

With respect to section 2.3 - Establishing record-keeping requirements

From an integrity perspective:

What is not a record?

Will primary records be destroyed?

Will records be post quantum(PQC), time dilation, and aging resistant (i.e. single/multi event upsets)?

If yes, to what degree?

Will internal and/or external contradictions be dispositioned?

For example analyst and/or environmental measurements {time, space, measure, error, uncertainty}
suggestive of process state contradictions

How will sampling schemes be dispositioned? (i.e. point/space, time, frequency, count, etc.)

How will analyst findings be interpreted (i.e. limits of detection, limits of quantification, etc.)

How will statistical schemes be dispositioned? (rollup, estimation, aggregation, interpolation, extrapolation, etc.)

What events will not be analyzed?

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