B1 Regulatory Program Foundations (CC8021W)

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to the elements of feed and food regulatory programs.

a) Goal: The student will be able to exhibit introductory knowledge, skills, and abilities related to the elements of feed and food regulatory programs.
b) Scope: Topics covered in this course include foundations, laws and regulations, feed/food protection agencies, program standard areas, IFSS, mutual reliance (recognition and reciprocity).

Committee Review: Slide numbers would have been helpful. The very first course was long. Providing a projected time frame would be helpful. The content includes a lengthy history on how the law and enforcement actions were developed. It was nice to see a great list of tips for training new inspectors on when to involve a supervisor and how to think critically during the inspection. Program standards were mentioned. There was some terminology which was concerning for new inspectors to be translating this knowledge to the retail food industry. For example: the word violative seems to have been used interchangeably with "hazardous" or "priority". The coursework frames were not very interactive. Perhaps the relevant terminology could have been hyperlinked throughout the course instead of being featured at the beginning. The knowledge checks and final exam does not give a detailed performance summary; it just gives a score.

Committee Recommendation: No action

B2 Allergens (CC8029W)

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to food allergens, controls and regulatory requirements.

(a) Goal: Discuss the control of allergens in relation to food safety.
(b) Scope: This course will cover introductory knowledge, skills, and abilities related to food allergens, controls, and regulatory requirements. Topics include foundations of allergens, labeling requirements, FSMA, control measures, and educational resources.

Committee Review: This course is currently under revision by IFPTI. The U.S. recognized allergens and allergens recognized overseas were explained well. The link for the full list of tree nuts did not lead us to the correct FDA page. We had to google search the FALCPA list to access the correct FDA page.

Committee Recommendation: We recommend replacing FD252, Allergen Management in "post" courses with this course.

B3 Biological Hazards (CC8028W)

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to biological hazards, focusing on sources of contamination, growth factors, and control methods.

Committee Review:

Unit 1

- Pathogens vs Spoilage Organisms slide mentions that off-flavors are a characteristic of food compromised by the outgrowth of pathogens. This should be included under the spoilage organism column.

- Sampling slides mention the term "for-cause" sampling. Where does this wording come from? The message could be rephrased to better represent circumstances such as traceback investigations for foodborne illness or precautionary circumstances. Also, the regulatory sampling slide gives the impression that the regulator will be completing the sampling in manufacturing environments.

Unit 2

- Aflatoxins slide mentions some effects of carcinogens. But, the slide does not explain that aflatoxins are carcinogens. Perhaps the previous slides could have included a brief explanation that many aflatoxins are considered carcinogenic.
- Other Mycotoxins slide mentions that fumonisin consumption can be fatal. But, it is unclear as to whether that fatality is found in humans or just horses and swine. Also, are humans becoming affected through consumption of swine or the rice and corn directly?
- Toxin-Mediated Infection slide does not explain that the terms toxicoinfection and toxin-mediated infection are interchangeable.
- Examples of Incubation Periods slide uses a bullet point format to provide the information. This may have been better as a data table.
- Biofilm slide could have included a nice tie-in to the messages about sampling, as L. monocytogenes is difficult to remove from a facility due to biofilms.

Unit 3

- Food Packaging slide provides an explanation of MAP below the bullet points for both MAP and general ROP without connecting the explanation directly to MAP.
- Vectors: Humans slide contains a photo of a food handler correctly wearing gloves and using a utensil to handle food. It would be better to show bare hand contact.

Unit 4

- Listeria slide shows a photo of a drain cover in a pool. This should be a floor drain photo within a food establishment.
- Food Contact Surfaces slide uses the terms direct and indirect food-contact surfaces. This is not in alignment with the term food-contact surface and nonfood contact surface used in retail food.

Unit 5

- Several slides continued to mention only MAP as a type of packaging which can aid in the control of pathogenic growth.
- Controlling campylobacter slide has the bacteria name misspelled in two of the sentences. Estimated time: approx. 2 hrs.

Committee Recommendation: Standard 2 curriculum microbiology section covers these topics, no need to replace.

B4 Biosecurity (CC8023W)

FDA Pathlore Course Description:
Introductory knowledge, skills, and abilities related to controlling disease transmission between people, animals, and plants. There are six modules in this course.

