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True or False? My company's EH&S program is compliant.

EDITORIAL

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I have observed a trend that is becoming increasingly common, and visible, especially among executives in larger companies. This trend is the overlooking of basic compliance to current regulations, if there is a grandiose corporate program that touts lofty Environmental, Health & Safety (EH&S) goals. I have also observed the many company executives who have the impression that if their operations are certified, or qualified, under various programs, then they are compliant with current applicable regulations. The false impression that a certification or recognition program will limit regulatory inspections, citations, or other actions is becoming common place. In my

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experience, a certified / recognized company will not enjoy any type of preferential treatment from an agency if a regulatory violation is discovered.

Lofty compliance statements are not a substitute for the requirements of any regulatory agency. Only a compliant company can achieve higher expectations. Compliance is the foundation on which greater EH&S programs are built. If there is no solid foundation, there is no possible way to build a higher level EH&S program.

How can executive management ensure they have a compliant EH&S program? -- BY GETTING SMART ON THEIR CURRENT EH&S PROGRAM LEVEL:

- Ask questions about your compliance status through internal and independent audits;
- Look at your corporate EH&S standards, procedures, policies, and make sure they are reviewed every year for completeness and adherence to current regulatory requirements;
- Make your EH&S program report on activities, challenges, and program status in detail on a regular basis to ensure that there is a satisfactory level of activity;
- Ensure you have a balance of internal and external resources, appropriately compensated, who are dedicated to EH&S based on your company's needs;
- Do not get blinded by the words in lofty EH&S program statements, certifications, recognition programs, and
- Support your EH&S program by including compliance considerations in every business decision.

How Can Your Company Save Money and Be More Effective? By Using Outsourced Professional EH&S Resources.

The answer captured by some, hidden from others.

TLG serves many of its clients as an outsourced professional EH&S resource. With the current marketplace demands, more and more companies are readjusting their respective in-house resources. Α number of companies have chosen to use outsourced resources. Companies quite frequently request TLG to augment both their corporate and site specific EH&S programs. This allows a company to have an effective method in addressing regulatory challenges in a professional compliant manner while controlling expensive overhead cost. The process is most successful when TLG serves an internal manager who is aware and sensitive to regulatory requirements for the company's operations.

Examples of programs that can be augmented by using outsourced professional EH&S resources:

FACILITY / OPERATIONAL AUDITS - Audits conducted to determine compliance status and regulatory program enhancement opportunities. *TLG is experienced in all aspects of auditing.*

REGULATORY PROGRAM UPKEEP AND <u>IMPLEMENTATION</u> - Specific regulatory programs that require time driven reviews, inspections, documentation updating, and employee training. *TLG provides these services including document updates and training programs via the Intranet.*

<u>REQUIRED AGENCY SUBMISSIONS</u> - Companies are required to make submissions to various regulatory agencies. Types of submissions include, but are not limited to:

Amounts and types of wastes disposed of from a facility, employee injuries, air emissions, water emissions, emissions related to rainwater, environmental impact statements, recycling efforts, and waste minimization.

TLG is experienced in all aspects of submissions.

GOVERNMENTAL AGENCY INTERFACE -

Occasionally there is a need for specific professional services when dealing with a regulatory agency. Issues are extremely varied and include negotiation regarding agency findings or requests, securing approval for building or expanding a manufacturing site, and third party inquiries. TLG has professional working relationships with agencies around the world.

INDUSTRIAL HYGIENE STUDIES - There are requirements under various regulatory agencies that require employers to undertake industrial hygiene studies. The catalysts for these requirements are based on certain processes or chemicals. *TLG conducts specialized studies to document the level of employee exposures.*

<u>ACQUISITION / DIVESTITURE</u> - An integral part of a company's process is the assessment of actual or potential liabilities related to any increasing or decreasing of their operations. *TLG can be utilized for third party acquisition / divestiture reviews*

PROCESS DESIGN REVIEWS AND OVERLAYS -Today's marketplace is placing demands on companies to constantly review their processes. These reviews include assessments to potential challenges of regulatory issues. *TLG has experience in conducting these evaluations and contributing towards improved process efficiency and compliance.*

