**Slide 2**

Welcome to the McKesson Pharma training on regulatory compliance, standard operating procedures, and auditing! This material is designed for both managers new to their position as well as a useful resource for those “seasoned” veterans. The intent of this course is to:

- Familiarize you with the regulatory agencies that oversee the McKesson Pharma operations
- Indicate the policies by which they govern
- Show you where and how McKesson interprets those policies to address our day to day pick/pack and ship
- Discuss our Standard Operating Procedures
- Help you to understand “why” compliance is important!
- Provide guidance on how to keep you and McKesson “out of trouble”.
- and highlight what is auditing and why is it necessary.

By understanding your roles and responsibilities and where to access information you can prepare yourself with the knowledge to address the challenging world of regulatory compliance, standard operating procedures, and auditing.

**Slide 3**

This course consists of three lessons. You must complete all three lessons to receive credit for this course. At the end of each lesson is an ungraded quiz to check your knowledge and understanding of the content. Roll over each of the Playbar buttons for information on the navigation of this course.

Additionally, please note that throughout this course there will be hyperlinks provided to various resource sites. You are strongly encouraged to explore those links and bookmark them for your future reference.

**Slide 4**

Please click on Lesson 1 to begin

**Slide 5**

The day to day operations of McKesson Pharma is a fairly simple one. We are in the business of "pick, pack and ship". That is, we receive product into our warehouses, fill orders for our customers and deliver the product to them…then do it all over again! However, due to the nature and volume of the product we distribute, everything we do is regulated or "controlled" by governmental agencies. These agencies have written policies, laws and regulations that have been created to safeguard the public health and safety and protect the environment. It is these regulations that McKesson must follow, or comply with, in order to carry out the pick, pack and ship and remain in business! Let's take a closer look at the agencies that govern our business.

**Slide 6**

McKesson Pharma must comply with a multitude of laws and regulations in order to legally conduct business. Various licenses and permits are granted to individual distribution centers that allow them to operate. However those licenses and permits are given under the condition that the policies and regulations issued by those agencies will be followed and adhered to. Failing to comply with stated regulations can lead to fines, lawsuits, loss of license, suspension of business and even imprisonment. In the following slides, we will review the predominate agencies that govern our business, the specific areas that they govern and regulations that they govern by.

**Slide 7**

The Drug Enforcement Administration (or DEA) was created by President Richard Nixon through an Executive Order in July 1973

in order to establish a single unified command to combat "an all-out global war on the drug menace." At its outset, the DEA had 1,470 Special Agents and a budget of less than $75 million. Furthermore, in 1974, the DEA had 43 foreign offices in 31 countries. Today, the DEA has 5,235 Special Agents, a budget of more than $2.3 billion and 87 foreign offices in 63 countries.

The responsibilities of the DEA as it pertains to our McKesson distribution centers includes:

- Investigation and preparation for the prosecution of major violators of controlled substance laws operating at interstate and international levels.
- Management of a national drug intelligence program in cooperation with federal, state, local, and foreign officials to collect, analyze, and disseminate strategic and operational drug intelligence information.
- Enforcement of the provisions of the Controlled Substances Act as they pertain to the manufacture, distribution, and dispensing of legally produced controlled substances

**Slide 8**

The overarching regulations implemented to carry out the Controlled Substances Act and for which the DEA governs is found within the Code of Federal Regulations or CFR 21 Part 1300. The CFR is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. It is divided into 50 titles that represent broad areas subject to Federal regulation (4). The CFR provides the minimum requirements that must be complied with to participate in that industry. In 1970, the federal government established the Control Substances Act which gave the government the legal foundation to fight illegal/ illicit drugs and distribution.

**Slide 9**

The Act consolidated various laws regarding the manufacture and distribution of controlled substances into one area within the CFR – Title 21/Chapter 13. The DEA established the Office of Diversion Control to specifically administer the regulations for which McKesson Pharma operates. These regulations cover every aspect of the distribution and handling of controlled substances such as ordering, receipt, storage, security, order fulfillment, shipping, registration, reporting, destruction, inventory, and monitoring.

**Slide 10**

The Food and Drug Administration (or FDA) was formed as a result of the passage of the Pure Food and Drugs Act of 1906. The Act was the culmination of about 100 bills over a quarter-century that aimed to rein in long-standing, serious abuses in the consumer product marketplace. At present the FDA employs 11,500 individuals and operates from six product and one research center. The FDA operates within the department of healthcare and Human Services. As it pertains to our business, the FDA regulates the creation of drugs and medical devices, their distribution, overall safety and effectiveness. They monitor new to market items as well as the post market follow up. Additionally they will enact recalls or withdrawals of items thought to be unsafe or ineffective for their intended use. The safety of the general public regarding food, drugs, medical devices and other over the counter medications is their primary concern.