Committee Review:

Unit 1

At the beginning of the Unit 1, the definition of biosecurity is very broad. It seems to reference what we understand to be the basics of food protection within retail/restaurant environments. Is it the best definition? Is this term more widely used in manufacturing?
Three parts of a facility's biosecurity plan: exclusion, management, and containment. All of which should be SOPs for the facility.

Unit 2

The definition for fomite includes living and non-living matter. I understood fomites to be inanimate objects or materials which can become contaminated and transfer pathogens. Explanations for food processing were nicely worded. Nice use of plain language to differentiate between harvest/slaughter and processing.

Unit 3

Biosecurity zone slide defines a controlled access point as the third point. However, it would be better suited as the first definition because personnel would have to enter controlled or restricted zones through this point of access.

The slides which describe the types of PPE need some additional wording to relate the subject to its significance in the prevention of contamination within a facility or operation.
Is the term enhanced inspection interchangeable with the term investigation as an inspection type? This was included on the slide which described how inspectors should protect themselves.

Unit 4

The slide which discusses the importance of planning for the regulatory visit includes a non-working link to the FDA Investigations Operations Manual. The distinction between disinfection and sanitizing needs to be better explained. The material did not include an explanation of communicating breaches within the sanitation chain as part of the recall protocol.

Unit 5

The FDA Investigation Operations Manual link at the beginning on unit 5 did navigate to the correct webpage. The knowledge check question 2 seems to assess whether the learner has read the material at the provided links to both the FDA and USDA documents. The slide with those links could be improved by including a brief explanation of the main focuses of those two documents. FDA being routine operations and USDA being emergency preparedness and response to adverse events.

Committee Recommendation: Currently, there is no biosecurity in the curriculum. It's more in depth than we consider to be necessary. Overall, it seemed to have been designed for manufacturing instead of food service. Several case studies were included. That is beneficial for the learner. We do not recommend addition.

B5 Communication Skills (CC8030W)

FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to effective communication in the regulatory field.

(a) Goal: Discuss the skills required for an effective communicator in the regulatory field.
(b) Scope: Inspectors can expect to be introduced to the basic knowledge, skills, and abilities related to effective communication in the regulatory field. Topics discussed include foundations, specific communication skills (oral, written, effective listening, feedback, etc.), situational awareness, agency policies on communication, and educational resources.

Committee Review:

Unit 1

A slide mentions that an inspector may need to use the services of a translator. Should this say interpreter rather than a translator?

Unit 2

The slides which describe assertive communication as the preferred style for regulators contradict themselves. While assertiveness was described as a tool to achieve mutual respect and understanding, one of the slides gave a recommendation to use "I" statements. For example, "I would like begin the tour so that we can finish by 5 pm".

Unit 3

Several of the situational awareness photos need to be replaced with photos which better suit the content.

Some of the course exam questions were poorly worded. For example, the question asks if one should contact a supervisor if the facility operators is perceived to be lying is poorly worded.

Committee Recommendation:

Covers many of the same topics as "Communication Skills for Regulators" currently required in "pre" courses which seems more applicable for retail food establishments. Recommend no action.

B6 Data & Information Systems (CC8017W)

FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to systems used by regulatory agencies to store, process, and manage data and information.

Committee Review: Mostly a basic computer course hardware, software, data, database, mainframe, etc. The Unit 1 foundational information seemed largely irrelevant except for the distinction between data and information and the databases used by health departments and FDA.

Section 4, FDA 20.88 agreements provided useful information new inspectors may not be aware of. Section 2 also provided useful information on social media, but most jurisdictions have internal policies covering this for employees.

The "FOOD Tool" slide in Unit 1 is described as the CDC's database for foodborne illness outbreak data. Food Outbreak Online Database (FOOD) Tool. Is this still used? Shouldn't this be NORS (National Outbreak Reporting System)?

The Unit 3 and Unit 4 content does well in supporting the regulator's training on basics of inspection. These units provided good information on the knowledge a regulator must manage and the access and control of information: Freedom of Information Act, securing and updating passwords, etc. The bulk of the content seems to be common knowledge for new inspectors. Perhaps individuals who are unfamiliar with the internet and web-based applications would find the information beneficial.

Committee Recommendation: Overall, information not recommended to add to Standard 2. Most of this information is general knowledge of computers currently taught in school. Social media, malware, specific databases are usually often covered by jurisdictional internal policies. No action.

B7 Emergency Response

FDA Pathlore Course Description: The course is still under development
Committee Review: N/A
Committee Recommendation: No action

B8 Environmental Hazards (CC8024W)

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to environmental hazards as sources of contamination, and associated control methods.

