Approaching accreditation of a PGD centre

ESHRE Campus symposium
London, United Kingdom
22-23 March 2010

Audits

- types of audits
- how to conduct an audit
- key indications of quality in PGD

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Types of audits

Edith Coonen

PGD Workinggroup Maastricht, NL

Maastricht UMC+

azM | Maastricht University

CCKL GEACCREDITEERD

certificaat

De Stichting Raad voor Accreditatie, opererend als accreditatieverlener onder de naam CCKL voor de accreditatie van laboratoria in de gezondheidszorg, verklaart hierbij dat

VPG-laboratorium
Maastricht Universitair Medisch Centrum
Maastricht

Het laboratorium heeft aangetoond competent te zijn laboratoriumdiensten uit te voeren ten behoeve van patiënten en het medisch personeel dat verantwoordelijk is voor de zorg van deze patiënten. Deze accreditatie is gebaseerd op een beoordeling tegen de vereisten zoals vastgelegd in de CCKL Praktijkrichtlijn 4e versie:2005, gebaseerd op de ISO 15189:2003, en de CCKL-reglementen.

De accreditatie is van toepassing op de werkterreinen zoals gespecificeerd in de gewaarmerkte bijlage die is voorzien van het accreditatienummer.

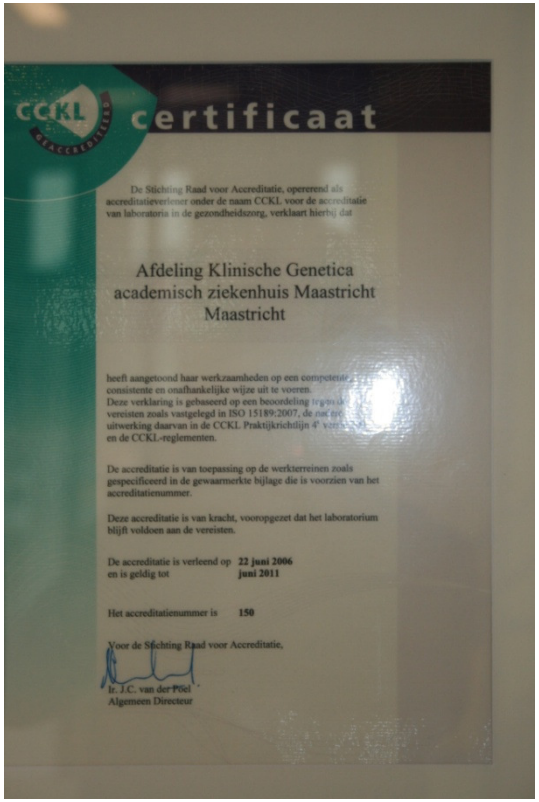
Deze accreditatie is van kracht, vooropgezet dat het laboratorium blijft voldoen aan de vereisten.

De accreditatie is verleend op **25 november 2009**
en is geldig tot **november 2014**

Het accreditatienummer is **242**

Voor de Stichting Raad voor Accreditatie,

Ir. J.C. van der Poel
Algemeen Directeur



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Afdeling Klinische Genetica
academisch ziekenhuis Maastricht
Maastricht

heeft aangetoond haar werkzaamheden op een competente, consistente en onafhankelijke wijze uit te voeren.
Deze verklaring is gebaseerd op een beoordeling tegen de vereisten zoals vastgelegd in ISO 15189:2007, de daarop uitwerking daarvan in de CCKL Praktijkrichtlijn 4e versie en de CCKL-reglementen.

De accreditatie is van toepassing op de werkterreinen zoals gespecificeerd in de gewaarmerkte bijlage die is voorzien van het accreditatienummer.

Deze accreditatie is van kracht, vooropgezet dat het laboratorium blijft voldoen aan de vereisten.

De accreditatie is verleend op **22 juni 2006**
en is geldig tot **juni 2011**

Het accreditatienummer is **150**

Voor de Stichting Raad voor Accreditatie,

Ir. J.C. van der Poel
Algemeen Directeur

Accreditation in the Netherlands

- based on ISO 15189, outlined in CCKL Code of Practice
- CCKL, incorporated in Dutch Accreditation Council, accredits laboratories in health care sector

Maastricht UMC+
azM
Maastricht University

Quality system – ISO 15189 standard

- Technical requirements
- Management requirements
  - internal audits 4.14

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Audit

Systematic, independent and documented process of obtaining evidence and evaluating it objectively to determine conformance against criteria set by the ISO standard.

