

[Your Name/Organization Name]
[Your Address]
[City, State, Zip Code]
[Phone Number]
[Email Address]

[Date]

[Recipient Name/Department Head]
[Regulatory Agency Name]
[Agency Address]
[City, State, Zip Code]

RE: Response to Notice of Substantial Noncompliance - [Case/Reference Number]

Dear [Recipient Name],

This letter serves as the formal response from [Your Organization Name] regarding the Notice of Substantial Noncompliance received on [Date of Notice]. We acknowledge the findings detailed in the report following the inspection/audit conducted on [Date of Inspection].

We take these regulatory matters seriously and are committed to full compliance. In response to the specific violations cited, we have developed the following Corrective Action Plan (CAP):

1. Immediate Actions Taken:

[Describe the immediate steps taken to mitigate the risks or stop the noncompliant activity.]

2. Root Cause Analysis:

[Provide a brief explanation of why the noncompliance occurred, such as equipment failure, training gaps, or procedural oversight.]

3. Long-Term Corrective Measures:

[Detail the systemic changes implemented, such as new software, revised SOPs, or staff retraining, to prevent recurrence.]

4. Monitoring and Verification:

[Explain how the organization will audit its own compliance moving forward and who will be responsible for oversight.]

5. Timeline for Completion:

[State the date by which all corrective actions will be fully operational.]

Attached to this letter, please find [List of attachments: e.g., photos, updated policy manuals, training logs] as evidence of our progress toward resolution.

We request that you review this response and advise if any further information is required to move this matter toward closure. We are available for a meeting or phone call at your convenience to discuss these measures in detail.

Sincerely,

[Signature]

[Printed Name]

[Job Title]