**Slide 11**

As with the DEA, the FDA governs under the Code of Federal Regulations, specifically, title 21 CFR. McKesson's Pharma operations must comply with applicable sections within 21 CFR such as Parts 203, 205, 210, 211. For example, CFR 21, part 205

provides the basic requirements for day to day operations. This includes licensing requirements, storage conditions, cleanliness, security, record keeping, returns, shipping, inventory, recalls, and policies and procedures.

**Slide 12**

In 1988, the President signed into law the Prescription Drug Marketing Act or PDMA. The PDMA was enacted to ensure that drug products purchased by consumers are safe and effective, and to avoid the unacceptable risk to American consumers from counterfeit, adulterated, misbranded, sub-potent, or expired drugs. The legislation was necessary to increase safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs. The law was incorporated into CFR title 21, part 203. This part is important to McKesson operations because it provides the framework of our drug pedigree compliance.

**Slide 13**

The United States Occupational Safety and Health Administration, or OSHA, is an agency of the United States Department of Labor. It was created by the Congress of the United States under the Occupational Safety and Health Act, and was signed by President Richard Nixon in December 1970. Its mission is to prevent work-related injuries, illnesses, and occupational fatality by issuing and enforcing standards for workplace safety and health. The agency is headed by a Deputy Assistant Secretary of Labor. OSHA federal regulations cover most private sector workplaces. Additionally, OSHA permits states to develop approved plans as long as they cover public sector employees and they provide protection equivalent to that provided under Federal OSHA regulations. ***(OSHA - pronounce as O Sha)***

**Slide 14**

The Act established the regulations for which McKesson Pharma operations must comply. As with previous Federal agencies, they can be found in the CFR under title 29, specifically part 1910. Partner safety is extremely important to McKesson and every aspect of our day to day business is covered under the CFR including, lock out/tag out, protective equipment, blood borne pathogens, chemical spill, cleanliness, power equipment, accident investigation and first aid, just to name a few.

**Slide 15**

The Department of Transportation, or DOT, was established by an act of Congress in October 1966 and was signed into law by President Lyndon Johnson. It currently consists of 11 individual operating administrations with 58,000 employees. The DOT's main focus is to "develop and coordinate policies that will provide an efficient and economical national transportation system, with due regard for the need, the environment, and the national defense".

**Slide 16**

In 1958, Congress passed the Federal Aviation Act, or FAA, which was signed into law by President Eisenhower. It wasn't until 1966, with the creation of the DOT, that the Federal Aviation "Administration" came to be. While the DOT is the governing body for all modes of transportation, the FAA is solely responsible for "aerospace", or as it relates to McKesson, air transportation. The overall mission of the FAA is to provide the safest, most efficient aerospace system in the world.

**Slide 17**

As a federal agency, the DOT/FAA adheres and governs by the regulations found in the CFR, specifically title 49. Since McKesson Pharma operations utilizes ground and air transportation to ship its goods and services, it must comply

with title 49 CFR. The regulations found there deal with the handling of hazardous materials, labeling goods and packages, safety and security, to name a few.

**Slide 18**

While complying with title 49 CFR is the mandate, McKesson has chosen to utilize rules and guidelines as established by the International Air Transport Association or IATA. IATA is an international trade body, created over 60 years ago by a group of airlines. Today, IATA represents over 230 airlines comprising 93% of scheduled international air traffic. The organization also represents, leads and serves the airline industry in general with guidelines that are actually more stringent than is required in the CFR. ***IATA (pronounce as" I ah ta")***

**Slide 19**

In addition to the mandatory federal agencies and the laws/ regulations that our McKesson Pharma operations must comply with, the individual states that our distribution centers operate in have their own regulatory requirements. State Boards of Pharmacy, or BOP, have been established in all 50 states as well as in the District of Columbia, Guam, Puerto Rico and the US Virgin Islands. These state government agencies are responsible for protecting the health and welfare of the citizens of their state. They regulate and oversee the pharmacy practices as well as the distribution and sale of prescription drugs, non prescription items and medical devices within their state. All told the mandate of a BOP is to:

- Issue license to pharmacists, pharmacy interns and pharmacy technicians
- Issue permits to pharmacies, manufacturers, wholesalers and distributors and,

- To conduct compliance inspections of permitted facilities, investigate complaints & resolve violations of applicable state and federal laws and rules

**Slide 20**

While federal laws and regulations take precedence, individual states may enact laws and regulations that either align with federal laws or are more stringent. Additionally, states may enact laws and/or regulations that are specific to that state such as pedigree or identifying controlled substances.

