**CORRECTIVE ACTION AND PREVENTIVE ACTION PLAN FOR RADIATION FACILITIES**

|  |  |
| --- | --- |
| Name of Radiation Facility: | Address: |
| Inspector/s: | Inspection Date/s |
| Prepared by:  *(Name & Designation of Facility’s Authorized Representative)* | Date prepared: |

*Note: Facility to fill columns #2 to 5.*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **No. (#)** | **List of Deficiencies / Findings** | **Description of deficiency** | **Corrective / Preventive Action Plan** | **Timeline for Compliance** | **Evidence of Compliance** | **Inspector’s Comment/s** | **Response accepted (Yes/No)** |
|  | *List all noted findings by the FDA inspector/s with description.* | | *Propose a plan to address the root cause of the noted finding / deficiency with specific timeline for compliance maximum of 15 working days from CAPA submission.* | | *Specify the proof of compliance to proposed plan* | *(FDA-CDRRHR use only)* | |
| **1** |  |  |  |  |  |  |  |
| **2** |  |  |  |  |  |  |  |
| **3** |  |  |  |  |  |  |  |
| **3** |  |  |  |  |  |  |  |
| **4** |  |  |  |  |  |  |  |
| **5** |  |  |  |  |  |  |  |
| **6** |  |  |  |  |  |  |  |

**-------------------------------------------------**

For FDA use only:

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| --- | --- | --- | --- |
| **Remarks** | | | |
| **Recommendations / Directives** | | | |
| **Reviewed by** | (Name / Designation of Evaluator/Inspector) | **Date** |  |
| **Noted by** | (Name / Designation) | **Date** |  |