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Global Application of the Process Safety Management Standard

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In the early morning hours of Dec. 3, 1984, more than 40 tons of methyl isocyanate (MIC) leaked from the Union Carbide India plant in Bhopal, India. More than 3,000 people immediately perished from the accidental release of highly toxic MIC gas and another 15,000 deaths, along with many health-related claims, were attributed to this event.

On July 6, 1988, the Piper Alpha oil production platform, operating in the North Sea, suffered a series of explosions that led to an uncontrollable fire that engulfed the platform and claimed the lives of 167 crew members. A leak of natural gas condensate, which had built up beneath the platform, was deemed to be the cause of the first explosion that eventually led to the demise and sinking of the platform. Like the Bhopal catastrophe, the sudden and unexpected release of a highly hazardous substance initiated a series of events that led to a significant loss of life and assets.

These are only two examples of the disasters that have plagued the evolution of industrial processing and manufacturing. While technology and control systems have advanced significantly, the opportunity for these incidents to be

repeated continue to exist. To prevent these critical loss occurrences, a systematic approach toward hazard identification and risk analysis is also needed.

In 1992, OSHA formally recognized this vital component for managing high-hazard chemical processes within the U.S. A company involved in high-hazard chemical processes or activities must implement a process safety management system. This system must include the systematic identification of hazards, risk level and control strategies or corrective actions needed to prevent and/or minimize the consequences of a hazardous substance release. These requirements are defined by the Process Safety Management (PSM) of Highly Hazardous Chemicals, Explosives and Blasting Agents Standard (OSHA 29 CFR 1910.119).

Process Safety Management

Process hazard management (PHA) is also called safety systems management or process safety management. Regardless of the terminology, these systems have

continued on page 7

Country Profile: Italy

Editor's Note: This is the ninth in a series of articles summarizing various countries' government and SH&E legislative processes. It is intended to serve as a useful planning tool for SH&E professionals preparing to conduct business in the profiled country. All previous profiles are available on the ASSE International Practice Specialty website (www.asse.org/practicespecialties/international/). The material contained has been provided courtesy of ENSR International. Direct requests for additional country information to Halley Moriyama at hmoriyama@ensr.aecom.com; +1-978-589-3233; or Jack Fearing at jack_fearing@ars.aon.com; +1-973-463-6240.

Italy encompasses about 116,300 square miles, which makes it about the size of the state of Arizona. Italy continued on page 4

This Issue

Global Application of the Process Safety Management Standard	1
Country Profile: Italy	1
Administrator's Message	2
Enterprise-Wide Fleet Risk Profiling	3
Singapore Safety Conference	15
SH&E Conference in Spain	15

Country Profile: Italy

continued from page 1

includes the Mediterranean islands of Elba, Sardinia and Sicily and many lesser islands. Within the boundaries of mainland Italy are two independent countries, San Marino and the Vatican City. Italy is part of the European Union (EU).

Italy is situated in southern Europe. The country is bordered by Switzerland and Austria on the north, by Slovenia and the Adriatic Sea on the east, by the Ionian and Mediterranean seas on the south, by the Tyrrhenian, Ligurian and Mediterranean seas to the west and by France on the northwest.

More than half of Italy consists of the Italian Peninsula, which extends in a southeasterly direction into the Mediterranean Sea. The rugged Apennines extend along the central part of the peninsula. At the far northerly end of the country are the Alps, which extend in a wide arc from Ventimiglia on the west to Gorizia on the east. Also in the north is the broad Plain of Lombardy, comprising the valley of the Po.

Italy has a predominantly Mediterranean climate, though the far north has an Alpine climate. The map on p. 5 shows Italy's major cities.

Population

Italy's population was estimated to be nearly 58.3 million in 2007 (CIA Factbook). The nation is largely urban in the north and rural in the south. The country's major cities include Rome, the capital and largest city; Milan, an important manufacturing, financial and commercial center; Naples, one of the busiest seaports in the country; Turin, a transportation hub and commercial center; Bologna, a major transportation center and agricultural market; and Florence, a cultural center. The leading manufacturing centers include Genoa, Milan, Rome and Turin.

The people of Italy are almost entirely native-born. Most of the population speaks Italian, although German is spoken around Bolzano, in the north near the Austrian border. The predominant religion of the country is Roman Catholic. The constitution provides for freedom of worship to the religious minorities, which primarily involve those of the Protestant, Muslim and Jewish faiths.

