



Administrative Changes to FDA's CLIA Categorization Program

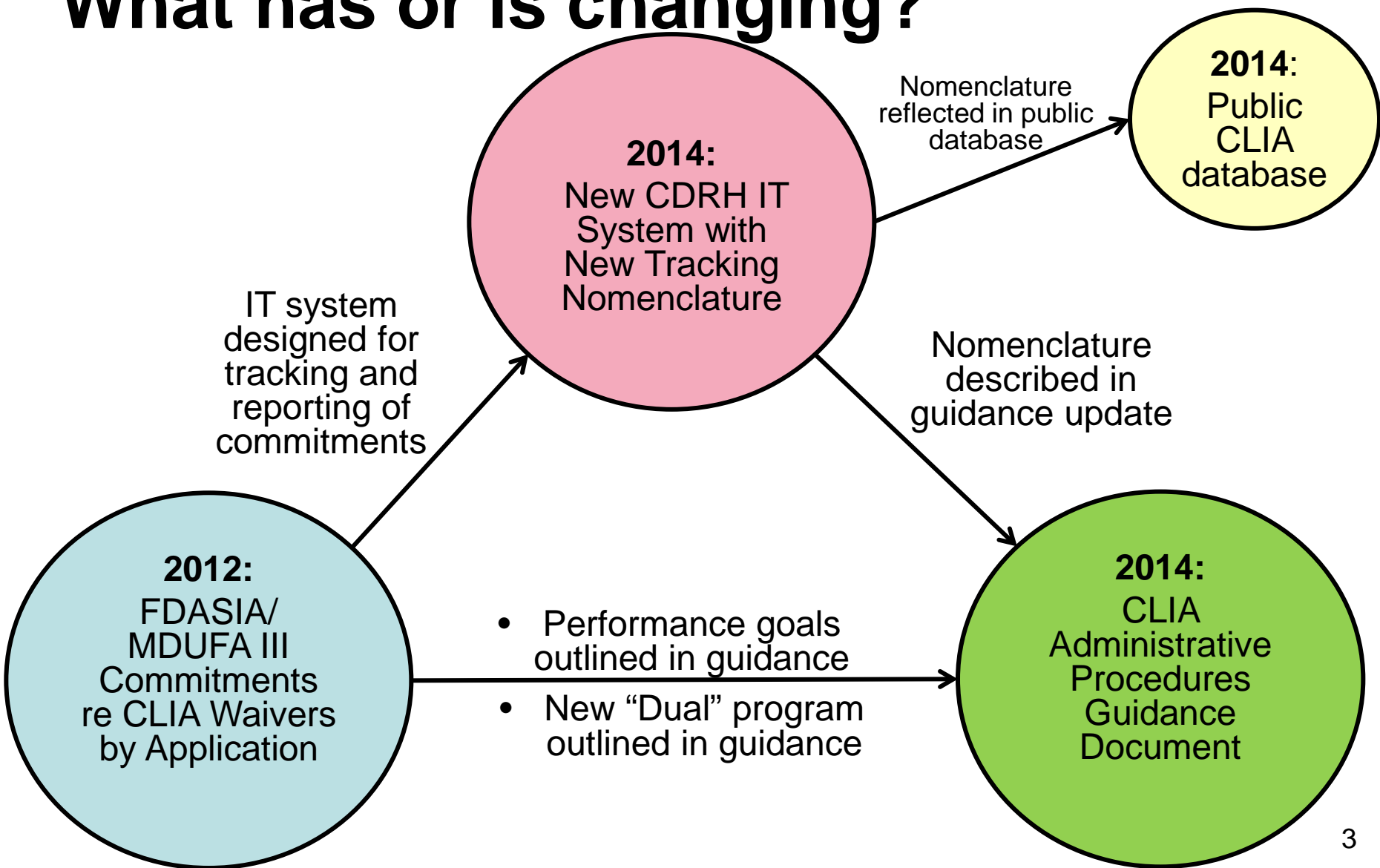
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Food and Drug Administration
Office of In Vitro Diagnostics and Radiological Health

March 5th, 2014
Clinical Laboratory Improvement Advisory Committee
Centers for Disease Control and Prevention
Tom Harkin Global Communications Center
Atlanta, GA

Overview of What has or is changing

- Administrative Tracking Mechanisms
- MDUFA III Commitment Letter
- Guidance for CLIA Administrative Procedures
- Public CLIA database

What has or is changing?





