G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

LAB Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

February 2019

INSIDE THIS ISSUE

Compliance Perspectives: A 10-Step Compliance Strategy for OSHA Recordkeeping Rules

January is the season when employers must compile their OSHA logs for the previous year. The good news is that many labs are exempt from these requirements. Here's an overview of the OSHA Recordkeeping Standard and a 16-step strategy to ensure compliance in case your lab is covered.

Step 1: Figure Out If Your Lab Is Covered

Labs are among the industries listed by North American Industry

Continued on page 2

From DAIA to the VALID ACT: The Latest Chapter in FDA Diagnostic Test Oversight Reform

While FDA oversight over new diagnostic tests is perfectly acceptable, what is objectionable is the agency's continued reliance on a regulatory regime designed not for lab tests but medical devices. Accordingly, the industry had high hopes for proposed legislation that would remove diagnostic tests from the FDA's Section 510(k) process. But now the future of that bill has come into doubt. The good news, however, is that the apparent successor bill may provide the relief necessary to facilitate the approval of new diagnostic tests.

The DAIA Bill. . .

For the past two years, a bi-partisan bill called the Diagnostic Accuracy and Innovation Act (DAIA) has been working its way through Congress. DAIA, which enjoys bi-partisan support in both houses, would remove diagnostic tests from the definition of a medical device and thus outside the scope of the FDA's 510(k) process for medical devices which requires test makers to compare their assays to products approved back in the 1980s.

After hearing from both industry and the FDA, legislators drew up a draft of the DAIA bill and submitted it to the agency for technical assistance. But instead of the expect technical edits, the FDA proposed an entirely new framework to overhaul and modernize the

Continued on page 6

A 10-Step Compliance Strategy for OSHA Recordkeeping Rules, *from page 1*

Classification System (NAICS) as being partially exempt from the Standard (Section 1904.39), as shown below:

Partially Exempt Industries by NAICS Code	
NAICS Code	**Industry**
6211	Offices of Physicians
6212	Offices of Dentists
6213	Offices of Other Health Practitioners
6214	Outpatient Care Centers
6215	Medical and Diagnostic Laboratories
6113	Colleges, Universities and Professional Schools
8122	Death Care Services

Result: You don't have to keep OSHA injury and illness records (aka OSHA 300 Logs) for any establishment classified under the applicable NAICS code (subject to exceptions that we'll discuss below) unless one of the following agencies asks you in writing to do so:

- OSHA;
- The Bureau of Labor Statistics; or
- A state agency operating under the authority of OSHA or the BLS.

Even if you're not on the partially exempt list, you don't have to keep OSHA 300s if you have 10 or fewer employees or already keep equivalent records for the Department of Energy, Federal Railroad Administration or other federal government agency.

Step 2: Record All Recordable Injuries & Illnesses

Even if you're on the partially exempt list (or subject to one of the other exemptions), you must report to OSHA any employee:

- Fatality;
- In-patient hospitalization;
- Amputation; or loss of an eye.

Non-exempt labs must keep records of each fatality, injury and illness that:

- Is work-related;
- Qualifies as a new case; and
- Results in:
  - Death;
  - Days away from work;
  - Restricted work or transfer to another job;

LCA

Glenn S. Demby, Executive Editor
Elayne Demby, Contributing Editor
Paula Santonocito, Contributing Editor
Lori Solomon, Contributing Editor
Catherine Jones, Contributing Editor and Social Media Manager
Barbara Manning Grimm, Managing Editor
Jim Pearmain, Layout & Design
Myra Langsam, Business Development
Michael Sherman, Director of Marketing
Pete Stowe, Managing Partner
Mark T. Ziebarth, Publisher

Lab Compliance Advisor
(ISSN 2332-1474) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 888-729-2315
Fax: 855-649-1623
Web site: www.G2Intelligence.com.

- Medical treatment beyond first aid;
- Loss of consciousness; or
- A significant injury or illness diagnosed by a physician or other licensed health care professional; and

You must also keep records for specific types of injuries or cases required under other OSHA standards, including needlesticks and sharps injuries, medical removal, occupational hearing loss, work-related tuberculosis and musculoskeletal disorders (MSDs).