Foundations

1. Define relevant terminology
2. Give examples of food and feed products that may be affected by environmental hazards.
3. Describe where to find resources.
4. Describe the consequences of contamination by environmental hazards.
5. Discuss how sampling is used to detect environmental hazards.
6. Give examples of how a milestone event impacted public policy.
7. Give examples of illness caused by environmental hazards.

Environmental Hazards of Concern

1. Identify the categories of environmental hazards.
2. Give examples of each category of environmental hazard.
3. Associate environmental hazards with products or processes.

Sources and Pathways

1. Discuss how environmental hazards contaminate products and processes.
2. Describe vectors of contamination.
3. Give examples of food contamination sources.
4. Give examples of feed contamination sources.
5. Differentiate between intentional and unintentional contamination.

Control Factors

1. Explain the concept of acceptable levels of exposure.
2. Describe best management practices that are used to prevent spread of environmental hazards.
3. Give examples of preventive controls.
4. Describe control point monitoring.

5. Explain why source is important as a control factor.
6. Discuss response options for contamination

Duration
Unit 1: Foundations - 23 minutes
Unit 2: Environmental Hazards of Concern – 21 minutes
Unit 3: Sources and Pathways – 38 minutes
Unit 4: Factors – 11 minutes
Estimated time = 1 hour and 33 minutes

Committee Review:

Unit 1

Foundations – is course content geared towards Retail Food or Manufacturing? Many of the examples and pictures emphasize manufacturing. We also suggest adding radiological hazard language in the opening slides. Also, be consistent with use of Radiological throughout if it is going to be used and mirror FSMA rules.

Unit 2

Virus slide. Suggest rewording or structuring slide so that Norovirus is clearly the #1 cause. Currently worded that viruses in general are the number one cause of illness in US.

Unit 3

Suggest adding more retail food pictures to balance out all the manufacturing pictures.
Assessment Knowledge Check 1 – sampling question not covered very well in module.

Unit 4

Control Factors Slide – Food Safety Plans: personnel safety pictures used instead of food safety symbolic pictures.

Control Factors: expound more on why source is important as a control factor. GRAS definition clarification needed that explains that GRAS is a chemical or substance added to food.

Course Assessment – Question 9: is the question asking about pre or post packaging. Needs to be reworded so that its clear.

Overall, we thought courses were good foundation for new regulatory staff. We also thought that it would be helpful for the modules to have slide number to be able to reference slides later. We concur with others that the exams at the end of the courses should provide feedback on questions that were missed so that the "student" learns the correct information. The assessments taken during each unit would also be better if the answer was reiterated why it was correct or why the answer chosen was incorrect. We like that a description pops up when hovering over photos.

Committee Recommendation: Good introduction to hazards, add to "pre" courses.

B9 Food / Feed Defense Awareness

FDA Pathlore Course Description: N/A

Committee Review: Unable to review this module because the course was not submitted by the course developer, is not on Pathlore or in the course catalog. Dave Read checked into it and found that the course does exist, but the course was not provided on Pathlore.
Committee Recommendation: No action

B10 HACCP (CC8033W)

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to the hazard analysis and critical control points (HACCP) system There are five modules in this course.

Committee Review:

Unit 2

Record Review for Accuracy – consider changing "validity" wording. Too much like verification vs validation and makes you think you are talking about validations whereas the slide is discussing verification. Overall comment: Verification vs Validations needs better disused and language on slides needs to stay true their meaning.

Unit 4

Videos. Seem out of place, not necessary, too short if they are going to be used. Would be better if video clips provided snippet of each of the 7 steps of HACCP instead of just 2.

Unit 5

Laws Regulations and Guidance: suggest creating stand-alone paragraph to explain implementation of FSMA. Need better clarification of State Agriculture programs, USDA, FDA, State and local oversight and co-regulation. Also, better explanation of FSMA (food safety plans) vs HACCP.

Assessment question—there was a question for recall procedure. We felt this was not adequately covered in module for use as a question.

Committee Recommendation: Comparable to current "post" HACCP series (FDA16-18). If possible, merge with current courses. Recommend no action.

B11 Imports (CC8034W)

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to the regulation of feed and food products grown, produced or manufactured outside of or returned to the US.

a) Goal: The student will be able to apply knowledge of import requirements.
b) Scope: The topics in this course include foundations, acts and regulations, entry process, inspection, investigation, compliance and enforcement actions, import fraud.

