

# D187: DEMO OF ISO 35001:2019 DOCUMENT KIT **Price 999 USD**

Complete editable document tool kit on ISO 35001 Bio Risk Management (Manual, procedures, exhibits, SOPs, forms, audit checklist etc.)

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## Chapter-1.0 CONTENTS ISO 35001:2019 DOCUMENT KIT (More than 80 document files)

A. The entire editable document kit has 8 main directories as below.

Sr. No.	List of Directory	Document of Details
1.	System Manual	01 files in MS Word
2.	Procedures	17 procedures in MS Word
3.	Exhibits	11 exhibits in MS Word
4.	Standard Operating Procedures	05 Standard operating procedures in MS Word
5.	Blank Formats / Templates	46 formats in MS Word / excel
6.	ISO 35001:2019 Audit Checklist	More than 250 questions
7.	Filled sample risk assessment sheet	01 files in MS excel
8.	ISO 35001:2019 document matrix	01 file in MS excel

**Total 80 files quick download in editable form by e delivery**

### B. Documentation: -

Our document kit is having sample documents required for system certification as listed below. **All documents are in word and you can edit it.** You can do changes as per your company need and **within 5 days your entire documents** with all necessary controls are ready and our many organization are certified globally in 1<sup>st</sup> trial with the help of our documents from any stringent certification audit. The ISO 35001:2019 is the latest edition of standard available from international organization for standardization web site.

Under this directory further files are made in word document as per the details listed below. All the documents are related to any kind of manufacturing/process industry.

#### 1. System Manual:

It covers sample copy of system manual and clause wise details for how Bio risk Management systems are implemented. It covers list of procedures as well as overview of organization and covers tier1 of ISO 35001:2019 documents.

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## (A) Table of Contents

Chapter No.	Subject	Amend. No.	Page No.	ISO 35001 Clause Ref.
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3	Control and distribution	00	8 – 9	=====
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	4.1	Understanding the organization and its context	00 10	
	4.2	Understanding the needs and expectations of interested parties	00 11	
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	4.4	Bio risk management system	00 11	
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	5.1	Leadership and commitment	00 13	
	5.2	Policy	00 13	
	5.3	Roles, responsibilities, and authorities	00 14 – 16	
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	6.2	Bio risk management objectives and planning to achieve them	00 19 – 20	
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## 2. Procedures (17 procedures):

It covers a sample copy of mandatory procedures as per ISO 35001:2019 covering all the details like purpose, scope, responsibility, how procedure is followed as well as the list of exhibits, reference documents and formats. The list of sample procedures provided is as below.

### List of Procedures

1. Procedures for risk assessment
2. Procedure for competence
3. Procedures to guide implementation of personnel reliability measures
4. Procedures to control individual's access to facilities or work
5. Procedures for personnel and training
6. Procedure for control of documented information
7. Procedures for managing the identification, handling, storage, transmission, access control, and destruction of sensitive information
8. Procedure for selection, approval and evaluation of externally provided products and services
9. Procedure for purchasing of products and services

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10. Procedures for identification, purchase, maintenance, and calibration of equipment and elements of the facilities, including ancillary support facilities
11. Procedures for verification of performance of physical security system for biological materials
12. Procedures for waste storage, identification, segregation, packaging, transport, decontamination, inactivation and disposal
13. Procedures for emergency response and contingency plans and procedures
14. Procedure for monitoring, measurement, analysis and evaluation
15. Procedure for internal audit
16. Procedure for management review
17. Procedure for root cause analysis, and corrective action

### **3. Exhibits (04 exhibits)**

It covers sample copy exhibits for ISO 35001:2019 Bio risk Management for Laboratory and other related organizations.

#### **List of exhibits**

1. Quality Policy
2. Operational Control plan
3. Biorisk management plan
4. Vaccination policy
5. Implementation of personnel reliability measures policy
6. Competence requirements
7. Communication process
8. Physical security monitoring and maintenance plan
9. Waste management and decontamination policy
10. Emergency preparedness and response plan
11. TREM Card

### **4. Standard operating procedures (06 SOPs)**

It covers sample copy of standard operating procedure as per ISO 35001:2019.

#### **List of Standard operating procedures**

1. SOP for Collection and transportation of sample
2. SOP for Specimen acceptance & rejection criteria
3. SOP for Treatment and disposal of biomedical waste
4. SOP for Housekeeping
5. SOP for Use of PPE and personal safety

### **5. Blank Formats (46 Blank formats)**

It covers sample copy of blank forms required to maintain records as well as establish control and make system in the organization. The samples given are as a guide and not compulsory to follow and organization is free to change the same to suit own requirements.