U.S. Food and Drug Administration
Protecting and Promoting Public Health

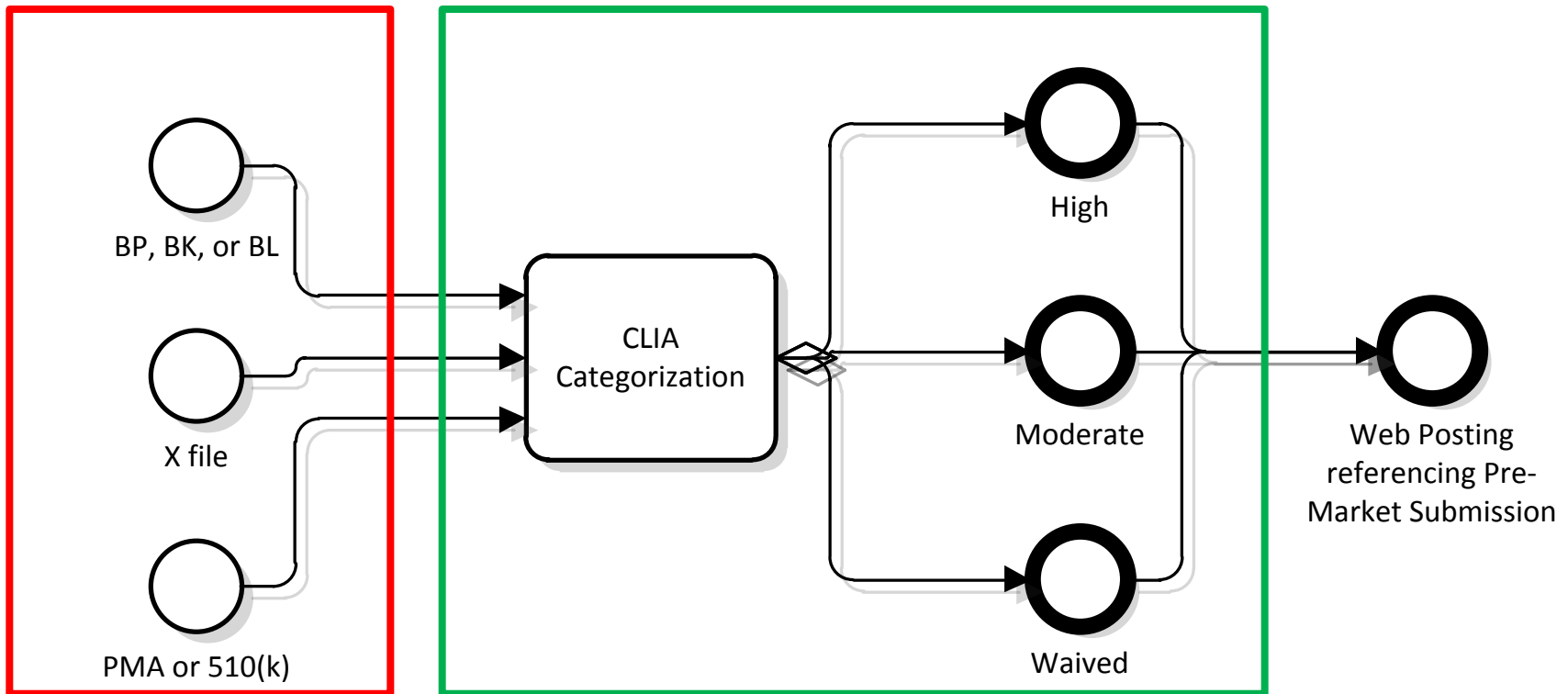


CLIA CATEGORIZATION RECORDS (CR)

What is Changing on March 21st 2014?