Committee Review: The slide which explains the term custom(s) broker includes the abbreviation CBP. The phrase CBP custody is used but is not explained until later slides. At which point, CBP is defined as Customs and Border Protection. The text under the example figure for Harmonized Tariff Schedule Code has very low resolution and is difficult to read. Unit 5 includes a "Real World Applications" video on investigations which took a very long time to load. Upon completing the final unit, there was no button available on screen to navigate to the actual course assessment. FD251 references imports, so the material presented in the module is covered there. Course completion time was 47 mins.

Committee Recommendation: We do not recommend the material replace FD251, An Introduction to Food Security Awareness, but differing information is important; add to "post" courses to supplement FD251.

B12 Integrated Food Safety System (CC8018W)

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to the concept of a national collaborative and cooperative network of federal, state, local, tribal, and territorial feed and food protection agencies working in concert to protect the U.S. human and animal food supply.

(a) Goal: Describe how collaborative interrelationships of regulatory agencies promote and protect public health in a global environment.

(b) Scope: This course will cover introductory knowledge, skills, and abilities related to the concept of a national collaborative and cooperative network of federal, state, local, tribal, and territorial feed and food protection agencies working in concert to protect the U.S. human and animal food supply. Topics include foundations of IFSS, stakeholders, mutual reliance, and program standards.

Committee Review:

Reading – reading description of images not helpful stating same thing as image that is presented.

"Example" images – throughout presentation – placeholders?

Module covered the basic foundations of an IFSS and identified the stakeholders. Also covered mutual reliance between stakeholders and covered the different program standards. 35 minutes to complete.

Committee Recommendation: Add to "post" course work.

B13 Inspections, Compliance, & Enforcement (CC8019W)

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to ensuring regulatory compliance through inspection and enforcement activities.

a) Goal: The student will be able to explain compliance activities as they relate to the safety of feed and food programs.

b) Scope: Topics in this course will include Foundations, Jurisdiction, inspection classifications, Inspection tools, Inspection techniques, Pre-inspection, Inspection process, post inspection, enforcement measures

Committee Review: Would be nice to be able to modify and brand to individual jurisdictional procedures.

Introductory knowledge, skills, and abilities related to ensuring regulatory compliance through inspection and enforcement activities. We have covered foundations, jurisdiction, inspection classification, inspection tools, inspection techniques, pre-inspection, inspection process, post-inspection, and enforcement measures.

Committee Recommendation: Only replace if the FDA 38, 39 & Communication can be merged with this course. No action.

B14 Investigation Principles (CC8020W)

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to conducting an investigation of a food safety-related event.

a) Goal: The student will be able to describe an investigation.

b) Scope: Topics covered in this course include foundations, communication, agency collaboration, investigation skills pre-investigation, investigation, post-investigation.

Committee Review: Example of Collaborating on Releasing Information, Released Early-

"EXAMPLE image" used – also on the following:

Unit 3- Examples of Potentially Involved Agencies

Unit 5 -Commodity Research Example One, two

Unit 6 -Observational Evidence Example

Exam - Question 5, not clarified in reading material:

The Incident Command System (ICS) is:

a) A flexible system that allows agencies the ability to innovate as necessary.

b) A rigid system.

After successful completion of exam, suggest providing a reference slide or information to inform learner of correct choices for the incorrect selections that were made.

Committee Recommendation: Some material covered in FDA38 – Basics of Inspection course; no action.

B15 Jurisdiction (CC8037W)

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to various regulatory agencies and their authority over feed and food.

a) Goal: The student will be able to describe which agencies have authority to conduct specific regulatory activities.

b) Scope: The topics covered in this course include foundations, law, crossing boundaries, inter-agency agreements.

Committee Review: We thought the course gave a good overview of the subject and was well designed to provide the information in a logical order. The course does not have slide numbers, so as with regards to feedback we have provided the slide header:

Unit 1

Foundations State & Local Jurisdiction Authority. Suggest a change to a word in the paragraph that states food 'consumed', suggest changing to food 'sold or distributed'. It would be inaccurate to describe food purchased at a retailer and then consumed at a home just across the state line as intrastate commerce.

Unit 3

Activities under the State Retail Food Program. It states FDA develops the Retail Food Program, we felt that the CFP process develops with input/oversight from FDA.

