

Establishing a Proficiency Testing Program at the University of Kentucky

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- [Tobacco Products](#)

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- Tobacco Products
- News & Events

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- [Features](#)
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- [Fact Sheets](#)
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Tobacco Product Analysis - A Scientific Workshop - July 2013

[Final Agenda for Tobacco Product Analysis: A Scientific Public Workshop](#)

Federal Register Notice of Public Hearing

The purpose of this workshop is to discuss and obtain input on the chemical analysis of tobacco products. Tobacco product analysis experts from academia, industry, government, and contract testing laboratories will share information on understanding the testing of cigarette smoke and tobacco filler from cigarettes, roll-your-own (RYO) tobacco, and smokeless tobacco products for tar, nicotine, and carbon monoxide (TNCO), tobacco-specific nitrosamines (TSNAs), and polycyclic aromatic hydrocarbons (PAHs). FDA will invite speakers to address specific scientific and technical matters related to

- TNCO in cigarette smoke
- TSNAs (total TSNAs, NNN, and NNK) in cigarette smoke and tobacco filler (cigarette, RYO, and smokeless)
- PAHs (benzo[a]pyrene, naphthalene, chrysene, benz[*jj*]anceanthrylene, benzo[a]anthracene, benzo[b]fluoroanthene, benzo[k]fluoroanthene, benzo[c]phenanthrene, cyclopenta[*cd*]pyrene, dibenz[*a,h*]anthracene, dibenzo[*a,e*]pyrene, dibenzo[*a,h*]pyrene, dibenzo[*a,i*]pyrene, dibenzo[*a,l*]pyrene, indeno[*1,2,3-cd*]pyrene, and 5-methylchrysene) in cigarette smoke and tobacco filler (cigarette, RYO, and smokeless)
- General method testing for TNCO, TSNAs, and PAHs in tobacco filler (cigarette, RYO, and smokeless) and cigarette smoke
- Validation or method performance for TNCO, TSNAs, and PAHs in tobacco filler (cigarette, RYO, and smokeless) and cigarette smoke

3 Take-Home Messages from FDA Workshop-- Tobacco Product Analysis: A Scientific Public Workshop

July 30-31, 2013

Matthew Holman, Director, Division of Product Science, Office of Science, CTP

- 1) Uniformity in methods/platforms for TNCO and TSNAs but not for PAHs.
- 2) Need for Certified Reference Products across a range of characteristics, both product types, as well as yields of particular analytes or constituents.
- 3) Need for increased Proficiency Testing.

<http://www.fda.gov/tobaccoproducts/newsevents/ucm355041.htm>

KTRDC Reference Cigarette Program

- International standard
- 1R1 produced in 1968
- Current products include 3R4F and 1R5F along with small quantities of 14 other types
- Held workshop with industry, FDA, CDC, TTB to discuss production and characterization of future reference cigarettes (US TAG ISO/TC 126)
- Establishing contract for production of 2R5F, 2R5F(L) and 1M6F



THE
REFERENCE CIGARETTE

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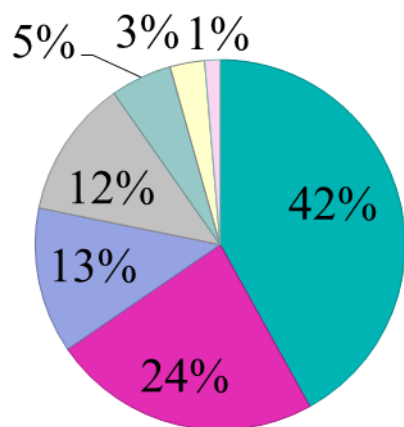