Professional organizations such as the National Association of Boards of Pharmacy, or NABP, exist to provide support to the state boards of pharmacy in creating uniform regulations to protect public health. You can reference the NABP website to navigate the individual states BOP information.

**Slide 21**

Individual states may require additional licensing and permits in order to handle or distribute controlled substances. Commonly known as Bureau's of Narcotics and Dangerous Drugs in states that have them, these agencies provide additional oversight for the safe and legal handling and distribution of controlled substances within their state.  A good resource to determine whether your state has additional controlled substance laws or whether a Bureau of Narcotics and Dangerous Drugs exist in your state is the National Association of State Controlled Substance Authorities or NASCSA.

The NASCSA is a non-profit organization that works to educate and communicate issues regarding controlled substance diversion, regulations and enforcement of laws as well as serving as a liaison between states and federal controlled substances authorities, the pharmaceutical industry, and other interested parties.

**Slide 22**

Help regarding all things regulatory and compliance is as close as your phone or email! You can find this information at the McKesson Distops webpage regarding regulatory affairs. On the regulatory affairs website you will find links to important information in addition to the contact information to the Director of Regulatory Affairs, or DRA, specific to your region. All DRA's are willing and able to assist you regardless of the location…so you are never alone!

**Slide 23**

To conclude this lesson, McKesson Pharma operations is in the business of providing the best distribution network of pharmaceuticals and products to our customers. We pride ourselves on daily accuracy, speed and dedication to our customers. However, all that is for naught if we fail to remain compliant to our regulatory requirements. Failing to comply has serious consequences. It can lead to injuries, loss of life, fines, citations, loss of licenses, loss of business, loss of faith in our company and even incarceration depending on the infraction. Maintaining a diligence toward compliance keeps both you and McKesson out of regulatory "trouble" and instills confidence amongst our customers and business partners.

**Slide 24**

We have now completed lesson 1. Let's take a moment to go through a couple questions based on what we have just learned.

**Slide 29**

Thus far you have been introduced to the agencies that govern our business and provide the regulation backbone that McKesson must comply with. Now let's proceed on in discussing Standard Operating Procedures.

**Slide 30**

Click lesson 2 to continue

**Slide 31**

Within the SOP lesson there will be Pause Points in which you'll be asked to self-read various content. These specific Pause Points will be designated with this color border. When you see these, please take the time to read through the content, then click on the Forward button to proceed.

**Slide 32**

What is a Standard Operating Procedure, or SOP? (pronounce as S-O-P) The proper definition is – an "established procedure to be followed in carrying out a given operation or in a given situation". What that means to our McKesson Pharma operations is that every major component of our day to day operations has a set of "instructions" to be followed in order to remain consistent and reduce any defects or variation in our processes. Everything in our pick, pack and ship is addressed by an SOP… including regulatory compliance!

**Slide 33**

McKesson Pharma operations addresses all of its SOP's in the McKesson Operations Manual, or more affectionately known as MOM. Here you will find the compilation of all the SOP's that McKesson Pharma operates by.

**(MOM- Pronounced Mom, as in mother)**

**Slide 34**

There are three major types of SOP's that make up the bulk of the MOM.

- Process SOP – A process SOP is a high level description of related groups of tasks or procedures that lead to a specific outcome.

- Procedure SOP – A procedure SOP is more detailed than a process SOP. Procedures tell what is supposed to happen, in what order and by whom.
- Policy SOP – A policy SOP is a high level description of either McKesson Corporation policy or an interpretation of a federal/ state regulation. Policy SOP’s help managers and workers make sound decisions and remain compliant.

**Slide 35**

Regardless of the type of SOP, they will all contain some form of what the SOP is, when it is to be followed, why it is important, where it should be used and who is responsible. All SOP’s are owned by a process owner within McKesson Pharma. It is the responsibility of the process owner to review, approve or reject new SOP's or SOP changes. Process owners may solicit feedback or assistance in determining SOP effectiveness, but no SOP will be posted or distributed without process owner approval.