The Exam at the end of the course only provides a score, it does not let you know which questions you got incorrect. This could help determine what part of the course you may need to retake etc.

On AFDO's website, the courses are cross-referenced. There was not much interactive content within the course. The lack of interactive features seems like a step back considering the way that online coursework is developed today. The terminology is bridged from the manufacturing content. Violative is commonly used in manufacturing regulation. We scheduled an hour. However, we had to move through the content more quickly toward the end.

Committee Recommendation: Add to "pre" courses.

B16 Labeling (CC8038W)

FDA Pathlore Course Description:
Introductory knowledge, skills, and abilities related to labeling requirements, and the components of feed and food product labels.
a) Goal: The student will be able to explain label requirements.
b) Scope: The topics covered in this course include foundations, labeling laws and regulations, labeling components, feed, food.

Committee Review:
Course Overall:

- No slide numbers or time to complete course/sections.
- inconsistency on knowledge base confirmation on whether a question was answered correctly or not.
- There were a few videos (a little basic), but not sure if they were positioned correctly i.e. they seemed to introduce a new topic, would prefer an intro slide prior to the video.
- Some of the label images were too small to read, even on a large screen.
- The course did seem very long.

Course Design:

- The course design may benefit from being aligned under regulated areas i.e. Human Food – FDA / FSIS, Dietary Supplements, and Animal feed and then having the specific topics under each area i.e. regulations, label requirements, etc. this could help with repetition, flow and refresher training. It is a lot of information for a new employee, especially if they are not responsible for a certain regulated area i.e. animal feed, the information becomes irrelevant.
- The competency flow did not align with the course, so by having it aligned under regulated areas could help better align it.

Unit 1

Label Vs Labeling Slide. Include supplement labeling on a website

Unit 2

Labeling components required allergy information is referencing 'Produced in a facility that processes peanuts' which is not required

- Labeling components trail mix labeling confusing

Unit 3

Labeling laws referencing outdated FDA 2013 Food code

Committee Recommendation: No action in current condition. Like the topic of labeling to be included in curriculum; consider addition if course is revamped.

B17 Laws, Regulations, Policies, & Procedures (CC8039W)

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to the system of federal, state, and local laws that provide the authority to regulate feed and food, and associated policies and procedures.

a) Goal: The student will be able to employ legal authorities when conducting regulatory activities.

b) Scope: The topics covered in this course include foundations, constitution, law, regulation, policy, procedures, guidance.

Committee Review: We do not have any significant feedback. We thought the course was well aligned with the competencies and covered all the topics. As stated on previous calls the content is a little dry, and we believe in future the courses will have more interaction.

Committee Recommendation: Replace FDA35, Basic Food Law for State Regulators in "pre" courses.

B18 Personal Safety (CC8031W)

FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to hazards encountered by regulators, and appropriate protective actions to mitigate hazards.

(a) Goal: Choose safe practices based on assessment of risk.

(b) Scope: This course will provide introductory knowledge, skills and abilities related to hazards encountered by regulators as well as appropriate protective actions to mitigate hazards. Specific topics include foundations of personal safety, chemical hazards, equipment hazards, physical/environmental hazards, miscellaneous hazards, safety equipment, and educational resources.

Committee Review: It sounds like there is some redundant material in other courses regarding PPE. We noticed that the course provided specific instructions on how an inspector should execute personal safety rather than describing the types of PPE. It mentioned that an inspector should reach out to a facility in advance to determine what types of hazards to personal safety may be there. The buddy system for entering coolers and freezers was also mentioned for personal safety reasons. However, there may not always be more than one inspector conducting the inspection. Ladder safety was also included. We considered the content to be focused on more OSHA recommendations than necessary for the food protection field. Examples of hazard signage and PPE requirement signage was very useful. The content should be more of an overview and could be confusing. Basics of inspection course, FDA 38, includes a brief inclusion of personal safety by informing the inspector of appropriate clothing, shoes, head cover.

Committee Recommendation: Given that the material is not covered, it would not replace the current curriculum; no action.

B19 Pest Control (under development)

IFPTI Course Description: Explain how pest activity can impact food safety. Discuss pests of significance to human and animal health. Discuss the importance of facility design for pest control. Describe sanitation practices for pest control. Discuss detection of pests. Discuss how pest management is used to control pests.

Committee Review: This course is currently under development and unable to review. However, this topic is important for new inspectors.