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Evidence

- information that proves or demonstrates a truth
- is verifiable (same evidence can be collected by independent auditors)
- can be hold in your hand (records, statement of fact)

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Audit

Systematic, independent and documented process of obtaining evidence and evaluating it objectively to determine conformance against criteria set by the ISO standard.

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Criteria

- policies (general)
- procedures (detailed)
- requirements (what should be in place)

Audit - functional parties

Auditee
organization being audited

Auditor
person with competence to conduct an audit

Audit client
organization or person requesting audit

Auditor

The person with the competence to conduct an audit

Competence

Ability to apply the skills and knowledge gained through education, training, work experience and audit experience

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What does an auditor need to know

- knowledge of the standard
- knowledge of the process being audited
  - can't audit what you don't understand
  - field experts

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Types of audits - I

- vertical audit
- horizontal audit
- examination audit

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Vertical audit

- follow all elements of a process from one sample or case
  - top-down
  - bottom-up
- easy to start with
- used as regular activity and for training purposes
- time consuming, not all aspects covered each time

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Vertical audit – example

- **PGD administration process (top-down)**

- select random PGD case
  - start with patient *medical* IVF file
  - compare content to written procedures

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Vertical audit – example

- **PGD administration process**

- patient *laboratory* IVF file
  - compare content to written procedures

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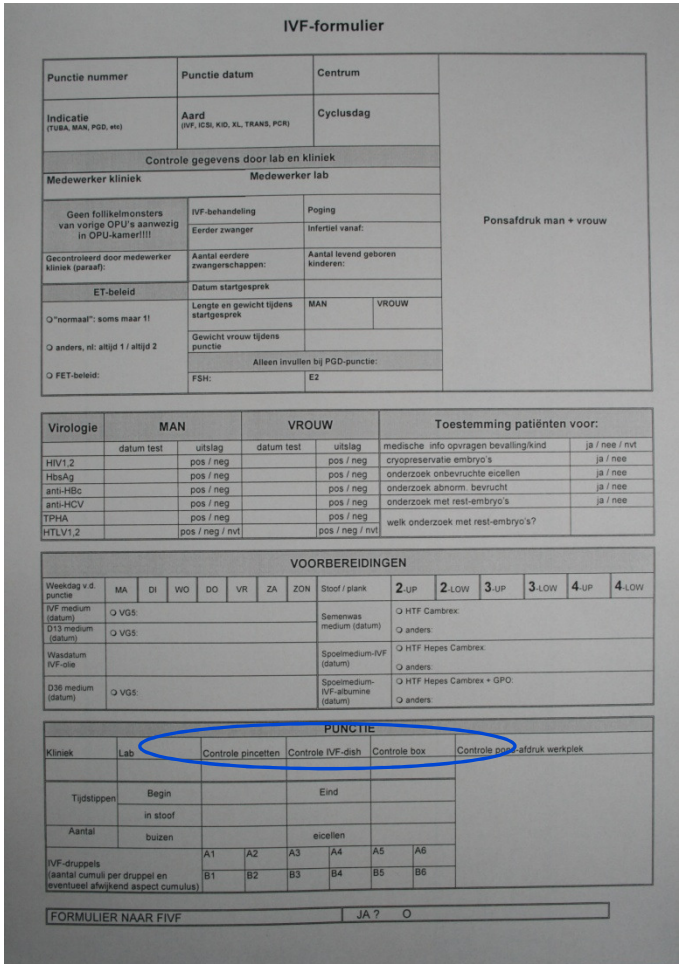
Vertical audit – example

- **PGD administration process**



IVF-formulier

Punctie nummer	Punctie datum	Centrum	Ponsafdruk man + vrouw
Indicatie (TUBA, MAN, PGD, etc)	Aard (IVF, ICSI, KID, XL, TRANS, PCR)	Cyclusdag	

Controle gegevens door lab en kliniek

Medewerker kliniek — Medewerker lab

Geen follikelmonsters van vorige OPU's aanwezig in OPU-kamer!!!!	IVF-behandeling	Poging	
	Eerder zwanger	Infertiel vanaf:	
Gecontroleerd door medewerker kliniek (paraaf):	Aantal eerdere zwangerschappen:	Aantal levend geboren kinderen:	
ET-beleid	Datum startgesprek		
○ "normaal": soms maar 1!	Lengte en gewicht tijdens startgesprek	MAN / VROUW	
○ anders, nl: altijd 1 / altijd 2	Gewicht vrouw tijdens punctie		
○ FET-beleid:	Alleen invullen bij PGD-punctie:		
	FSH:	E2	