Administrative processes for CLIA Categorizations are changing

Scientific Review Processes for CLIA Categorizations are NOT changing





CLIA Categorization Record Changes

Type of CLIA Categorization	Today CLIA Categorizations tracked under:	On <u>March 21th</u> 2014 CLIA will be filed as:	Parent Document
Devices Approved / Cleared by CDRH/OIR	510(K), PMA, HDE, De Novo	<u>CR</u> xxxxxxx	Kxxxxxx, Pxxxxxx, Hxxxxxx
Devices Approved / Cleared / Licensed by CBER	BP, BL, BK	<u>CR</u> xxxxxxx	BPxxxxxx, BLxxxxxx, BKxxxxxx
Pre-Market Review Exempt Devices	X-file (Xxxxxxx)	<u>CR</u> xxxxxxx	<u>CR</u> xxxxxxx
Name Changes (e.g., name, distributor)	510(k) Add-to-File or PMA supplement	<u>CR</u> xxxxxxx	Kxxxxxx, Pxxxxxx, Hxxxxxx,



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Protecting and Promoting Public Health

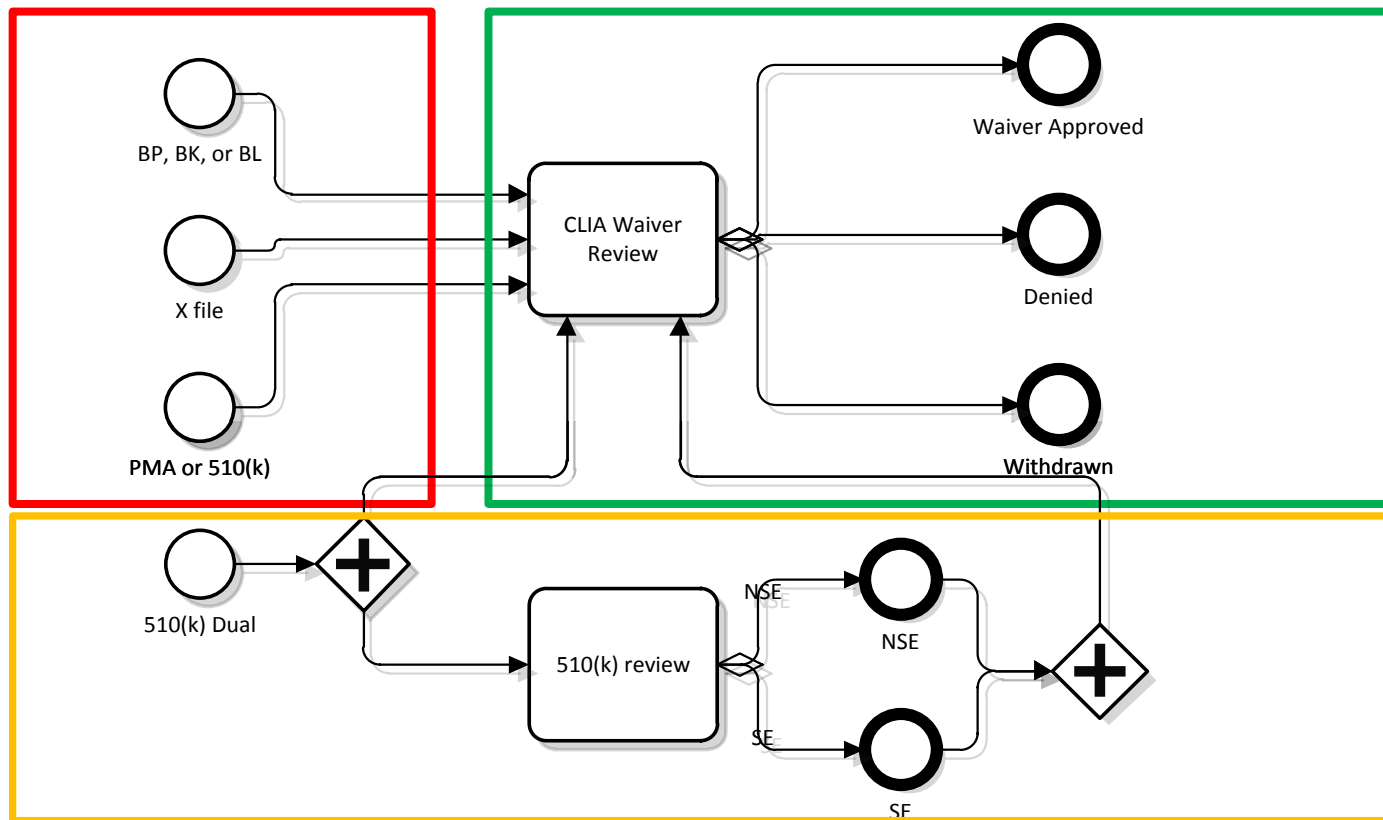


CLIA WAIVER BY APPLICATION (CW)

What is Changing on March 21st 2014?

Administrative processes for CLIA Waiver by Applications are changing

Scientific Review Processes for CLIA Waiver Reviews are NOT changing



DUAL



CLIA Waiver By Application Changes

Type of CLIA Waiver by Application	Today CLIA Waiver By Application tracked under:	On <u>March 21th</u> 2014 CLIA will be filed as:	Parent Document
Devices Approved / Cleared by CDRH/OIR	510(k) Add-to-File or PMA supplement	<u>CW</u> xxxxxxx	Kxxxxxx, Pxxxxxx, Hxxxxxx
Devices Approved / Cleared / Licensed by CBER	BP, BL, BK	<u>CW</u> xxxxxxx	BPxxxxxx, BLxxxxxx, BKxxxxxx
Pre-Market Review Exempt Devices	X-file (Xxxxxxx)	<u>CW</u> xxxxxxx	<u>CW</u> xxxxxxx
Dual 510(k) and CLIA Waiver by Application	Manually	<u>CW</u> xxxxxxx	Kxxxxxx

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What has changed: MDUFA III Commitments