**Slide 36**

In addition to the step by step requirements of our day to day business, McKesson has interpreted the vast majority of the CFR and state regulations that are relevant to our regulatory compliance and put them in a format that is easily comprehended and specific to McKesson. While it is impossible to review every SOP here, the next few slides will address some very important and key SOP’s that will assist you in remaining compliant.

**Slide 37**

There is an SOP to address every DEA related process within our McKesson operations. Depending on your managerial position within McKesson, you will be trained on those SOP’s and processes as part of your continuing education.

**Slide 38**

There are, however, a couple of very important SOP's that every manager, regardless of your area of responsibility, should be familiar with.

The DEA Audit Procedures SOP is an important SOP because it details the steps and procedures to which a manager needs to adhere to complete a successful DEA audit.

**Slide 39**

In the event the DEA initiates an audit, be polite and professional upon greeting the DEA investigators or agents. You should immediately inform your senior management staff or the manager in charge of your facility. You should validate the credentials of the agents PRIOR to allowing access to the building. As with any guest you should have them sign the guest register as a form of formal identification. Lastly, you should provide the agents a comfortable work area where they can conduct their business. Overall, you can expect the agents to review your processes for inventory, ordering, shipping, transaction recording, and security of the facility operations.

**Slide 40**

It is your responsibility as a manager to ensure that adequate notes are taken as a record of the DEA audit. Notes can provide clarity and reference to what was said and asked. You should never respond to a question with your own opinion or speculate when you do not know the answer to a question. Obviously it is never appropriate to "make up" a response if you do not know the answer. Rather, you should reply that you will research the question and "get back" to the agents with an appropriate response. If you are presented with a question that you do not have the immediate answer to, it is important to engage the regulatory affairs and/or law department to ascertain the correct response. For any information you provide to the DEA,

you should also make and retain a copy for the distribution center.

**Slide 45**

As a manager for McKesson Pharma operations, you will likely have some responsibility regarding controlled substances. The DEA expects that the controlled substances McKesson distributes are ultimately being sold to customers that have a legitimate need and in turn are selling those controls to their customers that possess a legitimate prescription for a legitimate need. Because of that requirement, the CSMP SOP was created to provide guidance on monitoring sales of controlled substances to customers. You should become very familiar with the details of the SOP and understand the part you play as a manager regarding the sale of controlled substances.

**Slide 46**

While the DEA will ask information of you throughout the audit, you may never allow the DEA agents access to McKesson computer systems or files and at no time shall an agent be unaccompanied by a McKesson employee while in a McKesson warehouse or other facility. Distribution Center personnel should make notes of all records reviewed and copied by DEA; any inventory counts made for the purposes of an audit should also be recorded by DC personnel. When in doubt of a request or action, you should seek the guidance of the McKesson Law Department and/or a Director of Regulatory Affairs. Lastly, as with any contact with a government official, complete a Report of Government Contact form.

**Slide 47**

Because the FDA regulations cover almost every aspect of the pick, pack and ship process, nearly every operational SOP has some aspect of FDA regulatory compliance to it. Depending on

your area of responsibility within McKesson Pharma, you will be given further instruction on the various specific SOPs that you will need to know.

There are however two very important FDA SOP's that as a manager you need to pay close attention to. They are the General FDA Policies and Checklist SOP and the FDA Inspection Procedure SOP.

**Slide 48**

The General FDA Policies and Checklist SOP is a compilation of various FDA regulations condensed into a single document. It is a very clear and concise listing of the basic FDA requirements for a McKesson distribution center. It is intended to be both an informational policy as well as an instructional document for all warehouse partners as there is an expectation that all McKesson Pharma operations employees are trained in FDA requirements. The document covers storage, cleanliness, inventory management, building maintenance and licensure, among other items.

**Slide 49**

In addition to the directives, the SOP contains the FDA Tri Annual checklist.  This form is to be completed by management, signed, dated and marked with corrective actions (if needed) every four months. The purpose of the checklist is to put the responsibility for adherence to the FDA directives on the management team to ensure that their DC remains in compliance. If an item on the FDA Tri Annual checklist is found to be out of compliance, management will notate their corrective action on the form.

**Slide 50**

As with the DEA, the FDA has the legal authority to inspect any McKesson facility at any time, day or night. The inspection process is very similar and as a McKesson manager you should

review the FDA Inspection Procedures SOP in depth and acquire a significant understanding of the process.  There are a couple of significant differences to be quickly reviewed. While the DEA concerned itself with controlled substances, the FDA looks at a larger picture of your operation such as license, all inventory, recalls, returns, records for all items, and temperature and cleanliness, to name a few.