Virologie	MAN		VROUW		Toestemming patiënten voor:	
	datum test	uitslag	datum test	uitslag	medische info opvragen bevalling/kind	ja / nee / nvt
HIV1,2		pos / neg		pos / neg	cryopreservatie embryo's	ja / nee
HbsAg		pos / neg		pos / neg	onderzoek onbevruchte eicellen	ja / nee
anti-HBc		pos / neg		pos / neg	onderzoek abnorm. bevrucht	ja / nee
anti-HCV		pos / neg		pos / neg	onderzoek met rest-embryo's	ja / nee
TPHA		pos / neg		pos / neg	welk onderzoek met rest-embryo's?	
HTLV1,2		pos / neg / nvt		pos / neg / nvt		

VOORBEREIDINGEN

Weekdag v.d. punctie	MA	DI	WO	DO	VR	ZA	ZON	Stoof / plank	2-UP	2-LOW	3-UP	3-LOW	4-UP	4-LOW
IVF medium (datum)	○ VG5:							Semenwas medium (datum)	○ HTF Cambrex:					
D13 medium (datum)	○ VG5:								○ anders:					
Wasdatum IVF-olie								Spoelmedium-IVF (datum)	○ HTF Hepes Cambrex:					
D36 medium (datum)	○ VG5:								○ anders:					
								Spoelmedium-IVF-albumine (datum)	○ HTF Hepes Cambrex + GPO:					
									○ anders:					

PUNCTIE

Kliniek	Lab	Controle pincetten	Controle IVF-dish	Controle box	Controle poliet-afdruk werkplek
Tijdstippen	Begin		Eind		
	in stoof				
Aantal	buizen		eicellen		

IVF-druppels (aantal cumuli per druppel en eventueel afwijkend aspect cumulus)	A1	A2	A3	A4	A5	A6
	B1	B2	B3	B4	B5	B6

FORMULIER NAAR FIVF — JA ? O

- check all necessary forms
  - complete, witnessed

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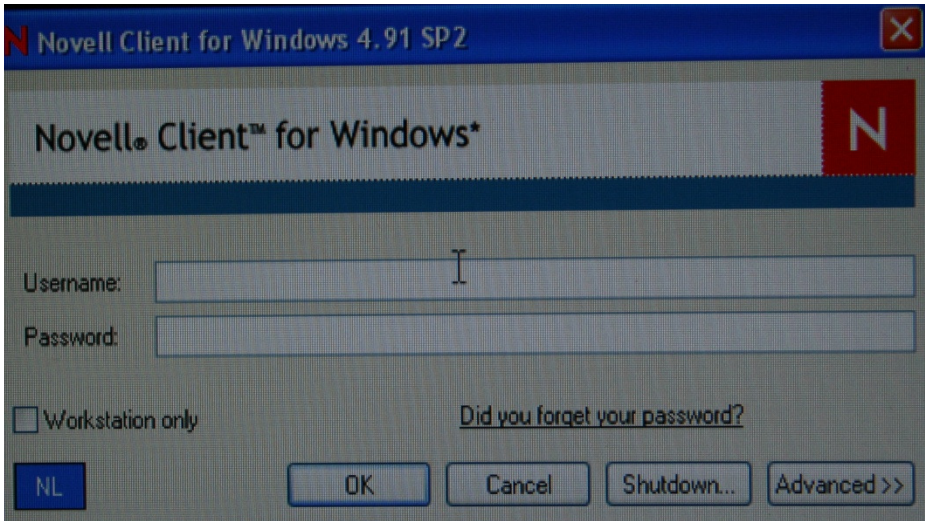
Vertical audit – example