THE
REFERENCE CIGARETTE

Kentucky Reference Cigarette Sales

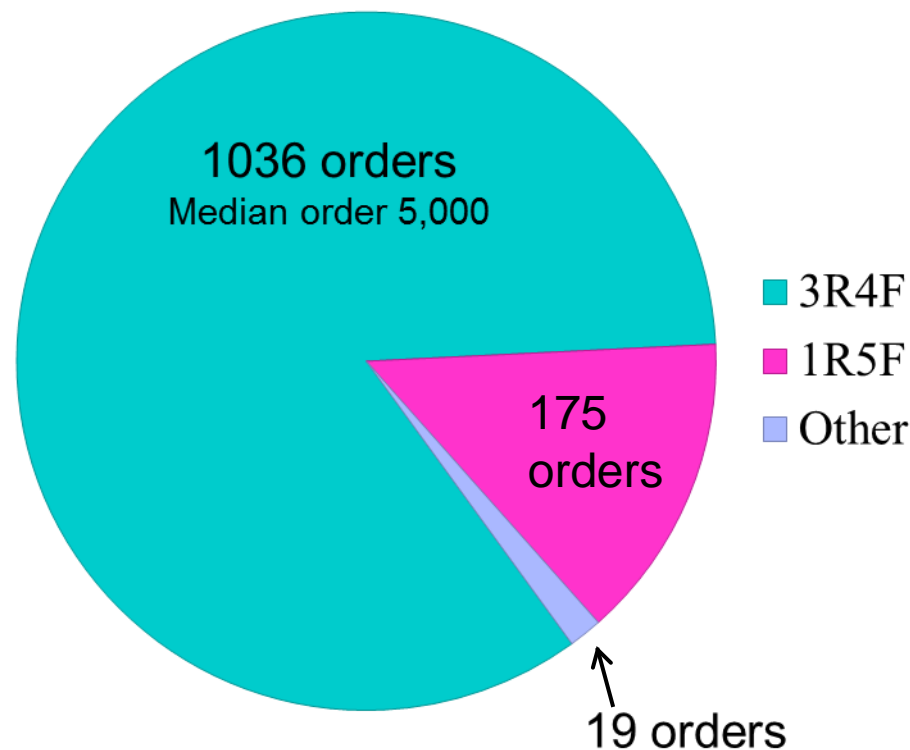
Purchasers

- University
- Health/Pharmaceutical/Toxicology
- Tobacco Company
- Research
- Equipment/Suppliers
- Analytical Testing
- Other



of Orders

(July 2007- Jan 2012)



Current Stocks of Relevant UK Tobacco Reference Products

- 3R4F stocks ~ 25 million (original ~60 million)
- 1R5F stocks ~ 260,000 (original ~5 million)
- 4A1 stocks ~ 191,000 (original ~5 million)
 - Ultra-low alkaloid, non-filtered, smoke composition similar to smoke from higher nicotine cigarette (TNCO 26.8, 0.142 and 17.2 mg/cig)