**Slide 51**

There are a couple of significant differences to be quickly reviewed. While the DEA concerned itself with controlled substances, the FDA looks at a larger picture of your operation such as license, all inventory, recalls, returns, records for all items, and temperature and cleanliness, to name a few.

Another significant difference is the possible issuance of form 463 Affidavit. The 463 form is an affidavit that is used to take a sworn statement. As a manager you are required to contact the McKesson Law Department prior to completing / signing a form 463.

**Slide 52**

Photographs are allowed to be taken but only if the pictures do not reveal any proprietary or security information. You should take the pictures of the same subject, while in the presence of the agents, as to provide a McKesson photo perspective and point of view. Once the inspection is complete you should request copies of any pictures taken by the agents for McKesson’s records. If at any time there is a problem or concern with these steps or implementing the policy you should immediately contact the McKesson Law Department.

**Slide 53**

Photographs are allowed to be taken but only if the pictures do not reveal any proprietary or security information. You should

take the pictures of the same subject, while in the presence of the agents, as to provide a McKesson photo perspective and point of view. Once the inspection is complete you should request copies of any pictures taken by the agents for McKesson's records. If at any time there is a problem or concern with these steps or implementing the policy you should immediately contact the McKesson Law Department.

**Slide 54**

Because the FDA may be entering your facility to conduct an inspection, they may request to "record" the proceedings or certain aspects of the proceedings with an electronic device. You will need to respectfully request the agents to refrain from doing so due to partner safety and facility security concerns. The agents are prohibited from using a recording device such as a video camera as per their inspection manual guidelines. They can however use a personal digital or tape recording device as long as it is used only for the agent's personal notes and dictation.

**Slide 55**

Regardless of your managerial responsibility, your safety and the safety of those around you is of upmost importance. The McKesson Corporate Safety Department has created numerous and specific SOP's regarding training and partner safety that can be found in MOM. However, there is one SOP, the General Safety Policies and Safety Tri-Annual Checklist SOP that provides a complete list of safety "to-do's" for all McKesson Pharma managers. This SOP is intended to direct the McKesson manager towards the key important safety requirements as well as provide for periodic testing of how well your distribution center is remaining compliant.

**Slide 56**

As mentioned earlier, the DOT and FAA focus their efforts on the safety and security of the transportation systems. While McKesson Pharma operations tend to not engage in their own delivery of goods, it does ship goods to customers using various methods of couriers and parcel delivery companies. So as it relates to the regulations of the DOT and FAA, McKesson is actively engaged in compliant shipping. The preponderance of those requirements can be found within the Hazardous Material Tri-Annual Checklist SOP. While you may not deal directly with the shipping of goods in your day to day job, as a manager you are likely responsible for others that are. As such, it is important to understand the nature of these requirements.

**Slide 57**

Boards of Pharmacy are state entities that take responsibility for the sale and distribution of drugs, non drugs and medical devices within their states. They follow federal regulations and sometimes enforce more stringent rules for the license holders in their state depending on the individual state's laws. The BOP's are wholly responsible for the issuance of the required states licensure for sale and distribution of drugs and medical devices. McKesson Pharma operations has a dual responsibility regarding state licenses.

**Slide 58**

First, distribution centers are responsible to maintain their own licenses required by the states in order to distribute drugs and other goods. This includes the states in which they reside and the states that they distribute into.

Also, some states have a separate state controlled substance authority that regulates and licenses facilities that handle controlled substances as defined under state law. For example, Missouri and Oklahoma have what is called a Bureau of Narcotics and Dangerous Drugs. Separate licenses and regulations, in

addition to BOP laws and regulations, are enforced by these agencies.

**Slide 59**

McKesson has the responsibility to only distribute merchandise to those customers that have the proper state license that allows them to operate legally within their state. The "Distribution Center State License Process" and the "DEA and Customer State License Verification Procedure" SOP's address both of those concerns. Whether or not your immediate responsibilities require you to deal with licensure, as a manager you should become familiar with the processes that control them.

**Slide 60**

Help regarding all things regulatory and compliance is as close as your phone or email! You can find this information at the McKesson Distops webpage highlighting regulatory affairs. On the regulatory affairs website you will find links to important information in addition to the contact information to the Director of Regulatory Affairs, or DRA, specific to your region. All DRA's are willing and able to assist you regardless of the location…so you are never alone!