- **PGD administration process**



- patient privacy
- computerfiles protected

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Vertical audit – example

- **PGD administration process**

- patient *laboratory* genetics file
  - compare content to written procedures

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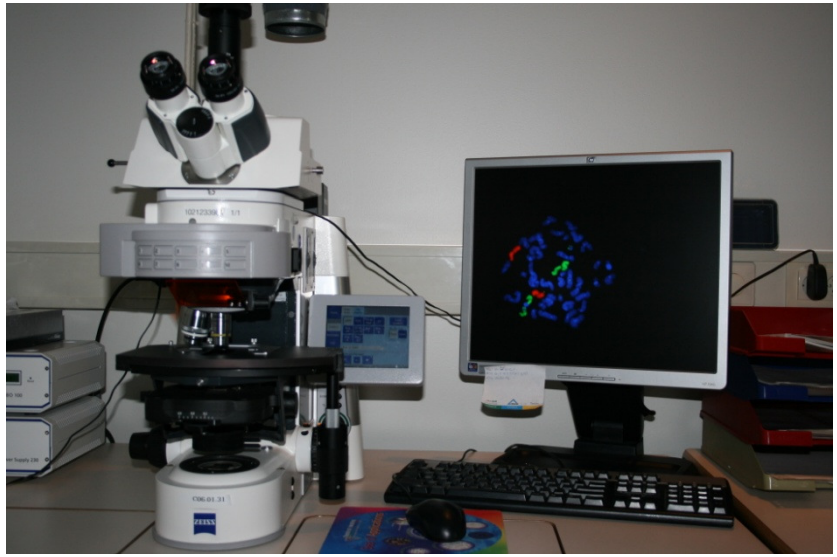
Vertical audit – example

- PGD administration process



- PGD data storage

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Vertical audit – example

- **PGD administration process**

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Afdeling Klinische Genetica

PGD FISH uitslag

Formulier: FC07.4

Naam:
Geb. datum: / /
Punctie nr:

Indicatie :
PGD nr:
IVF kliniek:

Datum OPU:
IVF / ICSI aantal eicellen:
Aantal gebiopteerde embryo's:

embryo nr	PN	embryo t=bioptie	bioptie	genotype			fenotype	vrijgegeven voor ET
paraaf								

AUTORISATIE

datum: naam: handtekening:

azM Cytogenetica 03/12/2008 Versie 7

- check all necessary forms
  - complete, witnessed

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Vertical audit – example

- **PGD administration process**

- cryopreservation PGD embryos

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VERTICAL ASSESSMENT FORM

Ref.No.		Department title	

Section of department		Examination or procedure	
Report number		Reporting assessor	
Laboratory Accession no.		Date and signature of assessor	

INSTRUCTIONS

1. Select a laboratory accession number either from the computer record or from work sheets/day book etc.

2. Audit from receipt of request to issuing of report.

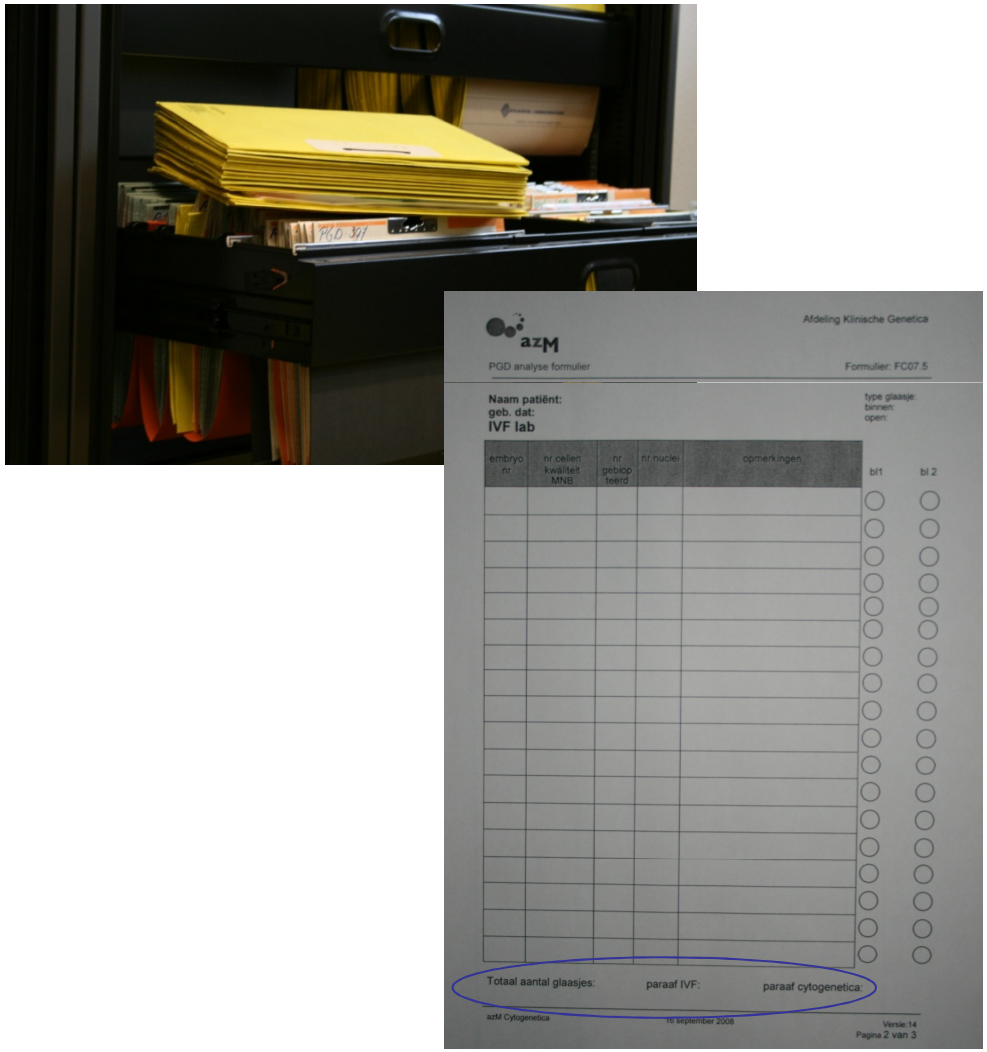
Audit area	Standard	Records/methods checked & procedures witnessed	Findings	Obs&NCs Sheet No.
.				