Committee Recommendation: Recommend adding to "pre" courses.

B20 Plumbing (CC8001W - under development)

FDA Pathlore Course Description: This one-hour online course provides information on plumbing controls used in commercial food establishments to protect the potable water supply from contamination. The course consists of 4 lessons: Course Introduction, Cross-Connection Fundamentals, Physical and Mechanical Backflow Prevention, Protection for Drains, Wells, and Septic Systems.

This online course is a prerequisite for several OTED face-to-face courses designed to increase knowledge in identifying plumbing issues in food manufacturing facilities when conducting food GMP inspections. The commodity specific face-to-face course will increase skills and ability to interpret industry situations related to conducting food GMP inspections by FDA investigators/State inspectors.

Committee Review: B20 Plumbing is still in development but appears to be largely complete; I was provided with PDFs of the storyboards and narration for this review. This course includes significant improvements over the other courses I reviewed, having expanded accessibility features, narration, and knowledge checks that include 4+ answers. Some knowledge checks had "choose all that apply" options or asked the participant to choose the correct diagram to match the concept described. The photos and diagrams are matched for backflow prevention devices and other fixtures, which is helpful. I would consider this course a big upgrade from CC8001W.

The course has 5 units: Foundations, Water Source, Wastewater Systems, Backflow Prevention and Jurisdictional Authority. It provides a rationale for proper plumbing, citing an example from the EPA Cross-Connection Control Manual. (Kool-Aid that got mixed with a now-banned pesticide; it would have been prevented with a backflow prevention device.) The material identifies the differences between public and private water supplies, informing the regulator as to which questions to ask. B20 also covers preventing cross-connections, air gaps, maintenance, transport, and so on.

Committee Recommendation: Add to the Standard 2 pre-requisite curriculum. As an aside, it could also replace CC8001W as the pre-requisite for FD207 Plan Review.

B21 Preventive Controls (CC8040W)

FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to measures implemented by feed and food manufacturing facilities to ensure feed and food safety.

a) Goal: The student will be able to describe the principles of preventive controls.

b) Scope: Topics covered in this course include foundations, food safety plans, hazard

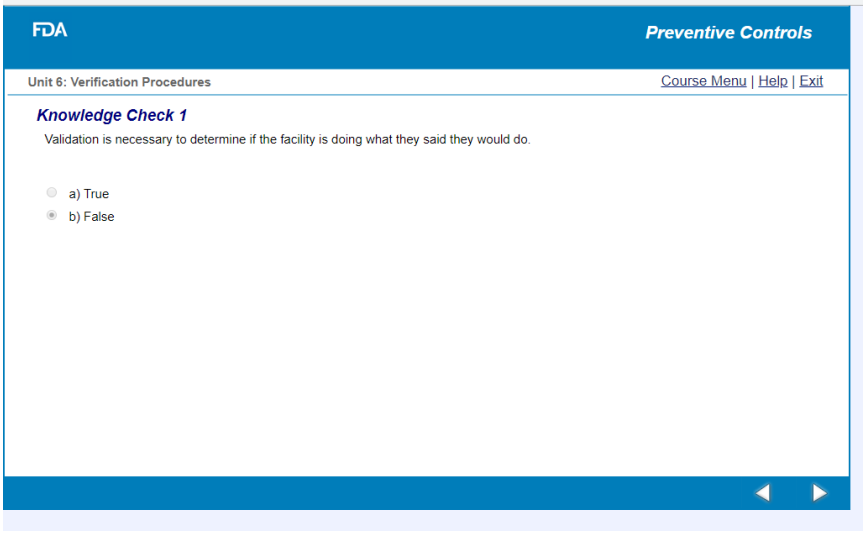
analysis, monitoring preventive control programs, corrective action plans, verification procedures, recordkeeping.

Committee Review: The course is geared towards manufacturing and could confuse if used for retail.

-Course flows well.

-Knowledge checks were good.

Unit 6 - Validation question incorrect. “Verification” should be the wording. Screenshot below:



-Final Exam – Q9 wording is confusing.

-Final exam does not state which question was answered incorrectly

Committee Recommendation: Not applicable to retail food; no action.

B22 Professionalism (CC8025W)

FDA Pathlore Course Description

Introductory knowledge, skills, and abilities related to ethics, integrity, and personal conduct during job-related activities.

(a) Goal: The student will be able to exhibit the use of integrity and positive interpersonal conduct in the performance of professional and personal activities.