Step 3: Figure Out Which Employees You Must Keep Records Logs for

You must keep records for all "covered employees," i.e., all employees on your payroll, whether they're labor, executive, hourly, salary, part-time, seasonal or migrant workers. You must also record recordable injuries and illnesses to employees who aren't on your payroll if you supervise them on a day-to-day basis, including temps, leased employees and others supplied by an outside personnel service.

Step 4: Fill Out the Right OSHA Form

You must record recordable injuries and illnesses in the right forms, including:

The 3 Kinds of OSHA Injury/Illness Records

OSHA Form	Information	When to Complete
OSHA 300 Log	Information for each recordable injury or illness	Within seven calendar days of receiving information that recordable injury or illness occurred
OSHA 300-A Summary of Work-Related Injuries and Illnesses	Summary of OSHA 300 information for year	End of the year
OSHA 301 Injury and Illness Incident Report (or equivalent)	Information for each recordable injury or illness for OSHA	Within seven calendar days of receiving information that recordable injury or illness occurred

Step 5: Determine If Electronic Reporting Is Necessary

Labs that are subject to, i.e., not partially or otherwise exempt from OSHA reporting and recordkeeping requirements must also meet electronic reporting and disclosure rules if they:

- Had 250 or more employees at any time during the previous calendar year; or
- Had 20 to 249 employees at any time during the previous calendar year and is in one of the industries designated as high-risk listed in Appendix A of the Final Rule for electronic reporting, including:

Continued on page 9

Guest Column: New Broad All-Payor Kickback Law Impacting Laboratories, Commission-based Compensation and more

By Danielle Sloane and Chris Climo

In a recent piece of federal legislation intended to address the opioid crisis across the United States, Congress enacted a new all-payor kickback law that applies to all clinical laboratories and seemingly eliminates laboratories' ability to, among other things, pay commission-based compensation to employees or contractors.

On Oct. 24, 2018, the President signed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (the "SUPPORT Act") into law. A late addition to the SUPPORT Act, the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA") was originally intended to address the problem of "patient brokering" in the context of treatment centers and sober homes. In general, patient brokering refers to instances where a third party enrolls an addicted patient into a private health insurance plan and/or arranges for the addicted patient to enter a treatment facility or a sober home (often in another state) in exchange for a payment.

In a late addition to EKRA, clinical laboratories were added in order to capture patient brokering connected with toxicology testing. However, the breadth of statute's language appears to criminalize payments made in exchange for referrals to all CLIA-certified clinical laboratories even if the laboratory does not provide any services related to drug treatment, recovery or testing. We understand that the American Clinical Laboratory Association is looking at both legislative and regulatory resolutions to reduce the impact of EKRA on common and historically accepted clinical laboratory business practices, such as paying sales employees commission-based compensation. However, given that any sort of fix is uncertain and the prohibition became effective as of Oct. 24, 2018, laboratories should evaluate their compliance with this new law now.

EKRA's New All-Payor Anti-Kickback Statute

Effective as of Oct. 24, 2018, EKRA makes it a federal criminal offense (punishable by a fine of up to $200,000, imprisonment for up to 10 years, or both) to pay, receive, solicit or offer a cash or in-kind kickback, bribe or rebate (directly or indirectly, overtly or covertly) in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory. EKRA captures kickbacks paid not only to individuals who refer patients to a recovery home, clinical treatment facility or laboratory, but also directly to potential patients. SUPPORT Act § 8122, *codified at* 18 U.S.C. § 220(a).

This criminal prohibition is subject to seven statutory exceptions, including discounts passed along to the payors, wage payments that do not take into account the volume or value of referrals, payments under personal services and management agreements, and good-faith, non-routine waivers of copayments. See 18 U.S.C. § 220(b). More specifically, the EKRA employment exception does

[1] Clinical Laboratory Improvement Amendments of 1988.

not permit employees to be paid based on the number of individuals or tests referred by such employee, or the amounts billed to (or received from) payors related to individuals referred. Those same limitations apply to amounts paid to independent contractors.

EKRA permits the Attorney General, in consultation with the Secretary of Health & Human Services, to issue rules clarifying those exceptions and promulgating new exceptions. SUPPORT Act § 8122, *codified at* 18 U.S.C. §§ 220(b), (c).

