



U.S. Environmental Protection Agency

Protecting human health, safeguarding the natural environment

Electronic Recordkeeping: Status of EPA's efforts

**SAMWG Meeting
Point Clear, Alabama
May 13 – 15, 2004**

Status of Electronic Recordkeeping 'Rules'

OGC (Office of Global Communications) considers the 'rule' for electronic records to be hardcopy printout archived; antiquated and unworkable.

Some federal agencies starting to have 'requirements' based on federal decisions, directives

- **Executive Orders: Presidential and OMB (E-gov Initiative)**
- **21CFR11 for NIH**
- **CROMERRR for EPA**

Status of Electronic Recordkeeping 'Rules' – cont

◆ What is CROMERRR?

- **Proposed rule to modify CFR to remove obstacles to electronic reporting and recordkeeping**
- Allow any regulated entity to submit any report or maintain any record electronically.
- Reports submitted electronically, require via CDX.
- Require validation of electronic signature on reports to EPA
- Set standards for e-record-keeping under any EPA program
- Set standards for State electronic reporting and recordkeeping programs.
- Unable to go final based on comments received

Status of Electronic Recordkeeping 'Rules' -cont

- ◆ FDA has taken the federal lead based on their required health study data workload; selected Documentum product
- ◆ NHEERL (National Health & Ecological Effects Research Lab) also selected NuGenesis/Documentum (based on FDA choice, in part)
- ◆ EPA effort is Electronic Records and Document Management System (ERDMS); Superfund-led program now moved to the Office of Environmental Information (OEI)
Now titled:

Enterprise Content Management System (ECMS)

What is ECMS?

- ◆ An enterprise information repository with search, workflow (document management) and records management capabilities
- ◆ A system to connect EPA's islands of information (databases, document repositories, etc.)
- ◆ Prototype selected: Documentum

Why ECMS?

- ◆ **To legally manage electronic records**

- Appropriate retention and destruction
- “Locks down” records so they are unalterable

- ◆ **To manage documents**

- Electronic collaboration and QA
- Centralized document storage and retrieval

ECMS: What's Included?

- ◆ Electronic Content
 - Working documents
 - E-mail
 - Forms
 - Websites
 - Scientific data (ie. Monitoring data)

Electronic Recordkeeping and environmental measurements

- ◆ **Fully-electronic environmental measurement systems eventually have to comply with EPA's electronic recordkeeping policy, when developed. Policy will likely come out of the ECMS efforts.**

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Criteria Development & Evaluation

