



Reference	Question	Assessment Result	Remarks
11.10(b) (continued) Preamble clauses 69- 70	• Can a copy of a single record (in electronic format) be supplied to an inspector? In paper format?	S:Yes	Electronic format: Database copy function. Paper format: Report.
	• Can a copy of the entire database (in electronic format) be supplied to an inspector?	S:Yes	The database consists of three files. They can be copied onto any medium with the operating system's file explorer.
	• Are procedures in place to describe HOW to accomplish these inspection tasks?	S:Yes	Please refer to the documentation and the online help, chapter, "Database Administration".
	• Are procedures in place to define what in format the electronic records will be provided?	S:Yes	On-line-Help contains a description of all Report template statements, their value and format.
11.10(c) Preamble clause 71	• Are the records protected to ensure their accurate and ready retrieval throughout the record retention period?	S:Yes	No measured data or data describing the circumstances of the measurement can be deleted from the database. If the database format is changed due to an update, a conversion utility is provided to ensure compatibility of old data to the new software.
	• Are records protected on the system to prevent unauthorized modification or deletion?	S:Yes	
	• Are data files written to a protected directory or database table such that only personnel with high-level access privileges can access the data files?	S:Yes	It is the system administrator's task to assign proper attributes to the directories in which the database(s) is/are located. The access rights of the WINDOX database server are "SYSTEM" level, so the database files may be write-protected for everyone except "SYSTEM".
	• Do system users have access to the data files or database records, such that they could accidentally or intentionally modify or delete data files?	S:Yes	The WINDOX client-server database concept supports a strict protection of the database files. No ordinary user needs to have write access to the database files.
	• Has any capacity planning been performed?	P:___	On modern PC's storage capacity is not a problem. After some time of use, however, the size of the database directory should be checked and compared to the amount of free space on disk.
	• Is there a written records retention policy?	P:___	
	• Does it include electronic records?	P:___	
	• Does it include audit trails?	P:___	The audit trail information is stored in the database, so it can never be separated from the electronic records.