EKRA's Ambiguities and Overbreadth

While some of the language of the prohibition is reminiscent of the federal Anti-Kickback law ("AKS") that already applies to services covered by federal and state healthcare programs, EKRA applies more broadly to all private and commercial insurers; and, its statutory exceptions are narrower than, and do not necessarily mirror, their AKS counterparts.

The language used to define the scope of this new private-payor liability seems to be significantly broader than what was intended at the outset. As written, the statute applies to laboratory referrals regardless of whether the laboratory services are related to addiction treatment or recovery services. EKRA cross references the CLIA definition of "laboratory" which broadly describes any "facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." Under that definition, EKRA extends to any clinical laboratory. The relevant legislative history does not reveal any specific Congressional intent to adopt such an extremely broad definition of laboratories for the purposes of this opioid-focused legislation.

> ... any "facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings."

Perhaps most pressing, however, is EKRA's immediate impact on common laboratory arrangements, particularly commission-based sales arrangements. The EKRA employment exception is more restrictive than the AKS employment safe harbor. Because AKS employment safe harbor has historically allowed a clinical laboratory (and other healthcare providers and suppliers) to pay bona fide employees in any manner it chooses based on the theory that the employer is vicariously liable for the acts of its employees, laboratories routinely pay commission-based compensation to employees. Laboratories often enter into similar arrangements with independent contractors, particularly with respect to private and commercial-payor business. Without clarification, EKRA seems to prohibit any sales commissions based on number of patients, tests, billings or collections, with significant potential criminal liability – a fine of up to $200,000, imprisonment for up to 10 years, or both, per occurrence.

Continued on page 8

From DAIA to the VALID ACT, *from page 1*

510(k) premarket review program to bolster medical device and diagnostic safety and advance new technologies. Under the proposed plan:

- Manufacturers would use more modern predicate devices of object performance criteria when they seek 510(k) clearance;
- The FDA would publicize devices and manufacturers that rely on predicates that that are over 10 years old;
- The FDA would finalize guidance establishing an alternative 510(k) pre-certification pathway allowing manufacturers of certain-well-understood device types to rely on objective safety and performance criteria to demonstrate substantial equivalence as a way to make it more efficient to adopt modern criteria as the basis for predicates that are used to support new products.

Additionally, FDA proposed to finalize its Expanded Abbreviated 510(k) draft guidance, which was issued in April 2018, in early 2019 and rename it the "Safety and Performance Based Pathway." Industry reaction to the FDA proposal was lukewarm at best. See, National Intelligence Report, September 2018.

. . . Morphs into the VALID Act

Now that Congress is back in session, the Representatives and Senators who originally sponsored DAIA have incorporated the FDA's ideas, including the pre-certification program concept, into a discussion draft of a new bill called the Verifying Accurate, Leading-edge IVCT Development (VALID) Act. Unlike DAIA, the VALID Act also makes FDA's authority to regulate IVCTs, and therefore LDTs, explicit. The aim is to establish a framework for overseeing IVCT's at the FDA.

The lab industry sees both good and bad in the new approach. While there's concern that the FDA proposal doesn't have a clear timeline, the industry is intrigued with the idea of a pre-certification process. Meanwhile, the sponsors of the VALID Act are hoping to make it a legislative priority, touting it as a sensible, risk-based approach towards regulation of IVCTs that protects innovation in an ever-changing sector of healthcare.

Cybersecurity: The 10 Things HHS Says You Should Be Doing to Stop Phishing, Ransomware and Other Threats

HHS published guidance on cybersecurity for healthcare organizations. Even though it's voluntary, the new HHS Guidance is significant to the extent it lays out the agency's expectations of the measures labs and other organizations should take to protect medical data from cybersecurity threats.

How the Guidance Came About

The genesis of the new guidance is a law called Cybersecurity Act of 2015 (CSA), Section 405(d) of which directs HHS to develop practical, healthcare industry-aligned cybersecurity guidelines to help providers reduce cybersecurity risks cost-effectively. To implement the Section 405(d) mandate, the CSA established a Task Group made up of over 150 healthcare and cyber-security industry experts and government agency representatives. Starting in May 2017, the Task Group

began working to develop a framework of voluntary, consensus-based principles and practices to provide healthcare entities with a better understanding of cyber-security risks and mitigation strategies.

