

Inspection Dates: 4/18/00 to 4/20/00

processed by [REDACTED] when it was faxed to them on August 1st. The annual review was not placed on their schedule for reapproval until August 29th.

We discussed the time lag between the provision of requested materials and the reapproval date with a representative from [REDACTED]. No explanation or reason for the delay were noted in the file. We acknowledge, however, that sending in the annual review a few days before the expiration date did not allow sufficient time for any questions or requests for additional information that might arise during the review and that there was a resultant lapse in the recorded approval dates.