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AnIML

in Regulated Environments

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Content

- Regulations
- Some Definitions
- Compliance Features in AnIML

Regulations

- FDA guidance documents for the industry:
  - 21 CFR 820 (Medical Devices)
  - 40 CFR 160 (Environmental GLPs)
  - 21 CFR 11 (Electronic Records/Signatures Rule)
  - 21 CFR 110 and following (Food)
  - 21 CFR 210, 211 (Pharmaceuticals)
  - 21 CFR 312 (Clinical)
  - 21 CFR 58 (GLPS for non clinical studies)
  - GALP (Good Automated Practices for EPA)

Electronic record

"any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system."

Controls

"Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine."

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Electronic Signatures

"Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:

(2) The printed name of the signer;

(3) The date and time when the signature was executed; and

(4) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.

(b) The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout)."

Electronic Signatures

"Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means."

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Audit Trails

"Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review."

Accuracy

"The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency."

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Reproducibility

Electronic records must be reproducible in electronic and paper form (including audit trail and metadata) in general and upon request.

- Long term stability of data formats
- Independence from software vendor
- Easy integration of data in existing applications
- Easy translation of data if required
- Enhance productivity by making archived data available as an expert knowledge resource corporate wide

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Compliance Features in AnIML

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Digital Signatures

- Protect (parts of) AnIML Document from undetected tampering
- “Signable Items”

- Multiple signatures with variable coverage
- Timestamping, roles, PKI integration
- Uses XML DSIG* by the W3C/IETF

* XML-Signature Syntax and Processing Specification
http://www.w3.org/TR/xmldsig-core/

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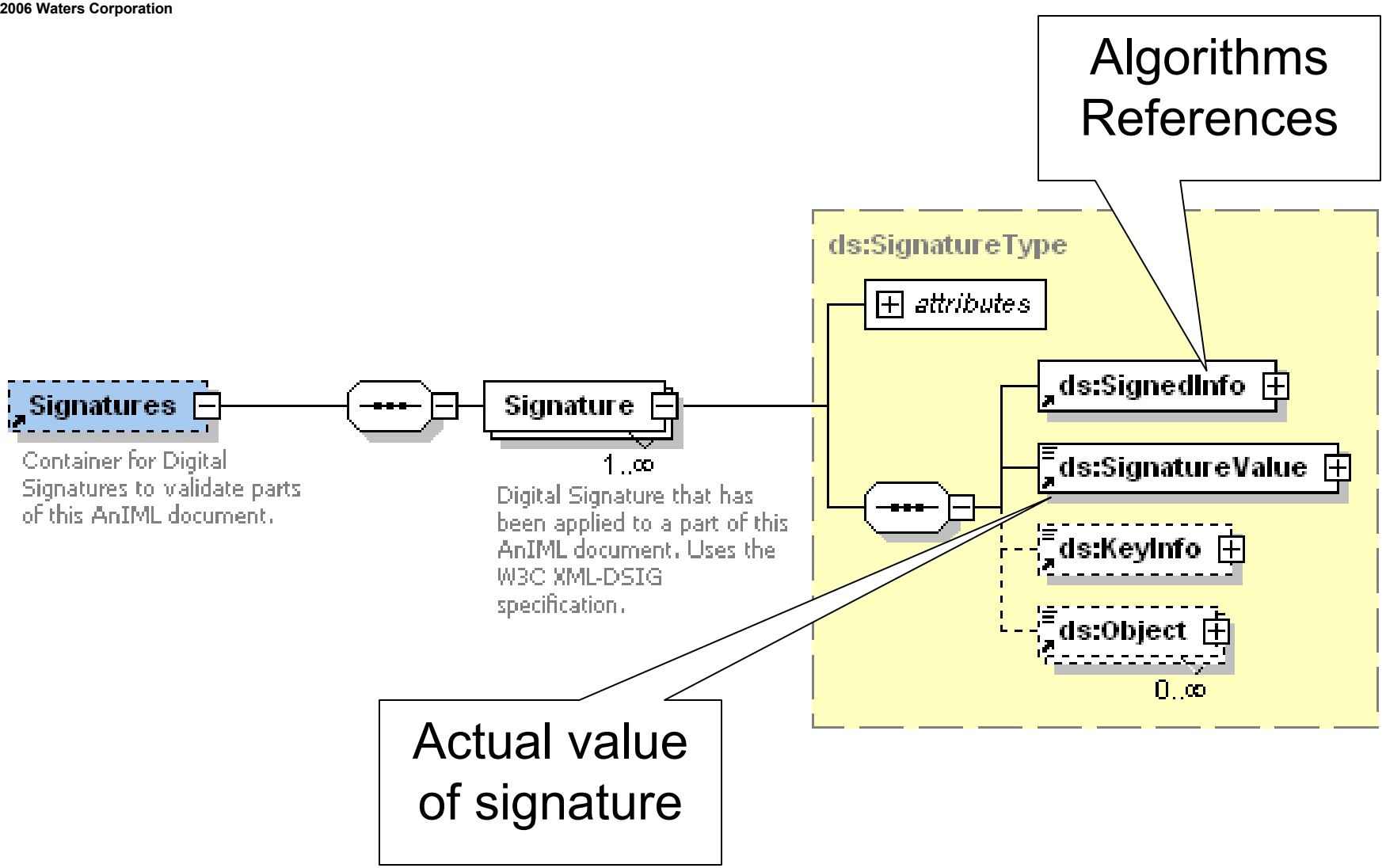
XML-DSIG in AnIML