What the Guidance Covers

Issued on Dec. 28, 2018, the new guidance is the fruit of the Task Group's labor offering practical cybersecurity strategies to healthcare organizations of all types and sizes. It's made up of several documents, the main one titled Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients (HICP), which identifies and explores five of the "most relevant and current threats to the industry":

- E-mail phishing attacks;
- Ransomware attacks;
- Loss or theft of equipment or data;
- Insider, accidental or intentional data loss; and
- Attacks against connected medical devices that may affect patient safety.

The Guidance's 10 Recommendations

The Guidance outlines 10 cybersecurity practice recommendations that healthcare organizations should implement to minimize the five threats, including:

1. E-mail protection systems;
2. Endpoint protection systems;
3. Access management measures;
4. Data protection and loss prevention measures;
5. Asset management systems;
6. Network management systems;
7. Vulnerability management systems;
8. Incident response policies and procedures;
9. Medical device security measures; and
10. Cybersecurity policies.

The Guidance lists 88 sub-practice recommendations for implementing the 10 required measures based on the attributes and size of the organization. Accordingly, the Guidance recommends that small healthcare organizations implement 19 or more sub-practices, medium organizations implement 36 or more, and large organizations implement all 88.

The New HHS Cybersecurity Guidance is set out in four documents, including:

- Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients listing five of the "most relevant and current threats to the industry"
- Technical Volume 1 discussing cybersecurity practices for small healthcare organizations
- Technical Volume 2 discussing cybersecurity practices for medium and large healthcare organizations
- Resources and Templates listing cybersecurity resources and templates

Guest Column: New Broad All-Payor Kickback Law Impacting Laboratories, Commission-based Compensation, From Page 5

What's A Laboratory to Do Now?

Many well-intentioned laboratories are no doubt likely to be left feeling frustrated with once again being impacted by a law stimulated by a few bad actors. That frustration is especially acute since EKRA was passed without considering the practicalities of the industry and the potential for laboratory tests to reduce unnecessary suffering and financial burden by finding the right treatment early and often. Our laboratory clients often say that one of the hardest aspects of being a laboratory is educating practitioners and payors regarding the potential value of their testing as compared to the historically used alternatives; and doing that, may have just gotten harder. With this new legislation, laboratories must reconsider how to effectively motivate their sales staff to tell the laboratory's story. Safeguards once viewed as sufficient, e.g., compliance training, strong policies regarding sales tactics, checks and approvals on sale's related spending, regular auditing and discipline, are no longer adequate in the context of commission-based sales arrangements.

Laboratories will want to watch the developments related to EKRA closely and consider implementing a new or at least interim compensation policy for its sales team while Washington hammers out the details related to the meaning and applicability of EKRA. Potential alternatives to volume-based commissions may include implementing sales bonus pools based on number of calls, lead generation, the number of new clients (e.g., a new physician office, regardless of the number of tests/patient samples it sends) and other effort-based criteria unrelated to volume of tests, patients, billings or collections originating from the sales employee or contractor.

***Danielle Sloane**, of Bass, Berry & Sims, helps national life science and healthcare clients navigate the complex maze of federal and state healthcare laws and regulations. With an analytical eye, Danielle helps her clients mitigate legal risk and achieve regulatory compliance consistent with their business goals. Danielle's practice involves compliance, regulatory and operational matters, mergers, acquisitions and joint ventures and government investigations. Danielle advises clients on how they can best innovate, evolve and improve patient care within the confines of current healthcare regulatory laws. Danielle was recognized by Law360 as a Rising Star in healthcare in 2017.*

***Chris Climo** represents healthcare clients involved in litigation at both trial and appellate levels with particular focus on government investigations. Prior to joining Bass, Berry & Sims, Chris served as a law clerk to Judge Gilbert S. Merritt, Jr. of the U.S. Court of Appeals for the Sixth Circuit. Chris earned his law degree from Vanderbilt Law School and a B.A. in economics of global health from Vanderbilt University. From 2011-2013, Chris served as an operational consultant to healthcare clients across the country, ranging from large academic medical centers to small community hospitals.*