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### List of blank formats

- |   |  |
|---|--|
| 1. Confidentiality and Impartiality Agreement               | 24. Inspection report                    |
| 2. Job Description and Specification                        | 25. Calibration Status of Equipment      |
| 3. Risk assessment and opportunity sheet                    | 26. Equipment history card               |
| 4. Employee Vaccination report                              | 27. Preventive maintenance records       |
| 5. Employees Competence Report                              | 28. Physical security monitoring report  |
| 6. Competence assessment Report                             | 29. Biological materials receipt note    |
| 7. Reliability measures report                              | 30. Biological materials stock report    |
| 8. Access report  | 31. PPE inspection report                |
| 9. Training Calendar  | 32. PPE issue report                     |
| 10. Training Report   | 33. Decontamination and disposal report  |
| 11. Induction Training Report                               | 34. Mock drill report                    |
| 12. Skill Matrix  | 35. Delivery challan / Gate Pass         |
| 13. Training Effectiveness check report                     | 36. Quality objective monitoring report  |
| 14. Master list and Distribution list of Documents          | 37. Performance monitoring report        |
| 15. Change Note   | 38. Audit plan / schedule                |
| 16. Periodic document review report                         | 39. Internal Audit Non-conformity report |
| 17. Master list of Records                                  | 40. Clause-wise audit report             |
| 18. Data security report                                    | 41. Circular                             |
| 19. Supplier registration report                            | 42. Minutes of Meeting                   |
| 20. Approved External Providers List (Approved Vendor List) | 43. Incident report                      |
| 21. Supplier Evaluation Report                              | 44. Root cause analysis report           |
| 22. Purchase requisition                                    | 45. Corrective action report             |
| 23. Purchase order  | 46. Continual improvement log            |

### **6. Audit Checklist (More than 250 Audit check list questions)**

There covers audit questions based on compliance management system requirements as well as for each departments. It will be very good tool for the auditors to make audit Questionnaire while auditing and make effectiveness in auditing.

### **7. Filled sample risk assessment sheet**

The ready-to-use risk template in editable form is given to prepare the risk document for the organization. It is given in an excel format and can be used as a template.

### **8. ISO 35001:2019 document matrix**

The ISO 35001:2019 requirement wise list of documented information reference of this kit is given in document matrix for ready reference to user to understand how this system is made.

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### Chapter-2.0 ABOUT COMPANY

Documentation Consultancy is a progressive company promoted by a group of qualified engineers and management graduates having rich experience of over 25 years in ISO consultancy and management areas. The company serves the global customers through on-site and off-site modes of service delivery systems. We offer a full range of consulting services geared towards helping all types of organizations to achieve competitiveness, certification and compliance to international standards and regulations. So far, we have **more than 2700 clients in more than 36 countries**. **Our readymade training kit and editable documentation kit help the clients in making their documents with ease and complying with the related ISO standard faster.**

1. Our promoters and engineers have rich experience of providing management training and ISO series consultancy for **more than 2700 companies** globally. We have clients **in more than 36 countries**.
2. We are a highly qualified team of 80 members (M.B.A., Degree Engineers). Our Director has rich professional experience in this field (since 1991).
3. We have 100% success rate in ISO series certification for our clients from reputed certifying bodies. We possess a branded image and are a leading name in the global market.
4. We suggest continual improvement and cost reduction measures as well as provide highly informative training presentations and other products that give you payback within 2 months against our cost.
5. So far, we have trained more than 50000 employees in ISO series certification.
6. We have spent more than 60000 man-days (170 man-years) in the preparation of ISO documents and training slides.

#### **Documentation Consultancy is committed for:**

1. Personal involvement and commitment from the day one
2. Optimum charges
3. Professional approach and globally helped many companies for this standard.
4. Hard work and updating the knowledge of team members
5. Strengthening clients by system establishment and providing best training materials in any areas of management to make their house in proper manner
6. Establishing strong internal control with the help of system and use of the latest management techniques.

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### Chapter-3.0 USER FUNCTION

#### 3.1 Hardware and Software Requirements

##### A. Hardware

- Our documentation kit can better perform with P4 and higher computers with a minimum of 10 GB hard disk space.
- For better visual impact, you may keep the setting at high color.

##### B. Software

- Documents are written in MS-Office 2007 and Windows XP programs. You are, therefore, required to have MS-Office 2007 or higher versions with Windows XP.

#### 3.2 Features of Documentation kit

- The kit contains all necessary documents as listed, and complies with the requirements of system standards.
- The documents are written in easy to understand English language.
- This kit will save much time in typing and preparing your documents at your own.
- The kit is user-friendly to adopt and easy to learn.
- The contents of this kit are developed under the guidance of experienced experts.
- The kit provides a model of the management system that is simple and free from excessive paperwork.

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### Chapter-4.0 BENEFITS OF USING OUR DOCUMENTATION KIT

1. By using these documents, you can save a lot of your precious time while preparing the ISO documents.
2. The kit takes care of all the sections and sub-sections of ISO 35001:2019 standards and helps you to establish better system.
3. This documentation kit enables you to change the contents and print as many copies as you need. The users can modify the documents as per their industry requirements and create their own ISO 35001:2019 documents for their organization.
4. It will save much cost in document preparation.
5. You will get a better control in your system due to our proven formats.
6. You will also get a better control in your system as our proven documents and templates are developed under the guidance of experts and globally proven consultants. The team has a rich experience of more than 25 years in the ISO consultancy.
7. Our products are highly sold across the globe and are used by many multinational companies. They have got total satisfaction as well as experienced value for money.
8. In the preparation of documentation kit, our team has verified and evaluated the entire content at various levels. More than 1000 hours have been spent in the preparation of this documentation kit.
9. The entire kit is prepared by a globally proven team of leading ISO consultants.

### Chapter-5.0 METHOD OF ONLINE DELIVERY

On completion of the secured purchase, we provide a username and password to download the product from our FTP server. We provide instant online delivery of the kit to the users by sending an e-mail of username and password.

**For purchase, Click Here** →



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