**Slide 61**

Within this lesson you have been shown how McKesson interprets regulations and forms them into SOP's. Those SOP's are kept in the MOM website for your convenience. Throughout your McKesson career you will be have many opportunities to read, review and even help to form SOP's relevant to your responsibilities. There is no way to memorize or remember every one, but the knowledge of where they are located is a big plus. Finally you have been shown a few specific SOP's that focus your attention

of basic regulatory requirements for every manager and resources on where to get help with them!

**Slide 63**

We have now completed lesson 2. Let's take a moment to go through a couple questions based on what we have just learned.

**Slide 69**

Let’s proceed now, in our final lesson, to the topic of compliance auditing.  Please click on Lesson 3 to continue.

**Slide 70**

Auditing is the act of formally examining and reviewing an organizations accounts or financial situation.  As the definition relates to McKesson Pharma DC’s, auditing is the act of reviewing multiple facets of DC operations to ensure compliance and control of standard operating procedures. Auditing is a powerful tool to help identify risk and exposure and allow the DC’s to correct and mitigate those risks.

**Slide 71**

Audits performed within McKesson Pharma operations are broken down into two types.  The first type, called external audits, are those audits that are conducted by external entities.  Those external entities are usually governmental agencies that are ensuring compliance to established laws, rules or regulations that allow McKesson DC’s to operate.

**Slide 72**

The DEA, FDA, OSHA, DOT, FAA and/or BOP may at any time perform an audit or inspection at a McKesson distribution center.  In addition to government agencies, McKesson Corporate has contracted with Deloitte & Touché LLP, an audit, financial advisory, Sarbanes-Oxley compliance, risk management, tax and

consulting company to perform periodic audits in McKesson distribution centers.

Because McKesson has entered into managed inventory agreements with some of our vendor partners, those vendor partners may also request to audit or solicit a third party to audit our facilities. They will inspect to ensure contractual compliance around product condition and stock rotation

**Slide 73**

By complying with McKesson standard operating procedures as mentioned in lessons 1 and 2, your distribution center will remain compliant with these governmental agencies and external audit firms.

**Slide 74**

In addition to the external entities that audit and inspect Pharma DC's, McKesson Corporate and the Pharma Operations Leadership team also conduct their own audit functions. Let's take a closer look at the activities of these two audit groups.

**Slide 75**

The original STARS program was conceived as a means to drive standardization, regulatory compliance and as a support tool of the six sigma methodology for distribution operations. The STARS program as it exists today incorporates the same concepts but additionally incorporates the need to react to legislative requirements (for example, SOX) and address the changes in the distribution workplace, for example, pedigree. The STARS program aids the business by maintaining distribution excellence. SOP compliance assists in maximizing quality, efficiency and speed of distribution operations thus outperforming our competition.

**(SOX - pronounce as sox),(STARS – Pronounce as Stars)**

**Slide 76**

All audit items are supported by a standard operating procedure and as such, STARS audits measure compliance against the SOP. However not every SOP is audited. Only those SOP's deemed crucial for day to day operations are tested. For an item to be considered STARS auditable, the noncompliance of the audit item would result in one or more of the following - a large financial loss, fines, censure, loss of licensure or the ability to operate as administered by a regulatory agency, partner injury, loss of life and/or unsafe work conditions.

**Slide 78**

A Pharma representative for each of the audit departments is a member of the STARS Audit Review Committee, or SARC. They are responsible for providing properly trained resources to conduct their specific audit and creating, maintaining and supplying calendars of audit dates for each fiscal year. They also review their specific audits periodically for updates and revisions.

**Slide 79**

The STARS "audits" are excel workbooks based upon a Risk Control Group design. The audit technique and methodology is rigorous and detailed and is designed to be non subjective, fact based and meaningful.

It is primarily a controls based audit whereby the theory behind it is that the audit can be conducted in such a way that it removes subjectivity of the auditor. It directs the auditor to perform a test of controls concisely whereby the results should be repeatable and reproducible which means, if administered properly, the audit could be re-conducted by different auditors, but produce the same audit result and outcome.

**Slide 80**

Auditors are directed to test the controls using fact based data utilizing various data sources, systems, programs, printouts and

interviews.  Data sampling is utilized to gain a "snapshot" of the overall process.  Sample sizes are determined by the following:

- Quarterly control = 1 sample
- Monthly control = 2 samples
- Daily control = 10 samples
- Weekly control = 5 samples
- When sampling is not based on frequency then 15% as a rough guide and not more than 25 total samples are used.  The sampling and testing of controls should be conducted for a testing period that is not to exceed 12 months prior to the date of the audit.

