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| **Inspection/Report Reference no.:** |  | |
| **Inspected NMVO:** | | |
| *Name and full address of the inspected organisation* | | |
| **Inspection Type** | On-site: | Remote (Desktop): |
| **Purpose of the Inspection** | Routine: | Other:  *Indicate reasons* |
| **Inspection Date(s):** | *Date(s), month, year* | |
| **Inspector(s) and Expert(s):** | | |
| *Name(s) of the inspector(s).*  *Name(s) of expert(s) (if applicable).*  *Name(s) of Competent Authority(ies).* | | |
| **Introduction:** | | |
| *Short description of the organisation.*  *Indicate whether the repository is national or supranational.*  *Include details of the NMVS Service Provider.*  *Indicate whether the NMVS is a Blueprint, Customised Blueprint or Bespoke System.*  *Include the following details, as applicable:*   * *Date of previous inspection.* * *Name(s) of inspector(s)/expert(s) involved in previous inspection.* * *Significant changes since the previous inspection.* | | |
| **Brief report of the inspection activities undertaken:** | | |
| Scope of Inspection: *Short description of the inspection.*  Inspected area(s): *Each inspected area should be specified.* | | |
| **Activities not inspected:** | | |
| *Where applicable attention should be drawn to areas or activities not subject to inspection on this occasion.* | | |
| **Personnel met during the inspection:** | | |
| *The names and job titles of key personnel met should be specified.* | | |
| **Findings and observations relevant to the inspection and non-compliances:** | | |
| *Relevant headings from the Commission Delegated Regulation (EU) 2016/161, as applicable.*  *This section can link the findings to the non-compliances.*  *Headings which may be used (other headings may be introduced when relevant):*  *Establishment of the repositories system*  *Structure of the repositories system*  *Uploading of information in the repositories system*  *Functioning of the hub*  *Characteristics of the repositories system*  *Operations of the repositories system*  *Obligations of legal entities establishing and managing a repository which is part of the repositories system*  *Data protection and data ownership*  *Qualification/Validation of the Systems*    *Quality Management System*   * *Overview of inspection findings from the last inspection and corrective action taken* * *System Access Management* * *Information Security Management* * *Connection of End-users* * *Management of Incidents/Potential Incidents of Falsification* * *Change Management* * *Complaint Management* * *Risk Management* * *CAPA Management* * *Training* * *Business Continuity* * *Audit Management* | | |
| **Annexes attached:** | | |
| *List of any annexes attached* | | |
| ***List of non-compliances:*** | | |
| *Non-compliances should be listed and the relevant reference to the Delegated Regulation should be mentioned.*  *The organisation should be asked to respond to the findings including proposed time schedule for corrections.* | | |
| **Compliance rating:** | | |
| *Indicate the compliance rating*  Compliant  Compliant with observations  Non-Compliant  Not Operational | | |
| **Competent Authority comments on the organisation’s response to the inspection findings:** | | |
| *i.e. are the responses acceptable?* | | |
| **Summary and conclusions:** | | |
| *The Competent Authority should state whether the organisation operates in general compliance with the requirements of the Commission Delegated Regulation (EU) 2016/161.* | | |
| **Name(s):**  *The inspection report should be signed and dated by all personnel having participated in the inspection.*  **Signature(s):**  **Competent Authority Name:**  **Date:** | | |