- Performance goals for CLIA Waivers by Applications (ie, IVDs that are legally marketed and for which the sponsor is seeking a waiver categorization)
 - FDA will engage in a substantive interaction within 90 days
 - FDA will issue a decision for 95% within 180* FDA days
 - *330 if advisory panel review is required*

What has changed: MDUFA III Commitments

- New Dual 510(k) + Waiver by Application
 - Requires Pre-Submission
 - FDA will engage in a substantive interaction within 90 days
 - FDA will issue a decision for 90% within 210 FDA days

Overview of What has or is changing

- Administrative Tracking Mechanisms
- MDUFA III Commitment Letter
- **Guidance for CLIA Administrative Procedures**
- Public CLIA database

What is changing: Updates to Guidance

- Categorizations and Waiver by Applications
 - Explains when a “CR” or “CW” number will be assigned
 - Includes review and management expectations throughout the entire submission process
 - FDA will post waiver categorization in public CLIA database upon notification of Waiver Granted
 - Option for sponsors to submit Pre-Submissions to request FDA feedback on planned protocols or study designs to support CLIA waiver
 - Explanation of Duals
 - lack of experience with process
 - Most useful recommendations are device-specific and covered during the mandatory Pre-Submission phase

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Public CLIA database changes

Current FDA website view:

U.S. Department of Health & Human Services

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

CLIA - Clinical Laboratory Improvement Amendments

510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards | Inspections
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