VENDOR / **SUPPLY CHAIN AUDITS** - As companies find ways to reduce their work in process inventories, they incorporate rigid "just in time" inventory controls that result in new liabilities. These liabilities include a vulnerability to business interruptions due to unforeseen supply chain. *TLG conducts vendor/supply chain audits and reviews.*

Other programs include DESIGN FOR THE ENVIRONMENT, REGULATORY IMPACT REVIEWS, PRODUCT LIFE CYCLE ANALYSIS, and MANAGEMENT UPDATES / TRAINING.

EtO - Sterilization and Aeration

A surprise challenge can emerge.

Ethylene oxide, (EtO), CAS Registry No. 75-21-8, is



used in the manufacture of ethylene glycol and higher alcohols, and used in many applications in automotive antifreeze, explosives, cellophane, polyester

resins, synthetic fibers and rubbers, and hydraulic

fluids. Some variations are used in plasticizers, humectants, lubricants, and solvents. In pharmaceuticals, it sometimes appears as an intermediate in the synthesis of choline, thiamine, and procaine. In mixtures with carbon dioxide and halogenated propellants, it is used as a fumigant, fungicide, and sterilizing agent. The subject of this article relates to the use of EtO as a sterilant.

In the use of EtO as a sterilant, it has been discovered that improper storing and handling can result in major health challenges to exposed employees, as well as violations of air emission standards in a number of regulatory jurisdictions. If the products are not allowed to aerate over a proper amount of time, the EtO off gassing will continue to be a hazard. The issue may be increasing industry wide, as there is more emphasis on inventory turns of raw materials and work in process.

The off gassing is obviously more of a challenge when the product is isolated and enclosed over time. *TLG clients are reminded that both employee exposure levels and air emissions should be considered.* Employee exposures may be experienced when there is an opening and unloading of materials out of enclosed areas (such as rooms, boxes, drums, and shipping containers). Air emission violations are potentially occurring when there are emissions from a point source or fugitive type created by the opening of these types of enclosures.

TLG Opinion / Comment

The following are factors that should be considered by clients who wish to review their operations:

- If the materials are sterilized by an outside company, or away from a client's main storage facility, all material investigations should be done there. This may minimize immediate notification issues.
- The sterilization cycle may be changed to increase vacuum cycles, temperature, and pressure differentials to increase off gassing. (Note: The off gassing process may continue even with changes.)
- Initial monitoring should be done in the areas where there is potential exposure, and then follow with employee exposure monitoring. This will allow clients to isolate where specific challenges may exist, in order to develop a personal monitoring protocol that would be appropriate.
- Air emissions may be determined by conducting air emission modeling rather than actual air sampling.

How the material is packaged when it is introduced into the sterilization chambers may have an effect on the off gassing rate. This includes packaging, strapping, pallet types, and the density of the load to be sterilized.

New Lead Standard Requires Review

A new expansion of the The United States Environmental Protection Agency's (EPA) Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) will require companies who use lead materials, including solders, to make additional entries in their respective submissions in the Toxic Release Inventory (TRI) reporting. Companies who have more than ten employees will be affected. If lead usage exceeds 100 lbs. on an aggregate basis, companies are required to report relative to any Toxic Release Inventory(s). The basis for the weight limits includes consideration as to lead being a

component of a material. The rule is effective immediately (the final rule was published on January 8. 2001); will apply to the year of 2001, and will apply all lead to



releases and waste management during 2001. As in other similar materials, there are the normal tracking and usage reporting requirements. *Additionally, TLG clients are reminded of reporting obligations such as those to local emergency planning agencies.* It is expected that applicable industry groups and associations will challenge the issue.

Contact TLG for detailed information or any questions.