A 10-Step Compliance Strategy for OSHA Recordkeeping Rules, From Page 3

High Risk Industries by NAICS Code	
NAICS Code	**Industry**
6219	Other Ambulatory Health Care Services
6221	General Medical & Surgical Hospitals
6222	Psychiatric & Substance Abuse Hospitals
6223	Specialty (except Psychiatric & Substance Abuse) Hospitals
6231	Nursing Care Facilities
6232	Residential Mental Retardation, Mental Health & Substance Abuse Facilities
6233	Community Care Facilities for the Elderly
6239	Other Residential Care Facilities
6242	Community Food & Housing, and Emergency & Other Relief Services
6243	Vocational Rehabilitation Services

Step 6: Determine Which Information to Report Electronically

Which information from the OSHA forms you must report electronically depends on why your lab is covered:

- If you're covered because your lab has 250+ employees, you must report information from all 3 forms; or
- If you're covered because your lab has 20 to 249 employees and is high-risk, you must report information only from your OSHA 300A.

The basic rule: You must report all information listed in the particular form each year by March 2, except information that reveals or could be used to reveal the identity of the injured or ill employee:

Which OSHA Form Information to Report Electronically	
OSHA Form	**Required Information**
OSHA 300	Everything except employee name (column B)
OSHA 300A	Everything
OSHA 301	Everything except: Employee name (field 1); employee address (field 2); name of physician or other health care professional (field 6); facility name and address if treatment given away from worksite (field 7)

Step 7: Prepare, Certify & Post Annual OSHA 300-A Summary

At the end of each calendar year, you must review the OSHA 300 Log as extensively as necessary to verify that the entries are complete and accurate, correct any deficiencies you find, create an annual summary of injuries and illnesses recorded on the OSHA 300, certify the summary and post the

[2] 43 U.S.C. § 263a

annual summary. You must still complete, certify and post the OSHA 300-A even if you had no recordable cases for the year.

Step 8: Retain Injury/Illness Records

You must save the OSHA illness and injury records for at least five years following the end of the calendar year the record covers.

Step 9: Revise & Update Injury/Illness Records

Over the five-year retention period, you must continually update your stored OSHA 300 Logs as information becomes available by listing any newly discovered recordable injuries or illnesses that weren't previously recorded. Modify the previous entry of any case that later information shows isn't properly recorded, e.g., a case listed as requiring medical treatment turns out to be worse and requires the employee to take days off. And make sure you take the above actions within 7 calendars of receiving the new information.

Step 10: Ensure Transfer of Records to New Owner of Business

If your lab changes ownership, you must recognize that you're responsible for recording and reporting work-related injuries and illnesses for that period of the year during which you owned the establishment. You must also transfer the Part 1904 records to the new owner.

▶ Download a Reporting Policy here: www.g2intelligence.com/tool-model-employee-illness-injury-reporting-policy/

Billing & Coding: Pathology Group Asks CMS to Raise Medicare Prices for BRCA1/2 Sequencing Tests

The Association for Molecular Pathology (AMP) thinks the final 2019 Clinical Laboratory Fee Schedule payment amounts shortchanges labs that provide BRCA genetic testing and is calling on CMS to increase the payments.

The 2 CPT Codes at Issue

The tests in issue are CPT code 81163 for full sequencing of BRCA1 and BRCA2 genes and CPT code 81165 for sequencing of just BRCA1, for which the CLFS lists the payment amounts as, respectively, $468 and $283.

CPT 81163: AMP contends that the methodology CMS used to arrive at the payment amount for CPT 81163, i.e., crosswalking to code 81406 for BRCA1 sequencing and to code 81216 for BRCA2 sequencing, fails to account for all the work and costs labs incur in performing full sequencing of the two genes. Instead, AMP is asking the agency to crosswalk CPT 81163 to CPT 81408 for

sequencing of large genes, which is paid at $2,000.

CPT 81165: In setting the payment amount for CPT 81165 full sequencing of BRCA1 at $283, CMS crosswalked to CPT 81406 covering sequencing analysis of 11 to 25 exons for genes such as RAF1 and ACADVL. But AMP argues that 81406 doesn't account for all the work required to fully sequence BRCA1, a large and variable gene with 24 exons and over 7,000 base pairs, as compared to RAF1's 3,300 and ACADVL's 2,200 base pairs. So, AMP wants CMS to crosswalk to CPT 81408 and price it 50% less at $1,000 to more accurately cover the resources required.