Horizontal audit

- check one element of a process for multiple samples or cases
- used for follow-up on shortcomings from vertical audit

Horizontal audit – example

- IVF-Genetics transfer of blastomeres and embryo data



- complete, signed, witnessed

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Examination audit

- witnessing an examination as it is performed

  and comparing to the written SOP

- used to ensure that
  - what is being done reflects what is described in the procedure
  - the person carrying out the examination has a good understanding of all aspects of the procedure

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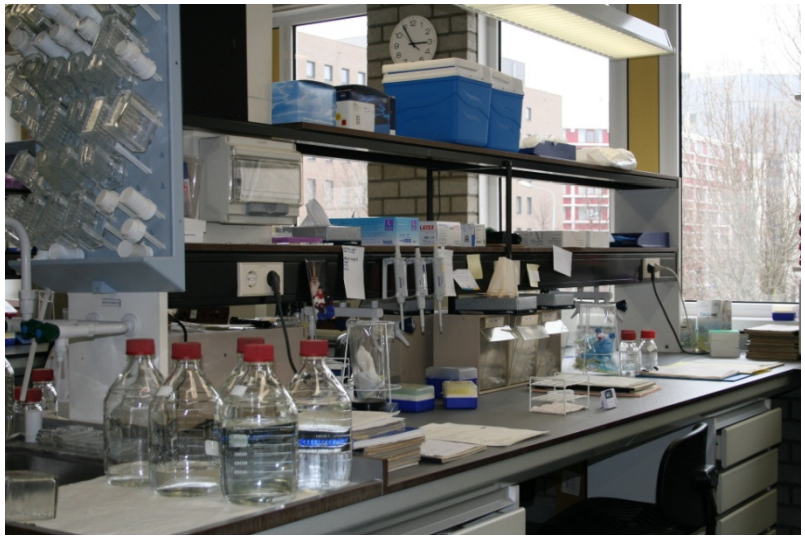
Examination audit – example