**Slide 81**

Let's take a look at the STARS spreadsheet. This is the STARS Section Overview tab. Roll over the blue outlined areas to see more information on each section.

**Slide 82**

For information onThe STARS Conclusions tab roll your mouse over the blue outlined areas.

**Slide 83**

Roll over the blue outlined areas for more information on the The STARS audit Test of Controls tabs.

**Slide 84**

During the audit process, the auditors will adhere to the audit principle and indicate whether a test passed or failed.  Any defect or exception found fails the test.  When a test fails the auditor will make a copy of the defect (up to three) and save along with the completed workbook.

**Slide 85**

Upon or near completion of the audit process, the audit team will schedule an exit interview with the DC management team. The exit interview consists of a review of the audit and findings as well as a discussion of the issues found. The management team will be informed that the exceptions found will be transferred to an "issues" list. The STARS auditor will then either schedule a follow up meeting for no longer than one week after the exit interview at which time the management team will be expected to provide a resolution / action plan to address each exception found, or request and obtain action plans in email format. The action plan will consist of an owner, a corrective action and a date for completion.

**Slide 86**

The issues will be maintained, monitored and communicated by the Director of Regulatory Processes. As audits are completed and action plans formulated, the information will be forwarded to the Director to be captured in the issues list. The Director will then complete the information in the list including type of deficiency, risk factor, status and additional comments. The list will then be posted to the STARS website as well as communicated to senior management, regional VPDO, VPGM, DRA, internal audit and risk control group.

**Slide 87**

The Director of Regulatory processes (or designee) will request updates on status of issues from the distribution centers on a monthly basis. DC's will be required to report the current status of issues, date of completion and any other additional comments as needed. Statuses that have become "open and/or behind schedule" will be forwarded to an appropriate VPGM, VPDO for response.

**Slide 88**

All issues are given a risk rating to help determine the severity of the issue. The ratings are low, medium and high. Issues rated low and medium can be addressed directly by the DC management and communicated to the Director of Regulatory Processes as being complete by way of an email. Issues rated as a "high" risk may be communicated as completed by way of an email as well, however, those items must also be validated as completed by a third party. That validation can be completed by retesting, via on site validation by the third party auditor or through presentation of supporting evidence to the auditor. The high risk issue will remain open until the validation has been completed.

**Slide 89**

At any time you may access STARS information from the STARS website. There you will find all of the STARS testing workbooks, issues list plus other relevant STARS auditing information that is beneficial to you and your team!

**Slide 91**

Let's now shift to McKesson's Internal Audit group, which is a function within McKesson Corporate Finance based in San Francisco. It is currently a group of 30 – 35 audit professionals that operate under the direction of the CFO, and report directly to the Audit Committee. Internal Audit has offices in San Francisco, Alpharetta Georgia and Carrollton Texas.

**Slide 92**

The vision of Internal Audit is "To provide value-added, quality audit and other services through a staff of employees dedicated to excellence. Through open communication, we will strive to partner with our customers to provide proactive risk management assistance."

The critical message to take note here is that Internal Audit focuses on the identification and mitigation of business risk.

**Slide 93**

As illustrated here Internal Audit has several areas of focus. These are but a few examples of the coverage for the company's independent risk management functions.

Overall, management has the ultimate responsibility for understanding, overseeing, and managing their specific business risks.

**Slide 94**

As previously mentioned, Internal Audit is an independent branch of McKesson Corporate Finance and as such reports and communicates their activities directly to the Audit Committee of the Board of Directors for McKesson. Their audits focus on financial, operational, compliance, information technology, and strategic risk.

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As part of their report issuance process the audit scope, audit issues, management action plans, and overall conclusion are outlined within the audit report which is distributed to the audit participants as well as executive management and the audit committee. Audit issues identified during the course of an audit followed up on to ensure the audit issue is remediated by the agreed upon action due date. As an audit participant, your feedback is valued and an important component of the audit process in order to help Internal Audit improve and grow.

**Slide 96**

Internal Audit conducts a variety of audits and provides a variety of services for McKesson Pharma and other McKesson business units. These include:

Financial Audits – These types of audits evaluate the integrity and accuracy of financial statement accounts and related financial controls, processes, policies, and procedures

Information Technology (IT) Audits – These audits evaluate the design and effectiveness of core IT system controls.

Integrated Audits – These audits combine financial, operational, and IT components to evaluate and assess the design, efficiency, and effectiveness of critical financial, operational and system controls.