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

Tennessee Pain Doctor Faces Jail for Opioid Abuses, Medicare Fraud

Case: The doctor is facing 45 charges, including 22 counts of illegal distribution of a controlled substance for routinely prescribing oxycodone and other Schedule II drugs without examining and diagnosing patients, including one Chronic Pain Syndrome patient who died as a result of ingesting "The Holy Trinity" of oxymorphone, Soma and alprazolam. According to the indictment, the doctor required Medicare beneficiaries to visit his office four to six times per month for the same services cash-paying patients only had to come in twice a month to receive. He also allegedly wrote 164 individual prescriptions for over 12,000 Schedule II controlled substance pills the very day the State of Tennessee permanently revoked his Pain Management Certificate.

Significance: As is commonly the pattern in these opioid distribution scams, the doctor allegedly exacerbated his wrongdoings by engaging in Medicare fraud (13 counts) and money laundering (9 counts), including:

- Upcoding claims to indicate a higher level of service than actually provided;
- Billing for services that weren't medically necessary;
- Causing submission of claims for unlawful prescriptions to Medicare; and
- Diverting proceeds of the fraud.

Wisconsin Health System Settles Stark Claims for $12 Million

Case: In a case that began as a whistleblower suit, a company affiliated with Advocate Aurora Health, Inc. has agreed to pay $12 million to settle claims of violating the Stark Law. The US and State of Wisconsin cited the company for improper relationships with a pair of physicians between 2008 and 2012, including providing compensation:

- At above fair market levels;
- That took into account the volume of anticipated referrals; and
- That covered unidentifiable services.

Significance: The case is a good illustration of how whistleblower lawsuits become a lingering pain in the side that may be hard to settle. Although the relator who brought the original suit will get a share of the $12 million recovery, the government intervention covered only some of the original claims. As a result, the settlement doesn't end the litigation and the whistleblower

suit will continue as a separate case covering the residual claims. The good news for Aurora is that:

- The government won't be involved in the subsequent case; and
- The settlement will have no bearing on its liability in that case.

HIPAA ePHI Violation Costs Colorado Hospital $111,400

Case: This case began when the Office of Civil Rights (OCR) received a complaint contending that an ex-employee of Pagosa Springs Medical Center (PSMC) still had remote access to the critical access hospital's web-based scheduling calendar containing electronic PHI of 557 patients. OCR investigators confirmed the allegation and found that the ex-employee had accessed the calendar on at least two occasions since leaving PSMC. To make matters worse, PSMC got the calendar from Google without having it sign a business associate agreement (BAA) (at the time, Google Calendar wasn't a HIPAA compliant service the way it is today). In addition to the $111,400 fine, the settlement requires PSMC to sign an onerous two-year Corrective Action Plan with OCR agreeing to overhaul its information security management, BAA and employee training systems.

Significance: The moral of this case is to ensure that your lab:

- Immediately terminates employees' access to ePHI when they leave your company or remain but no longer require access to do their jobs; and
- Enters into a BAA with vendors before disclosing your ePHI to them.

TOOL

Model Employee Illness/Injury Reporting Policy

The OSHA Recordkeeping Standard requires you to record and potentially report work-related illnesses and injuries. Reporting of illnesses and injuries is also crucial to investigating, identifying and correcting problems that can lead to further incidents and OSHA violations. So, it's crucial to establish a policy and procedure for workers to report workplace injuries and illnesses. You can adapt this Model Policy to ensure prompt and proper reporting of workplace injuries and illnesses.

EMPLOYEE INCIDENT & INJURY REPORTING POLICY

1.0 Purpose

It is the policy of XYZ Laboratories (XYZ Labs) that all incidents that result in either personal injury or illness, and or damage to XYZ Labs property be properly reported and investigated. This operating procedure establishes a systematic process to ensure that incidents are properly reported in a timely manner, that all causes (direct and contributory) are thoroughly identified and that the appropriate corrective actions are taken.