3R4F

20's

571

5M

Made on day 9th of
11 production days

Case Number
5279



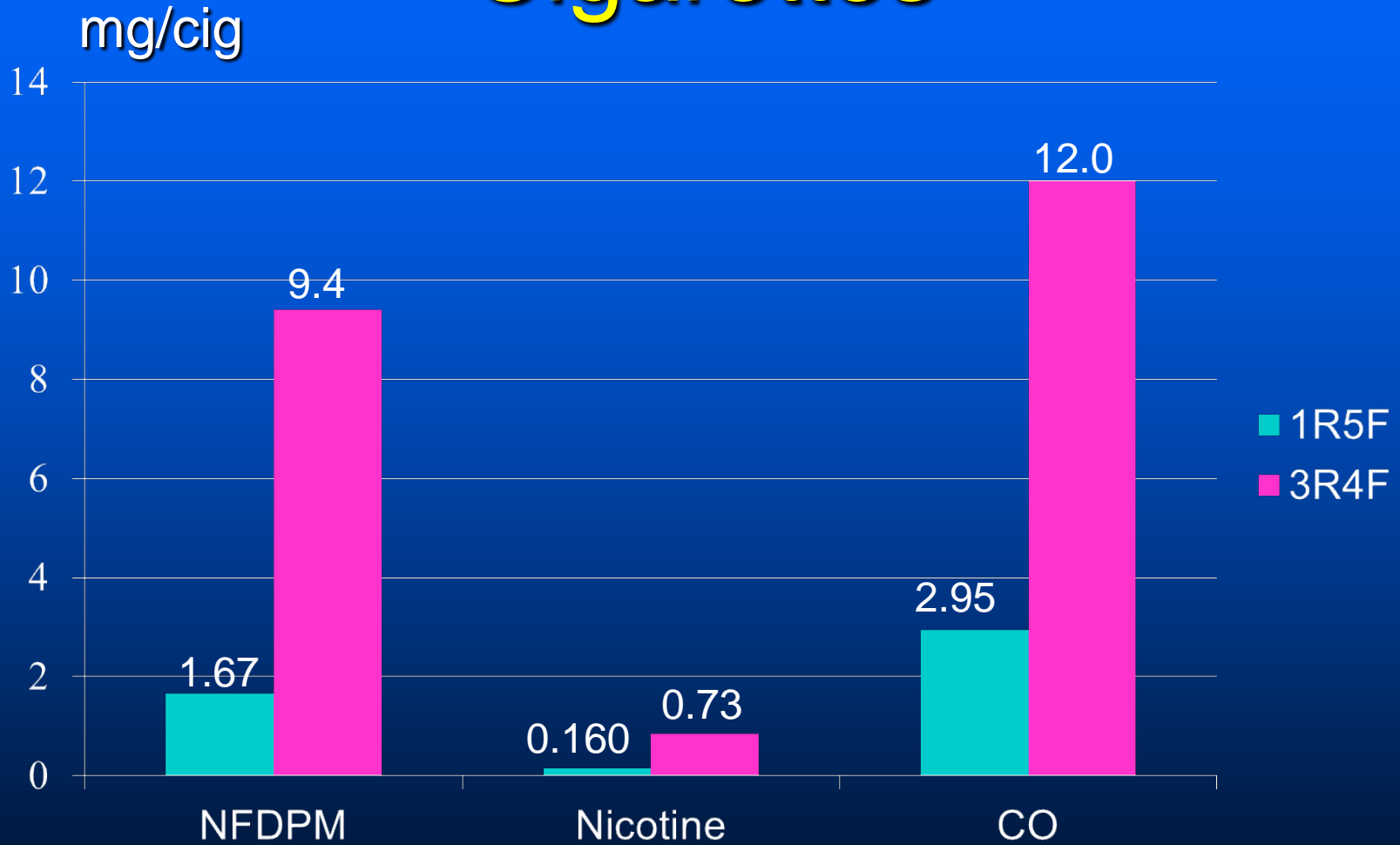
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Comparison of KY Reference Cigarettes