500 Records Found for BAYER. To NARROW Your Search Use Advanced Search:

Document	Analyte	Analyte Specialty	Effective Date
Bayer Contour Next USB Blood Glucose Monitoring System	Glucose Monitoring Devices (FDA Cleared/Home Use)	General Chemistry	WAIVED 07/12/2013
Bayer Clinitek 50 Urine Chemistry Analyzer {Medline Urinalysis Strips 10 Parameter Urine Reagent Strips}	Urine Qualitative Dipstick Ketone	Urinalysis	MODERATE 09/27/2012

Have document column with Marketing Application #

Complexity



Public CLIA database changes

Updated FDA website view:

Includes Document and Parent column

Newly entered IVD includes CR info in Document Column and Marketing Application info in Parent column

Legacy IVD Marketing App info remains in Document column

CLIA - Clinical Laboratory Improvement Amendments

FDA Home Medical Devices Databases

* HIGH Complexity designation – All test systems, assays or examinations used in compatibility testing when performed to determine donor/recipient compatibility: recipient & donor ABO group/D (Rho) type/antigen typing, direct antiglobulin test, tests for unexpected antibody detection & identification, & crossmatch procedures are HIGH Complexity. See: Federal Register notice, February 28, 1992 [57 FR 7245].

1 to 10 of 500 Results *

Test System / Manufacturer bayer Effective Date To 02/19/2014

1 2 3 4 5 6 7 8 9 10 >

Results per Page 10

New Search

Export to Excel

Document	Parent	Analyte	Analyte Special	Complexity	Effective Date
Bayer Advia 1650 (Diagnostic Chemicals Limited Calcium L3K)	CR140013 K130229 17 OH progesterone, neonatal		Endocrinology	MODERATE	01/24/2014
Bayer Clinitek 50 Urine Chemistry Analyzer (Medline Urinalysis Strips 10 Parameter Urine Reagent Strips)	K052719	Urine qualitative dipstick leukocytes	Urinalysis	MODERATE	08/27/2012

Complexity column with categorization



Public CLIA database changes

Updated FDA website view:

Newly entered IVD includes **CW** info in Document Column and Marketing Application info in Parent column

Legacy IVD Marketing App info remains in Document column

Complexity column with categorization

CLIA - Clinical Laboratory Improvement Amendments

[FDA Home](#) [Medical Devices](#) [Databases](#)

* HIGH Complexity designation – All test systems, assays or examinations used in compatibility testing when performed to determine donor/recipient compatibility: recipient & donor ABO group/D (Rho) type/antigen typing, direct antiglobulin test, tests for unexpected antibody detection & identification, & crossmatch procedures are HIGH Complexity. See: Federal Register notice, February 28, 1992 [57 FR 7245].

1 to 10 of 500 Results *

Test System / Manufacturer bayer Effective Date To 02/19/2014

1 2 3 4 5 6 7 8 9 10 >

Results per Page 10

[New Search](#)

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Document	Parent	Analyte	Analyte Specialty	Complexity	Effective Date
Bayer Advia 1650	(Diagnostic Chemicals Limited Calcium L3K)				
CW140027	K132636	21-hydroxylase antibody (21-OHAb)	General Immunology	WAIVED	03/31/2014
Bayer Contour Next USB Blood Glucose Monitoring System					
K121087		Glucose monitoring devices (FDA cleared/home)	General Chemistry	WAIVED	07/12/2013

CLIA IT Rollout Plan

- Updated guidance document: “Administrative Procedures for CLIA Categorization”
 - Will publish in the next few weeks
- Public Webinar Program Update
 - Online webinar shortly after guidance is published
- FDA IT internal systems and public website
 - Will go live March 21st 2014

References

- CLIA Administrative Procedures Guidance

Please search at [fda.gov](http://www.fda.gov) in a few weeks when it's published

- CLIA Waiver by Application Guidance

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm079632.htm>

- CLIA Public Database

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>



Thank you!

- Please contact Ann Chappie or Prakash Rath with CLIA related questions at:

CDRHCLIACoordinator@fda.hhs.gov