Operational Audits – These audits evaluate the efficiency and effectiveness of key operational controls, processes critical to the business, and standard operating procedures.

Regulatory and Compliance Audits – These audits assess compliance with applicable laws and regulations

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Internal audit also provides other service offerings such as –

• pre and post-implementation reviews

• risk assessments

• Investigation support

• General Business Reviews

• Or other special projects as requested by management or the Law department.

**Slide 98**

Internal Audit conducts quarterly risk assessments based on interviews with key executives to identify potential risks to the various McKesson business units. The risks identified during these risk assessments are documented, evaluated, ranked, and tracked in the Internal Audit risk tracking database. The top ranked risks are then fed into the Internal Audit annual

audit plan and refined on a quarterly basis. Internal Audit works closely with other McKesson risk management organizations to consolidate top enterprise risk lists and ensure coordination among the groups to minimize the duplication of efforts.

**Slide 99**

Roll over each topic in the grey bar for more information on each step in the Risk Assessment Process.

**Slide 100**

Internal Audit conducts a quarterly risk assessment process to identify key risks within the organization which in turn populates their annual audit plan and drives their audits of McKesson business units (which includes Pharma distribution centers). Dependant on available resources , Internal Audit can typically complete approximately 45-50 audits per year. The audit plan consists of mandatory annual audits, pre or post implementation audits, small business unit rotational audits, management requested audits, and risk based audits.

**Slide 101**

McKesson Pharma DC's fall under the mandatory annual audit criteria and can expect several distribution centers to be audited annually by Internal Audit. These audits typically leverage prior STARS audits and utilize STARS audit workbooks. Internal Audit may conduct re-performance for prior STARS audits or independently perform STARS testing to validate and replicate the results of a STARS audit.

In addition, Internal Audit evaluates new areas of risk that are identified or arise during the course of the year to incorporate into future audits. As an example, in FY11, Internal Audit assessed risks associated with privacy, customer licenses, and controlled substance monitoring.

**Slide 102**

Upon audit completion, Internal Audit issues a comprehensive audit report which includes an overall conclusion and audit rating derived from the results of the audit. Audit ratings are based on financial, operational, compliance, and information technology risk categories. These categories include defined criteria to assist in identifying audit report risk ratings. The risk ratings are classified in 3 distinct groups. Red is defined as unsatisfactory, Yellow is defined as Needs Improvement, and Green is defined as Satisfactory. Internal Audit reports are distributed to audit participants, executive management, and the audit committee.

**Slide 103**

Similar to the STARS audits, reported Internal Audit issues are flagged for follow-up to ensure remediation. Each audit issue is assigned a specific action owner who is responsible for issue remediation by the agreed upon action due date based on the action plan provided. Status updates should be provided to Internal Audit to inform them of the progress of remediation. Audit issues are tracked in a software package called "Team Central" that allows for the action plan owner to update information directly into the system. Action items are expected to be addressed in a timely manner as agreed upon in the action plan. Team Central has the ability to notify the action owner of required status updates when the action due date approaches. Issues that become significantly past due will be escalated to an executive committee owner and reported to the audit committee for resolution.

**Slide 104**

When it comes to audits…there is a saying posted on the STARS website that sums up the process…."It is easier to stay compliant than to get compliant"! Basically that means it is easier to incorporate SOP's into your daily routine and ensure

that your direct reports embrace the importance of SOP's than it is to recover from a poorly rated audit. There are a couple of important key concepts to consider regarding audits in general.

**Slide 105**

First, auditors will only audit against what is written in an SOP/law or regulation. Following SOP's as written will keep you and your distribution center in good "audit shape". Next, good organizational habits are key to a successful audit. Setting up reminders, files, signing, dating and retaining auditable materials will greatly assist you and the auditors in addressing audit items. Lastly, ensuring that all key DC partners are trained on the SOP's that affect their jobs as well as cross training in other job functions helps to ensure the continuity of knowledge. One of the leading audit issues found is the lack of compliance when a position or job function has been vacant due to vacation, illness, shift change or promotion. It is our goal to make sure that key compliance functions are covered and maintained.

**Slide 106**

You have completed lesson 3. Let's take a moment to answer some questions.

**Slide 113**

Congratulations! You have now completed the Pharma compliance course. Thank you for your investment of time today, and for taking overall compliance seriously. Please again note the various "help" resources available to you on this subject. They are all eager to assist with any questions or issues you may have