(b) Scope: Topics covered in this course include foundations, ethics, conduct, personal management, communication, and interpersonal skills.

Committee Review: The coursework is divided into 6 units: Foundations, Ethics, Conduct, Personal Management, Communications and Interpersonal Skills. It defines professionalism, explains its value and the rationale for regulators to act with integrity and the accountability to the public.

The course includes straightforward and relevant scenarios for situations where a regulator could fail to conduct themselves appropriately and how to avoid even the perception of improper conduct. This content is largely text but includes illustrations and photos on most slides.

Each unit has a pair of questions at the end; they are not difficult, only requiring the participant to choose between 2 options. That said, they do underscore important concepts and prevent the participant from just clicking through the course on auto-pilot. The 10-question assessment at the conclusion is similar and provides a final percentage upon completion.

The course required about 45 minutes to complete.

Committee Recommendation: Add to the "pre" curriculum courses.

B23 Public Health Principles (CC8026W)

FDA Pathlore Course Description: Introductory knowledge, skills, and abilities related to how regulatory agencies promote health and prevent and control feed- and food-related illness.

a) Goal: The student will be able to discuss basic public health concepts.
b) Scope: Topics in this course include foundations, assessment, policy development, education and outreach, disease mitigation, emerging health issues, feed/food safety professional's role in public health.

Committee Review: The course covers 7 units: Foundations, Assessment, Policy Development, Education and Outreach, Disease Mitigation, Emerging Health Issues and the Regulator's Role in Public Health. I reviewed FDA36 and B23 side-by-side to compare the content between the courses. I recommend B23 as a replacement for FDA36; it covers the much of the same material but is designed to be more relevant to a regulator working in food safety.

The course provides good examples to explain each of the principles. Rather than recount the history of John Snow versus cholera (FDA36), B23 cites more contemporary examples, including "mad cow disease" in Great Britain and E. coli O157:H7 at Jack in the Box in 1993. These examples are used to describe subsequent changes in public policy.

The course required about 75 minutes to complete. It follows the same format as B22, with text, illustrations and photos on most slides. The 10-question assessment at the end includes questions binary questions similar to those found in B22.

Committee Recommendation: Replace FDA36, "Public Health Principles" in "pre" courses.

B24 Recalls (CC8041W)

FDA Pathlore Course Description:
Introductory knowledge, skills, and abilities related to the process of removing a product from commerce.

a) Goal: The student will be able to describe the recall process in regulatory programs.
b) Scope: Topics covered in this course include foundations, risk assessment, documentation, communications, recall process, product disposition.

Committee Review: The course has 6 units: Foundations, Risk Assessment, Documentation, Communications, Recall Process and Product disposition. Units 1 and 2 each include a subtitled video, which is a nice addition and a nod to accessibility. Useful distinctions, like the difference between recalls and market withdrawals, and adulteration versus misbranding, are explained throughout the course. The information is relevant for state regulatory agencies that monitor recalls and notify local jurisdictions, and for those agencies that assist in verifying that a product is being removed. However, local jurisdictions are not always involved in recalls (and the course helpfully points out that local health departments don't typically have the authority to initiate a

recall). As a newer state regulator, I felt the content was useful in many instances, and was my first exposure to some of the information.

I am tentatively recommending that B24 be added, unless we are finding that too many courses are being added and not enough are being removed or replaced. I am concerned about adding an unnecessary burden to inspectors by including this in the Standard 2 curriculum if it does not pertain to their normal duties. It required about 70 minutes to complete.

Committee Recommendation: Add to the "post" curriculum courses.

B25 Sampling (CC8035W)

FDA Pathlore Course Description:
Introductory knowledge, skills, and abilities related to feed and food sample collection, and the role of the laboratory.

a) Goal: The student will be able to employ sampling protocols when collecting samples.
b) Scope: Topics covered in this course include foundations, sampling methodology, procedures, laboratory.

Committee Review: B25 has just 4 units: Foundations, Sampling Methodology, Procedures and Laboratory. It defines integrity and validity in regard to sampling, describing the rationale in collecting and documenting samples that are legally and scientifically defensible. Aseptic sampling and chain of custody is explained. The course references the FDA Inspections Operations Manual as a resource for determining how much of a sample is required to be representative. (Maybe include a link that to that manual?)