- **preparing PGD probe combination**



- observe
- ask questions
- compare to SOP
- check documentation

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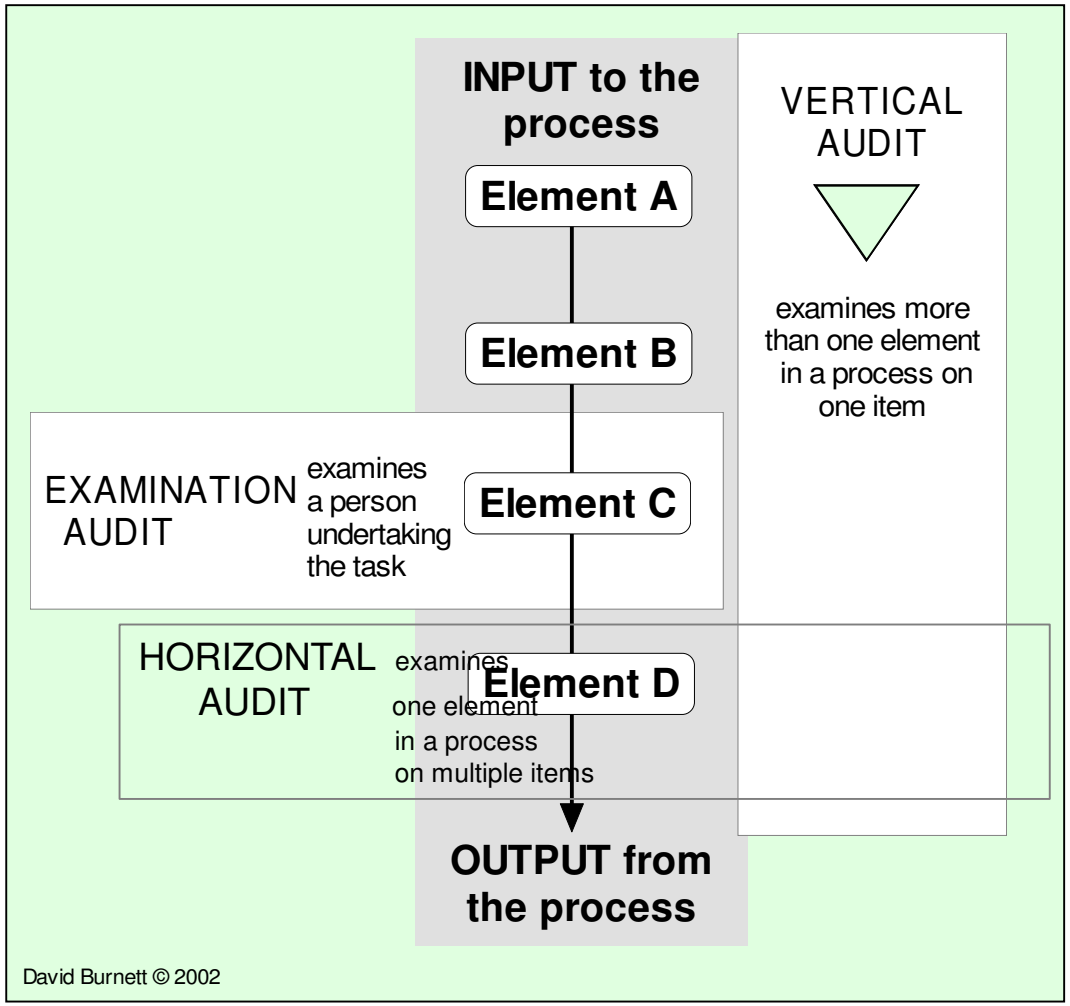
Types of audits - I



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Types of audits - II

- internal audit
- external audit

Internal audit

- organized by own organization
- conducted by own staff
- one (two) auditor(s)
- one day
- preferably independent of the work being audited
- less formal
- used for full system review at fixed intervals (annual)
- re-assessment of procedures, work instructions and day-to-day working practice (on-going)

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External audit

- 2nd or 3rd party surveillance
- conducted by colleagues in the field / quality professionals
- multiple auditors (different experts)
- multiple days
- formal
- used for assessment / (prior to) accreditation

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Audit process

- selecting matters for audit
- deciding the timing of the audit
- planning the audit
- executing the audit
- reporting the audit results
- follow-up and evaluation of audit findings, conclusions and recommendations

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Audit program

- main elements of QMS should be audited every year (system review)
- make annual audit calendar (audit master plan)

