

Corrective Action Plan

NC#: _____

Section 1: Item not in compliance:

Source and Description of Non-Compliance:

Pre-Inspection Questionnaire Item #: _____

Inspection Questionnaire Section: _____ Item #: _____

Potential Threat Yes No

Repeat Non-compliance Yes No

Related Medical Standard: _____

Description of non-compliance (*Include as much detail as possible. Attach documentation that may be relevant to specific non-compliance*):

Section 2: Eye Bank Corrective and Preventive Action Plan:

Possible Root Cause (*Describe, in your eye bank's opinion, the potential root cause of the non-compliance*):

Root Cause Investigation *(Describe the activities conducted to determine the cause of the problem / non-compliance and the findings from the investigation):*

Additional Corrective Actions Taken *(Describe additional corrective actions, if any, taken after completion of the root cause investigation):*

Preventive Actions to be Taken *(Describe the preventive actions your bank will take to prevent recurrence of this non-compliance):*

Did this preventive action require a Standard Operating Procedure (SOP) change? Yes No

If yes, enter SOP title in the following blank and attach a revised and signed copy to this form:

Preventive Action Plan Implementation *(Describe in detail the plan of implementation for the preventive actions listed above and the date the eye bank anticipates having this action fully implemented):*

Eye Bank Signatures:

Individual completing report: _____ Date: _____

Executive Director (or equivalent): _____ Date: _____

Medical Director: _____ Date: _____