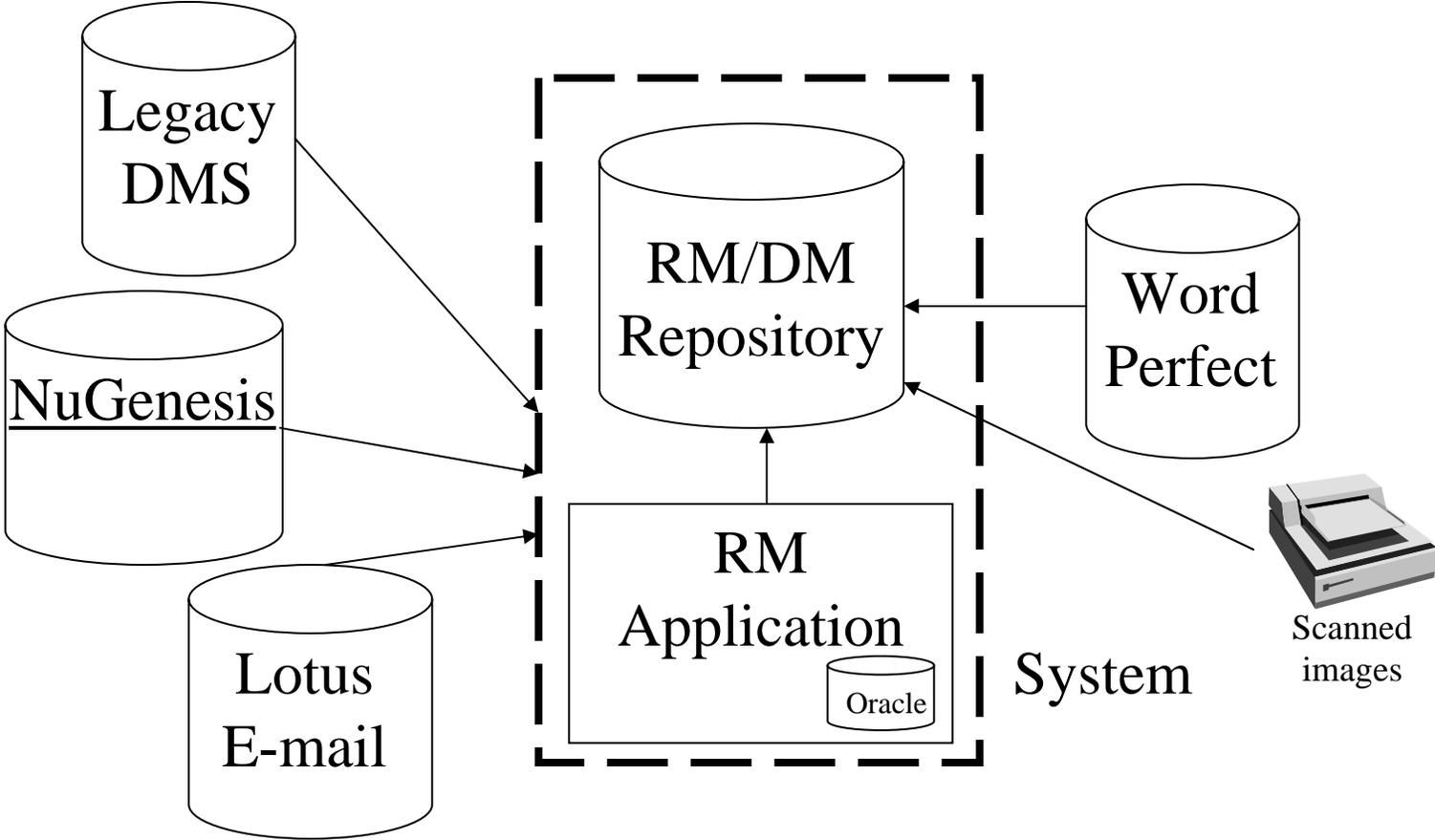
Criteria	Weight	X	Score	=	Weighted Score
Functional Requirements					
RMA Requirements	18		3.1		54.9
DMS Requirements	11		2.3		25.5
Integration Requirements					
DMS Integration	7		3		19.7
E-FOIA Integration	5		2		10.0
API Provided	7		3		22.1
Desktop Application Integration	3		2		5.8
Technical Requirements					
Infrastructure	3		3.2		9.0
XML import/export	2		2		4.9
Web-based	3		2		5.0
Security	3		3		7.6
Scalability	3		3		9.2
Section 508 compliant	1		3		3.4
Ease of Use	4		3		11.7
Search ERDMS functionality	2		3		6.8
Workflow	2		2		4.0
Public Key Infrastructure (PKI)	2		3		5.5
Deployment					
Cost	3		3		10.4
Professional Services	4		3		13.3
Training	4		3		13.2
Implementation Time	4		3		11.0
Market Presence					
Currently used by EPA	2		2		3.6
Viability of Vendor	5		3		14.2
Federal Implementations	2		3		7.3
TOTAL					278.0

Scored each product against the criteria:

- 0** Criteria not met
- 4** Exceptional

Weighted scores:
multiply the weight by the score. Products were ranked by weighted score.

ECMS' Architecture



Operational Strategy

- ◆ EPA Draft Strategy- moving to one Agency-wide RMA and DMS over time...
- ◆ EPA will establish and promote the use of an Agency-wide RMA with an Agency-wide Document Management System (DMS)
- ◆ Existing legacy document repositories will be migrated, or in cases where this is not practical, integrated with the Agency-wide system

ECMS Project Status

- ◆ **Two Independent Reviews**

- Information Technology Review Board (ITRB)
- Management Consultant

- ◆ **Policy Working Group**- to be formed

- ◆ **Senior Executive Steering Committee** - looking for nominations now

- ◆ **Selection of application to pilot:**

Documentum prototype being developed 2004 for Superfund Data Management System (SDMS) in Region 6

- ◆ **Selection of pilot sites: All of Region 6 in 2006**