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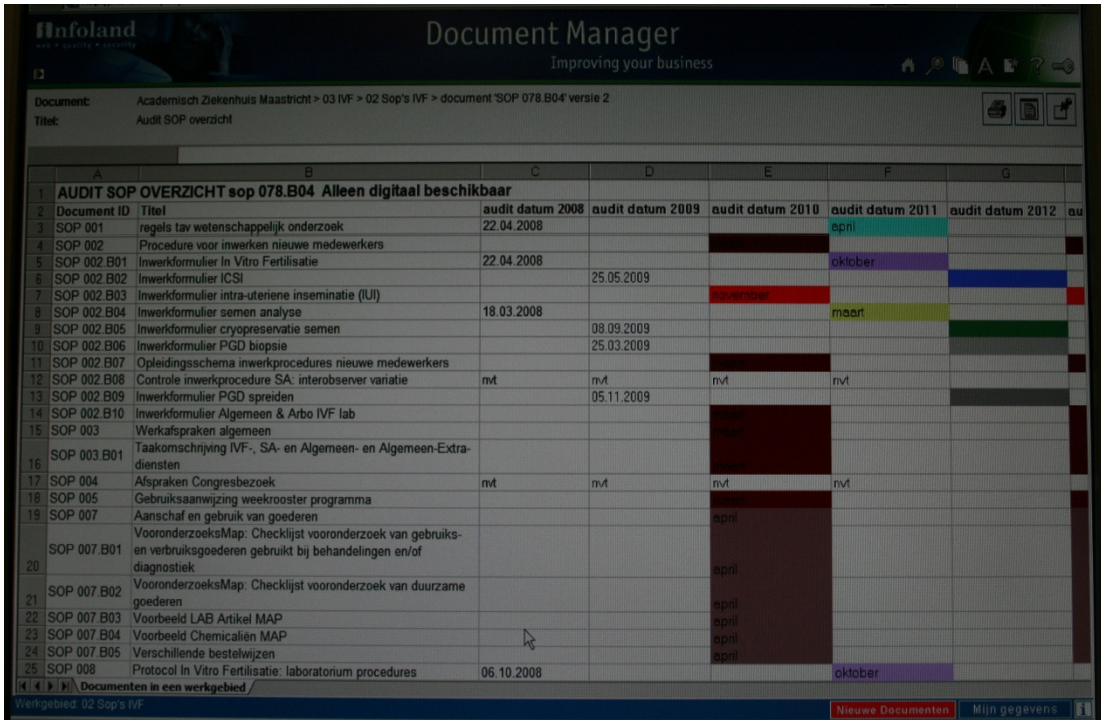
Audit calendar



- list of all quality documents
- documented audit date

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Audit – related quality documents

- implement policy for planning and performing audits,
  for reporting audit results, corrective and preventive actions and
  for communication of audit findings

  - audit calendar
  - SOP ‘how to perform an audit’
  - SOP ‘how to report audit results’
  - SOP ‘how to report corrective and preventive actions’
  - SOP ‘how to communicate audit findings’

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Audit approach

- find information that enables the auditor to judge whether the laboratory is operating in compliance with the Standards
- record audit findings in report
  - clear, timely, concise and objective
  - investigate findings thoroughly
  - record them accurately
  - attribute findings to the Standard
- use terms compliances, non-compliances or observations
  - classify the level of non compliance

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Audit report

- compliance
- non-compliance

  ‘the failure to fulfil the requirements of a Standard, in whole or in part’

  - critical non-compliance
  - non-critical non-compliance
- observations

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Critical non-compliance

‘a failure to fulfil the requirements of the Standards to such a degree that, in the opinion of the auditor, there is evidence of a system failure’

- evidenced by the failure to comply with the whole Standard and is a reason for referral

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System failure

evidenced by

- inability of a department to meet the agreed needs and requirements of its users ‘or’
- inability to ensure a safe environment for staff , patients or visitors ‘or’
- inability to ensure the quality of all the laboratory examinations performed

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Audit report

- compliance
- non-compliance

  ‘the failure to fulfil the requirements of a Standard, in whole or in part’

  - critical non-compliance
  - non-critical non-compliance

- observations

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Non-critical non-compliance

‘a failure to fulfil the requirements of the Standards at a level that would not lead to a *system failure’*

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Audit report

- compliance
- non-compliance

  ‘the failure to fulfil the requirements of a Standard, in whole or in part’

  - critical non-compliance
  - non-critical non-compliance

- observations

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Observation

‘are records of deficiencies noted by auditors, that have the potential to affect the functioning of the department’

- are reported to the department and form part of the final report

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Corrective / preventive actions

Audits generate corrective / preventive actions that should be described and implemented

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Corrective action

Taken to eliminate or reduce the effect of existing non-compliances and prevent recurrence of a known non-compliance

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Preventive action

Action to prevent the occurrence of a potential non-compliance

"Naughty, nice, nice, nice, naughty, nice…
This you call an audit report?"

Thank you