| SL NO | Audit Observations | Attribute to ISO 9001:2008 Clause | Status  |
| --- | --- | --- | --- |
| "OI" “O+” “NC” |
|  | Verified Organisation Chart – to be standardised  | 4.2.2 | "OI" |
|  | Verified List of Records & Documents – Maintained well  | 4.2.3 | "O+" |
|  | Verified List of Records – To be updated with Ref. No / Code & Retention Periods.  | 4.2.3 | "OI" |
|  | Verified Process Manual – abbreviation and Roles & Responsibility to be updated  | 4.2.3 | "OI" |
|  | Verified Procedure Manual for the department flow charts and Measures of Performance to be modified / Defined more clearly, either in terms of % or in terms of Nos.  | 4.2.3 | "OI" |
|  |
|  | Verified AIISH Prospectus & Category wise Admission report - well maintained.  | 5.2.1 & 7.1 | “O+” |
|  | Verified & asked for List of Chemicals used in the Department and MSDS for the Chemicals – not available  | 5.1 & 7.2.1 | "NC" |
|  |
|  | Verified the Skill Matrix– it is not updated and training & Certificate is required for special skills or Competency Mapping is required.  | 6.1.1 | “OI” |
|  | Verified flowcharts for the department activities – to be modified  | 6.2.1 | "OI" |
|  | Verified Training Programme Feedback – to be recorded properly and corrective action to be taken.  | 6.2.2 | "OI" |
|  |
|  | Verified the Examination process (for Entrance and Semester end). It is well maintained  | 7.1 & 7.2.1 | “O+” |
|  | Verified Agreement between AIISH & K.R. Hospital – Contract Review to be made & Documents to be updated.  | 7.2.1 & 7.2.2 | "OI" |
|  | Verified Work Environment in the department – there is no Do’s & Don’ts at the operation level for the operation of equipments.  | 7.2.1 & 7.2.2 | "OI" |
|  | Verified Design & Development procedure – not available  | 7.3.1 | "NC" |
|  | Verified process for Purchase of books – Acquisition of resources – still clarity is required  | 7.4.1 | “OI” |
|  | Verified procedure for Supplier Section Criteria - is well maintained  | 7.4.1 | “O+” |
|  | List of approved suppliers & pending PO’s list – there is no control and data is not available  | 7.4.1 & 7.4.2 | “NC” |
|  | Verified Outsourced activity procedure – like security, housekeeping etc. not available  | 7.4.1 | "NC" |
|  | Verified procedure for Rejected materials handling – to be explained in detail  | 7.5.1 | “OI” |
|  | Verified procedure / Work Instructions for selection of instruments & operation of instruments not available  | 7.5.1 & 8.2.3 | “NC” |
|  | Verified procedure for Data backup in the department – it is not designed.  | 7.3.1 & 7.5.1 | “NC” |
|  | Department procedure Manual in not adequate for the activities involved in the department. Detailed explanation is required.  | 7.5.1 | "OI" |
|  | Verified Shelf-life of items used in the department – list is not available and monitoring of shelf-life to be improved  | 7.5.1 | "OI" |
|  |  Verified process for distribution of seats for different training programs (year wise) – to be improved  | 7.2.3 | "OI" |
|  | Verified Procedure for Group Consulting – procedure not defined properly and data collection and follow-up action not proper.  | 7.2.3, 8.2.3 & 8.4 | "NC" |
|  | Verified Purchase order terms and conditions to the suppliers – to be elaborate in all the copies and mention the owners in the PO copies( like suppliers, stores, purchase, indenter, accounts) & explain in the procedure.  | 7.5.3 | “OI” |
|  | Verified Case sheets for two patients – No. 342887 & 338729 - well maintained and quick retrieval  | 7.5.3 | “O+” |
|  | Verified List of Equipments – there is no fixed frequency / preventive maintenance schedule is not available  | 7.5.3  | "NC" |
|  | Verified procedure for follow-up action for repaired equipment - not available | 7.5.3  | "NC" |
|  | Verified procedure for un-serviceable / condemnation of equipments. – Not available.  | 7.5.3  | "NC" |
|  | Verified Information related process for updating, modifying and data backup (overall IT management) – not defined properly.  | 7.5.4 & 7.5.5 | “NC” |
|  | Verified Design & Development Control for Research documents  | 7.3.2, 7.3.3 & 7.3.6 | "NC" |
|  | Verified control on Research output (product / Services & Documents) procedure – not available & Scope to be re-defined | 7.3.2 & 7.3.7 | "NC" |
|  | Verified procedure / Work Instructions / Control for medical West Disposable - not available  | 7.1 | "NC" |
|  | Verified Work Instructions / Control for Nursing Procedures & Autoclave operations - not available  | 7.1 | "NC" |
|  | Verified List of Equipments – To be update with proper codes location and Specifications  | 7.6 | "OI" |
|  | List of Agencies(Services & AMC) and List of Equipments – not available  | 7.6 | "NC" |
|  |
|  | Verified Customer Complaints / Feedback report – to be update & Use the Standard Formats.  | 8.2.1 | "OI" |
|  | Verified Monthly reports – data is adequate, but usage of data is not satisfactory ( data can be used for continual improvement ) | 8.5.1 | "OI" |
|  | Verified Procedure Manual for Data Backup from Server and other systems – not available  | 8.2.3 | “OI” |
|  | Verified the Procedure / work instruction for Accepting Criteria / norms for civil work- not available  | 8.2.3 | “NC” |
|  | Verified procedure / Work Instructions for equipment operations in particular labs and Ear mould section – To be defined in procedure / prepare the work instructions  | 8.2.3 | "OI" |
|  | Verified Summary for cases attended in a month – data is available but not controlled properly.  | 8.2.3 | "OI" |
|  | Verified Summary for Individual cases attended in a month – data not available or not controlled properly.  | 8.2.3 | "NC" |