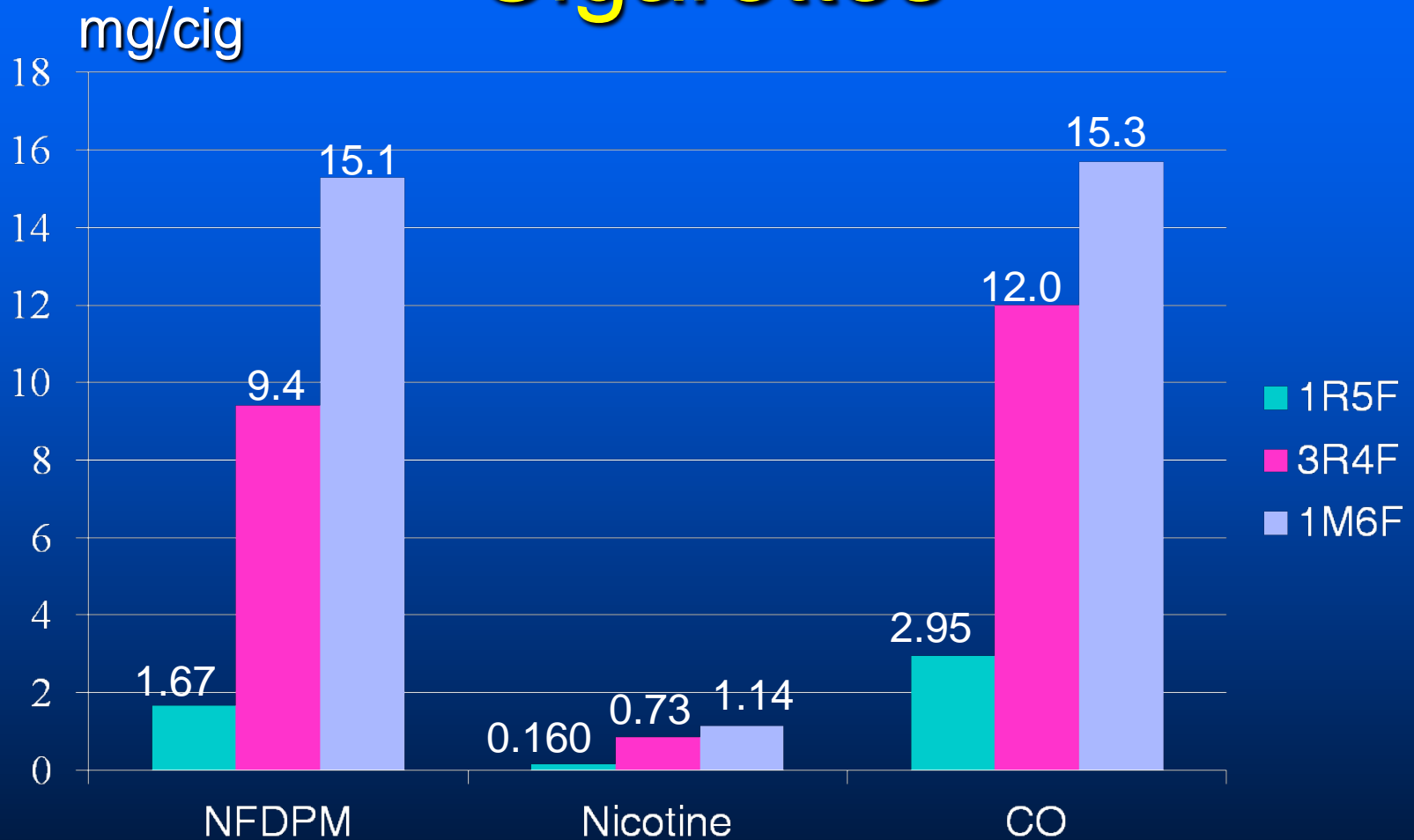
FTC Method

New KY Monitor Cigarette: 1M6F

- Production of 2.5 million
- ~ 122 randomized cigarettes per can
- Available fall 2013



Comparison of KY Reference Cigarettes



Definitions of Reference Products

- Reference Material (RM): material sufficiently homogenous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.
 - Uses include the calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.
 - A single RM cannot be used for both calibration and validation results in the same measurement procedure.

Definitions of Reference Products

- Certified Reference Materials (CRM): reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.
 - ISO Guide 31, Contents of certificates of reference materials
 - ISO Guide 34, General requirements for the competence of reference material providers
 - ISO Guide 35, Certification of reference materials – General statistical principles

Source: ISO Guide 30:1992/Amd.1:2008

Responsibilities of the Proficiency Provider

- At a high level the Proficiency Provider is responsible for four services;
 - Provide a Proficiency Schedule,
 - Provide a Proficiency Test Plan,
 - Provide Samples,
 - Provide a Proficiency Test Report which includes statistical analysis of the data.
- Relevant role for University of Kentucky

UK Proficiency Testing Program

- Initiating Process for A2LA Accreditation
 - Certified Reference Material Provider (ISO Guide 34)
 - Proficiency Testing Provider (ISO 17043)
- Draft White Paper Circulated for Comment
 - ISO 13528
 - Relevant data available for KY reference cigarettes to be used as certified reference for many aspects of a proficiency study
 - Data for 16 HPHCs on FDA short list for both 1R5F and 3R4F

UK Proficiency Testing Program

- Pilot Proficiency Test – January, 2014
 - No/minimal cost for pilot
 - Non-profit service for tobacco research community
- Full Proficiency Program in Operation
 - July, 2014
- Need feedback from stakeholders

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