2.0 Scope

This operating procedure applies to the reporting and investigation of all incidents that result in:

- A work-related injury and/or illness to any XYZ Labs employee;
- Personal injury and/or illness to non-XYZ Labs personnel while on or using XYZ Labs-owned property;
- Damage to XYZ Labs-owned property; or
- A near miss event that didn't but had the potential to cause harm or damage.

3.0 Responsibility

3.1 Department heads, managers and/or supervisors – are responsible for:

a. Ensuring that all accidents/incidents are properly reported and investigated in accordance with this operating procedure.
b. Ensuring that all corrective actions are promptly and completely carried out.

3.2 Employees – Are responsible for reporting any injury/illness work-related accident or non-injury incidents to their manager/supervisor as soon as possible. All accidents/incidents must be reported by no later than the end of the employee's regular work shift.

3.3 The Office of Environmental Health & Safety (EHS) – Must participate in accident investigations either directly or by review of the report as deemed appropriate to the incident. The Director of EHS shall determine the level of participation that is warranted. EHS is also responsible for administering the Workers' Compensation benefits program for work-related injuries or illnesses.

4.0 Definitions

4.1 Major Accident –Any injury or illness-related accident that results in:

a. Death;
b. Amputations involving the loss of bone tissue;
c. Loss of consciousness;
d. Possible permanent functional impairment of a body part (excluding those resulting from a back strain);
e. Admission to a hospital (other than 24-hour observation, hernia repair, back strain or outpatient visit).

4.2 OSHA Recordable Incident - Any accident/incident that results in:

a. Medical treatment other than first-aid, (examples: treatment of an infection, sutures, second or third degree burns, etc.);
b. Restriction of normal work activities (reduced work activities, or reduced work days);
c. In days away from work (lost-time); or
d. Any occupational illness.

4.3 First-Aid Only – Any accident/incident which results in a minor injury that can normally be treated or cared for by the employee and/or his supervisor, and does not result in any of the conditions identified in Section 4.2. Note First-aid can be administered by a medical professional and not result in an OSHA-recordable incident.

4.4 Near Miss Incident – An incident which does not result in personal injury or illness, or property damage, but had the potential to do so.

5.0 Notification Procedures

5.1 Notification During Regular Working Hours – Any XYZ Labs employee involved in an accident/incident (as defined in Section 4.0) during regular working hours shall:

a. Report the occurrence to their department manager or supervisor as immediately as possible, but by no later than the end of the regular work shift. Failure to properly report an incident can result in disciplinary action and/or denial of benefits.
b. If the incident only involves first-aid treatment administered by either the employee or his/her manager/supervisor, or is a non-injury incident, the incident shall be documented on the DEPARTMENT INCIDENT LOG.
c. If the work-related accident results in injury or illness requiring professional medical treatment,

Model Employee Illness/Injury Reporting Policy (continued)

TOOL

the employee shall be referred to the designated medical provider. If the injury or illness requires emergency medical treatment, contact 911.

d. The employee's manager/supervisor shall report the event to the XYZ Labs EHS Office by no later than the end of the work shift of the day on which the event occurred. At a minimum, the manager/supervisor must provide the employee's name, date and time of accident, nature of injury/illness, and how the accident/incident occurred.
e. The employee's manager/supervisor is responsible for conducting the initial accident investigation and completing the FIRST REPORT OF ACCIDENT/INCIDENT form.

5.2 Notification After Regular Working Hours – Any XYZ Labs employee involved in an accident, that results in a work-related injury or illness, after regular working hours shall:

a. Report the occurrence to the Police (Ext. 911) as soon as possible, but by no later than the end of the regular work shift. Failure to properly report an incident can result in disciplinary action and/or denial of benefits.
b. The responding Police Officer shall:

- investigate the incident as thoroughly as possible;
- if the incident/accident involves an XYZ Labs employee, the responding police officer shall document the event including the employee's name, department, the name of the employee's immediate manager/supervisor.
- forward a copy of the incident report to EH&S by no later than the end of the officer's work shift.

c. If the accident requires emergency medical assistance, the Police Dispatcher shall notify the appropriate emergency medical services.

5.3 Deaths and/or Hospitalization Injuries – Any incident which results in deaths, or injuries shall requiring hospitalization to any employee shall be immediately reported to EH&S.EH&S shall be responsible for notifying the Occupational Safety and Health Administration (OSHA) – Region [ ], within 8 hours in accordance with federal regulations.

