Criteria</th> <th style="width: 10%;">YES</th> <th style="width: 10%;">NO</th> <th style="width: 30%;">Basis for YES</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">New high risk technology without extensive use or regulation experience by industry, or licensee, or NRC;</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td></td> </tr> <tr> <td style="padding: 5px;">Enforcement History – Severity Level I, II, or III violation due to serious programmatic deficiencies and not singular events, in preceding 3 years;</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td></td> </tr> <tr> <td style="padding: 5px;">Possession-Only (Permanent Shutdown) – License authorizes no activities other than possession and storage of licensed material (2-year term);</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td></td> </tr> <tr> <td style="padding: 5px;">Renewal received a Comprehensive Review;</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td></td> </tr> <tr> <td style="padding: 5px;">Other, specify:</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> </tr> </tbody> </table>	Criteria	YES	NO	Basis for YES	New high risk technology without extensive use or regulation experience by industry, or licensee, or NRC;	<input type="checkbox"/>	<input checked="" type="checkbox"/>		Enforcement History – Severity Level I, II, or III violation due to serious programmatic deficiencies and not singular events, in preceding 3 years;	<input type="checkbox"/>	<input checked="" type="checkbox"/>		Possession-Only (Permanent Shutdown) – License authorizes no activities other than possession and storage of licensed material (2-year term);	<input type="checkbox"/>	<input checked="" type="checkbox"/>		Renewal received a Comprehensive Review;	<input type="checkbox"/>	<input checked="" type="checkbox"/>		Other, specify:	<input type="checkbox"/>	<input type="checkbox"/>				
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Other, specify:	<input type="checkbox"/>	<input type="checkbox"/>																									
If any of the above items are checked "YES", describe the basis above, determine the license term (usually 5 years) and document the determination below. All exceptions must be approved by a supervisor and a copy of that documentation attached to this checklist for placement in the docket.																											
Assigned License Term: <u>10</u> years																											
Additional Information or Explanation of Exception 																											
 Reviewer / Date <u>4/10/03</u>		Supervisor / Date (if less than 10 years or exception)																									