OSHA Recordkeeping Requirements

The U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) issued a revised rule that will change the current reporting by employers as to employee illnesses and injuries. It also classifies industry types as to those who will not be required to maintain the reporting data. There will continue to be a reporting requirement in the case of deaths or hospitalization of three or more employees. Companies who have been reporting in an aggregate submission, such as "melding" manufacturing operations with large administrative workforces, may have to review the impact for their upcoming submissions. The rule becomes effective on January 1, 2002. The new recordkeeping requirements will include standards such as needlestick injuries. Currently, the issue as to specifics for ergonomic injuries remains in question due to the current activity within the US Congress. TLG is of the opinion that employers who have ergonomic injuries/illnesses will have to make those types of submissions even if they are considered exempt from reporting.

The new recordkeeping rule includes specific definitions on restricted or light work. There are more involvement, awareness, and privacy requirements for employees. Detailed information is available by contacting TLG, or view details on the OSHA web site at:

http://www.osha-slc.gov/recordkeeping/index.html

OSHA Standards Interpretation and Compliance

OSHA Interpretation letter responding to a company letter on questions regarding the training obligations of temporary employment agencies and host employers.

A recent OSHA Standard Interpretation and Compliance letter has some interesting language that should be reviewed. The OSHA interpretation letter

states, "Although the host employers would, in most situations, provide the workplace-specific training that is necessary and appropriate for the employee's' job assignments and tasks, the temporary agency employer would still have the responsibility to ensure that the employees had been properly trained. Therefore, if a host employer provides any training, the temporary agency employer would have to have a reasonable basis for assessing that the host employer's training is adequate."

TLG Opinion / Comment

This interpretation underscores the importance of TLG clients' responsibility, as well as the temporary employee agency that is used as a resource. There should be specific written procedures / policies / standards referenced in every written agreement between all parties. Additionally, there should be periodic reviews of the entire business relationship to ensure that both parties are, in fact, doing what is

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required by the regulations to minimize any liability related to temporary employee training.

Other OSHA

SHORT TAKES

- Bloodborne Pathogens Standard is revised. Addresses a clarification as to employee involvement in the selection and use of safer devices to prevent needlesticks.
- Application of a cold (or hot) compress on a second or subsequent medical visit is considered a recordable injury.
- Noise exposure measurement records must be retained for 2 years, not the 30 year retention time for employee exposure records found in the Access to Employee Exposure and Medical Records, paragraph (d)(1)(ii) of 1910.1020 as in the case of employee health records.
- Ergonomics rule is doomed but not dead. TLG is of the opinion that companies should continue to actively address ergonomic challenges. Under the terms of the Congressional Review Act, OSHA is

prohibited from issuing similar another rule: however, it allows OSHA to approach Ergonomics using a different approach. OSHA has, in the past, successfully cited employers had that ergonomic problems by using "The General Duty Clause" and other differing legal mechanisms.

TLG Global Regulatory HIGHLIGHTS

BRAZIL TAX INCENTIVES

The tax incentives, which were unique to the Brazilian State of Amazonia, are now potentially available in other Brazilian states. It is expected that the impact will be felt in Manaus, Amazonia over the long term. One of the major components of most tax incentive zones is the environmental impact studies and the related regulatory permits. There are also mandates as to employee safety studies. TLG clients, who are considering expansions within the Latin American region, including Mexico and Puerto Rico, are encouraged to consult with TLG before pursing any business ventures or expansions

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FRANCE - RENEWABLE POWER MOVEMENT

New and more expansive regulatory oversight relative to energy use and consumption can be expected in France, and most other European countries. In most European countries, energy studies and impact studies are required by the regulatory agencies charged with approval of any new facility or expansions. Belgium is pursuing a federal requirement for studies of present facilities and mandated energy conservation measures. *TLG clients are encouraged to begin to review and document energy usage and methods considered for the attaining of greater efficiencies. Additionally, there are growing requirements for the measuring of energy consumption by clients' products.*

<u>CALIFORNIA PROPOSITION 65 -</u> INTERNATIONAL INFLUENCES

Companies within the state of California should review their activities to ensure they are not liable regarding warning label issues as are mandated in the regulation known as California Proposition 65. Activities include the actual manufacturing of product within the state and/or the sale or distribution of products. Those companies who have administrative offices only in the state should also ensure they are appropriately addressing warning issues within their respective offices. *For further details, please feel free to contact TLG.*

