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| **New Change Control** | |
| Requested By |  |
| Domain | ICONCR |
| Brief Description | QC Workflow – Arrangement for senior resources to review the work of junior resources. |
| Environment (PROD /TEST) |  |
| Severity (minor, significant, major) |  |
| Priority (Standard, Urgent, Emergency) |  |
| Category | Application |
| Server Name |  |

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| **Detailed Description and Reasons the Change is necessary** |
| Arrangement to allow the junior resource to pass on their works to senior resource for review along with any comments and similarly, senior resource allowed to review as well as pass this back on junior resource with any review comments.  Provision for users to upload files during QC work flow, before the QC is completed with maximum file size being 5MB  All comments from auditee and auditor should be stored in the tool for internal purposes and should be archived after 6 months along with the ICSF |

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| **Detailed Implementation Plan. (Is reboot required?)** |
| 1. Stop the IIS server 2. Back up    1. Copy the folders       1. App\_Data       2. assets       3. bin       4. DataFiles       5. Dist    2. Copy the files, web.config and index.html 3. Paste the above folders and files into a new folder 4. Copy and replace the above-mentioned folders and files with the ones provided by clarity 5. Check whether the folders exist, in the path given below. Create these folders if they do not exist already    1. DataFiles/Downloads/CIILFolder    2. DataFiles/Downloads/ExclusionDatabase    3. DataFiles/Downloads/FDAWarningLetters    4. DataFiles/Downloads/SAM    5. DataFiles/Downloads/SDN 6. Start the IIS server |

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| **Tests to Be Performed** |
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| **Backout Plan** |
| 1. Stop the IIS server 2. Paste the backed up files in the below folders    1. App\_Data    2. assets    3. bin    4. DataFiles    5. Dist    6. web.config and index.html   re-start the IIS server |

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| **Post Implementation Plan** |
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| **Proposed Start Date/Time** |  |
| **Proposed Finish Date/Time** |  |
| **Time Zone (GMT, GMT+1 etc)** | GMT |