Unit 3 includes a three-minute video with subtitles to demonstrate how to collect aseptic samples. The shots throughout the video are framed well and allow the viewer to clearly see each step as it is demonstrated. FI04, Foodborne Illness Investigations 4: Conducting a Food Hazard Review, covers the some of this sampling content but is more focused on preparing (logistics and interviewing) for the site visit. B25 is more analogous to MIC13. It took approximately 60 minutes to complete.

Committee Recommendation: Replace MIC13, Aseptic Sampling, in the pre-requisite curriculum.

B26 Sanitation Practices (CC8032W)

FDA Pathlore Course Description:
Introductory knowledge, skills, and abilities related to cleaning, sanitizing, and disinfecting, and the importance of facility and equipment sanitary design.

(a) Goal: Describe the importance of sanitary design and practices.
(b) Scope: This course will consist of introductory knowledge, skills and abilities related to cleaning, sanitizing and disinfecting as well as the importance of facility and equipment sanitary design. Topics include foundations of sanitation, cleaning, sanitizing, disinfecting, sanitary engineering, and educational resources.

Committee Review: The course consists of 6 units: Foundations, Cleaning, Sanitizing, Disinfecting, Sanitary Engineering and Sources/Routes of Contamination. It addresses construction materials, contact and non-contact surfaces, the distinction between cleaning and sanitizing, proper layout and so on. The material addresses the limitations and thresholds for different methods of sanitization (chemical, thermal, radiation). It also identifies barriers to

effective cleaning and sanitization. The course took about 75 minutes to complete, but it might be more like 90 minutes for someone new to the material.

Committee Recommendation: Replacing MIC15, Cleaning & Sanitizing, in the Standard 2 Pre-requisite curriculum; it's a significant upgrade across the board. Also, this course covers a lot of the fundamentals for FD207 Plan Review and may be a suitable pre-requisite for that course.

B27 Traceability (CC8042W)

FDA Pathlore Course Description:
Introductory knowledge, skills, and abilities related to tracking feed and food throughout the supply chain.

a) Goal: The student will be able to describe the role of traceability in feed and food programs.
b) Scope: Topics covered in this course include foundations, preliminary review, supply chain, documentation, communications, technology.

Committee Review: This course has 6 units: Foundations, Preliminary Review, Supply Chain, Documentation, Communication and Technology. It serves as a primer for tracking human and animal foods through the supply chain. The traceback processes and necessary documentation are clearly defined, and the rationale is provided for when and why a traceback is conducted. (Or a traceforward…) It has some overlap with the Foodborne Illness Investigations series. But, it is distinct and focused enough that it would not replace any of them. It seems most relevant to epidemiologists; most of the local jurisdictions I work with have epidemiological staff and perhaps one inspector that is crossed-trained on epi.

Unit 3:

Supply Chain has a 2-minute video, subtitled, that describes a traceability study, followed by a traceback diagram. The diagram might be better served as a larger image (expandable or clicking to enlarge), as it is difficult to see at the current resolution. Some images have the option of clicking a line of text to read a description of the image.

Like B24 (Recalls), this course has useful information for all regulators, but I am unsure as to how necessary it would be for regulators that work on teams with trained epidemiologists. It took about 75 minutes to complete.

Committee Recommendation: Add to "post" curriculum.

B28 Transportation (CC8036W)

FDA Pathlore Course Description:
Introductory knowledge, skills, and abilities related to preventing contamination of feed and food during transport.

a) Goal: The student will be able to describe how transportation affects feed and food safety.
b) Scope: Topics in this course include foundations, transportation methods, inspections, security, product safety.

Committee Review: The course contains 5 units: Foundations, Transportation Methods, Inspections, Security and Product safety. It required about 90 minutes to complete.

The first section includes a 4-minute video (subtitled) on the importance of transportation. Unit 2 includes a 2-minute video on a *Salmonella enteritidis* outbreak that sounds like it is referencing the Schwan's incident investigated in Minnesota. The video and header indicate the outbreak happened in 1984, but the well-known outbreak occurred in 1994. A minor detail; is this an error? Also found a typo in Unit: Product Safety on the Air Distribution Exchange slide in the heading.

The Security unit has useful information on chain of custody. The content is well-written and includes examples from relevant outbreaks. It appears to be more pertinent to manufactured foods and agriculture, rather than retail foods. Much of the content (pest control, HACCP, temperature control) that would be applicable to retail food inspections is covered in other courses.

Committee Recommendation: Add to "post" curriculum.