<u>"ENVIRONMENTALLY FRIENDLY"</u> PACKAGING - GLOBAL INITIATIVES

A number of companies are being affected by unforeseen challenges related to packaging requirements within various regions and continents. There are evolving global packaging restrictions as to material (density) volumes, inks, adhesives, plastics, metals, fibers, and labeling. Major markets experiencing continuous changes are those under the oversight of the European Union (EU). In Latin America, the countries of Brazil, Argentina, Chile, and



Peru are in the process of formalizing requirements and establishing a regulatory structure for review and enforcement. Packaging requirements and restrictions should be a consideration in all Design for the Environment and Life Cycle Analysis programs. For *further details, please feel free to contact TLG.*

<u>US / MEXICO BORDER PRODUCING</u> INCREASE IN AIR EMISSIONS

Recently, based on recent studies, it was announced that there are a number of pollutants showing dramatic increase along the US/Mexico boarders. Primary focus was centered on the specific traffic corridors. *TLG* clients who presently have border operations, or are reviewing expansion possibilities, should pay strong attention to this recent announcement. Proactive activity should include reviews of air emissions related, including transportation, to facilities. *TLG* has detailed information as to the study, and can recommend specific actions to avoid future operational concerns.

EU APPROACHING CLIMATE PACT APPROVAL BY JULY, 2002

Recently, Sweden's Environmental Minister stated that The European Union (EU) could ratify a 1997 United Nations agreement to combat global warming ahead of an earth summit of world leaders next year. Once ratified, the agreement would set legally binding targets on the world's richer nations to cut the pollution, which for the most part comes from burning fossil fuels. *For further details, please feel free to contact TLG.*

BREAKING OF EU ENVIRONMENTAL LAW CAN RESULT IN CRIMINAL SANCTION

The European Commission recently called for seven new environmental policies to be enforced with criminal penalties, in addition to governmental citations and civil liabilities. The Commission has asked 15 European Union Member states to agree that individuals or firms breaching any of over 50 existing EU laws by "intention or serious negligence" be subject to investigation by criminal authorities. *For further details, please feel free to contact TLG.*

SEMICONDUCTOR INDUSTRY TO SIGN FOR VOLUNTARY REDUCTIONS IN PERFLUOROCOMPOUNDS

The agreement will require perfluorocompound emissions to be reduced by 10% from 1995 levels. Twenty-one (21) semiconductor manufacturers will agree to the PFC Reduction Climate Partnership. The targets for global reduction are perfluorocompound gases, including perfluorocarbons, hydrofluorocarbons, and sulfur hexafluoride. *For further details, please feel free to contact TLG.*

Important information on the following subjects:

- British government fails to deliver environmental protection
- European Union sets guidelines for environmental checks
- Brazil Top can recycler
- Environmental performance of Ireland
- Nickel-Cadmium battery recycling information by country / region
- Canada Environmental fines rise sharply
- Europe defines new policy for Ecofriendly manufactured products

Contact TLG for further information 1.817.244.9107



Regulatory Affairs Team specializes in assisting clients as they address issues that are regulatory driven. These areas are primarily employee safety, health, and environmental. Services encompass all areas related to program development, policy implementation, and regulatory compliance.

Engineering and Technology provides engineering services to TLG clients as they require in-systems design, process improvements, and proactive services related to manufacturing expansion.

Industrial Hygiene and Health specializes in assisting clients in all aspects of industrial hygiene and employee health.

Regulatory Research and Systems provides global regulatory research for clients on specific regulations and laws. This team also administrates and assists clients in the design and implementation of THE LION GROUP **FOOTPRINT System**--a unique global base system that enhances EH&S compliance which saves time, effort, and money in the disciplines of an EH&S function.



Creative Design / Administrative Services

provides specialized services in presentation materials, regulatory submissions, and administration of regulatory compliance systems.



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