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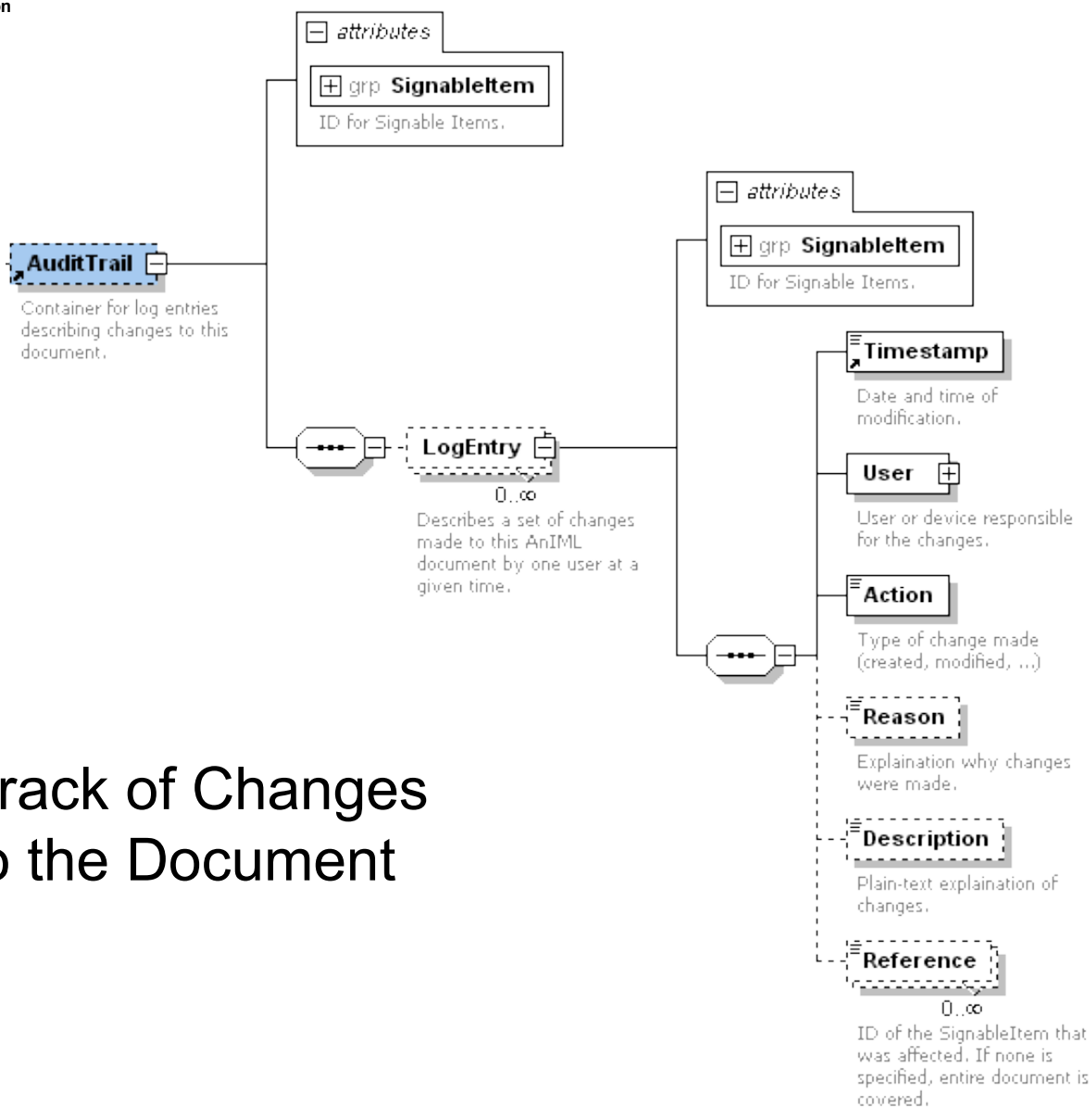
Audit Trail



Keeps track of Changes made to the Document

Really?

When?

Who?

What?

Why?

What?

Where?

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Long Term Stability

- XML-based
  - Human readable (although not meant to be read)
- Uses standard tools
  - XML schema
  - XML-DSIG
  - Base64 encoding

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Q&A

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