5.4 Amputations– Any incident which results in amputations shall be immediately reported to EH&S.EH&S shall be responsible for notifying OSHA – Region [ ], within 24 hours in accordance with federal regulations.

5.4 Near Miss Incidents – Any incident which does not result in injury or illness, but had the potential to do so, shall:

a. be reported to the department manager or supervisor;
b. the manager/supervisor shall document the event on the DEPARTMENT INCIDENT LOG;
c. the manager/supervisor shall evaluate the incident and take the appropriate action to reduce or prevent recurrence. The manager/supervisor should consult with EH&S if assistance is required in evaluating and responding to the event.

6.0 Investigation Guidelines

6.1 Accident Scene – When possible, the accident scene should be preserved and disturbance of any physical evidence should be prevented until the principal investigator(s) arrive. Unless necessary to prevent further damage or injury, clean up or repair activities should commence only after all pertinent information has been collected.

6.2 Witnesses – The principal investigator(s) shall identify and record the names of all individuals who witnessed the incident. Each witness shall be requested to provide a written statement identifying their account of the accident/incident. The witnesses shall be instructed to forward their written statements to EH&S.

6.3 Photographs – When feasible, the principal investigator(s) should obtain photographs and or measured diagrams of the accident scene. All photographs and or diagrams shall be forwarded to EH&S for inclusion as part of the permanent record.

6.4 Questioning Injured Employees and/or Witnesses – When questioning injured employees or witnesses, the investigator(s) shall stress that the purpose of the investigation is to identify facts and not to assign fault. At all times the investigator(s) shall ensure that proper medical treatment and care of any injuries is given priority over questioning of the personnel involved.

6.5 Investigation Findings – The investigation team shall identify and record the root and contributory causes of the incident. Upon completion of the investigation, the investigation team will identify the appropriate corrective actions, indicate the personnel responsible for implementing the actions and assign a target completion date.

7.0 Accident/Incident Report Forms

7.1 First Report of Accident/Incident – Department heads, managers and/or supervisors directly responsible for the employee(s) involved in an accident/incident shall:

TOOL

Model Employee Illness/Injury Reporting Policy (continued)

a. Complete all sections of the FIRST REPORT OF ACCIDENT/INCIDENT provided by EH&S;
b. The responsible department head or manager should involve the injured employee and all identified witnesses in the accident investigation and corrective action processes.
c. The original report forms shall be completed and forwarded to EH&S within 48 hours after the accident/incident has occurred. If additional time is required to complete the investigation, the manager/supervisor shall notify EH&S.

7.2 Police Report of Accident/Incident – Any accident/incident that requires the response of the Police Department and/or any incident that occurs after regular working hours, the responding officer shall:
a. Document the accident/incident using the Police Department Incident Report System. If the incident involves and employee, the report shall include the employee's department and the name of the employee's immediate manager/supervisor.
b. Identify any and all witnesses to the incident, providing and address and telephone number where the witness(es) can be contacted by an EH&S representative.
c. Forward a copy of the Police Department incident report form to the Office of Risk Management Department by no later than the end of the officer's shift.

7.3 EH&S – Upon receipt of the Police incident report, EH&S shall:
a. Contact the employee's manager/supervisor to verify the incident and collect the preliminary information required to establish a workers' compensation claim with the designated carrier (if required). The manager/supervisor will be instructed to complete the FIRST REPORT OF ACCIDENT/INCIDENT form and forward that document along with any additional report forms or documents pertinent to the accident to EH&S. If necessary, copies of all report forms will be forwarded to the manager/supervisor.
b. Upon receipt of the completed report forms, EH&S shall contact the XYZ Labs' designated workers' compensation insurance carrier to document a valid claim. EH&S shall also classify the incident and injury types and record all pertinent medical and treatment information; and
c. EH&S representatives shall review the investigation findings and proposed corrective actions with the affected department's manager/supervisor.

7.4 EH&S Supplemental Reports – for all major accidents/incidents (as defined) or when requested by the EH&S Director, a supplemental investigation and analysis report may be required. The report will include professional analysis of the investigation findings and recommendations of corrective actions and any photographs, documents and legal correspondence relevant to the incident.