Government

Since June 2, 1946, Italy has been a

democratic republic. The ceremonial head of state is the president, who is elected to a 7-year term by the bicameral parliament. The actual executive power lies in the prime minister (who is actually referred to as the president of the Council of Ministers). The president chooses the prime minister, who is generally the leader of the party having the largest representation in the Chamber of Deputies, which is the lower house of the parliament. The prime minister must form a government, including a cabinet (ministers), which is then subject to approval by both houses of parliament.

The legislative branch is represented by a bicameral parliament, which consists of the Senate and the Chamber of Deputies. Parliament members are elected on the basis of proportional representation by popular vote to a 5-year term of office. The Senate has 315 members who are elected on a regional basis. There are also many life members who are past presidents and their honorary nominees (each president can make up to five senate appointments).

The Chamber of Deputies consists of 630 members. Legislation (legislative, presidential or prime ministerial decrees) passed by parliament requires approval by the president of the republic, which in practice is always forthcoming. Parliament may also enact guidelines. The regional parliaments in turn interpret these guidelines and enact more specific regulations. There are also decree-laws issued by either the prime minister or a ministry. These require the president's approval. Once approved by the president, they have the force of law for 60 days. Within this period, parliament must approve the decree-law or it is voided.

The judicial system in Italy is a national one, with no regional or local judiciary. There are civil, criminal and special courts, with the latter dedicated to specialized areas such as administrative and tax matters. The appeals system involves a court of cassation and a constitutional court. The former hears civil and criminal appeals for all matters except those involving constitutional questions. The latter court addresses constitutional challenges.

The country is divided into 20 regions, which in turn are subdivided into 94 provinces. Each region is governed by an executive who is responsible to a popularly elected regional parliament (consigli regionali).

The regions have considerable authority. The chief executive of each province, who is called a prefect, is appointed by and answerable to the central government and has limited authority in effect. An elected council and an executive committee together administer each province. Below the provincial level is the commune, the basic unit of local government. Each commune is governed by a communal council who is elected to a 4-year term by popular vote. Each council elects a mayor.

The Ministry for the Environment generally issues regulations and guidelines to the regions, some of which have their own environmental department (assessorato all'ambiente) through which national requirements are implemented and enforced. The regions may further delegate responsibilities to the provinces and municipal authorities, although such responsibilities are more in the area of enforcement and recordkeeping rather than establishment of standards or requirements.

Environmental Authorities

In 1986, the Ministry for the Environment was established under Law No. 349/1986 to coordinate environmental matters. In practice, this ministry shares environmental responsibilities with several other administrative bodies, including the Ministry of Health (open water pollution), Ministry of Industry (pollution of natural resources), Ministry of the Merchant Navy (pollution of marine reserves) and Ministry of Public Projects (pollution of surface waters used for drinking water).

ANPA (Agenzia Nazionale per la Protezione dell'Ambiente or National Environment Protection Agency) was established in accordance with Law No. 61/1994 to supply knowledge and technical-based support for the Ministry of the Environment's environmental activities. ANPA is supported by regional agencies (ARPA or Regional Environment Protection Agency), which have the same duties relative to their respective regions. In general, ANPA's role is that of a technical consultant; it has no power to enforce any environmental legislation.

Safety & Health Authorities

Matters more specifically related to safety and health largely come under the purview of the Ministry of Labor. A special body of this ministry, the Ispettorati del

Lavoro (Factory Inspectorate), is responsible for carrying out workplace safety and health inspections. Such inspections can be conducted at any time. The Ispettorati del Lavoro can also conduct medical examinations of employees at any time.

The Ministry of Health and Safety operates in cooperation with the Ministry of Labor. The former authority has administrative regulatory powers to realize the policy of the government in the area of safety and health. The separation of responsibility between the two authorities is not clear-cut. In some areas, there is dual responsibility.

History of SH&E Legislation

Environmental

Environmental regulations in Italy are represented by a complex and sometimes overlapping mixture of constitutional provisions, special statutes, articles from the civil and criminal codes as well as by a series of special decrees issued by different levels of government. As a result, the regulatory system is fragmented and often difficult to interpret.

The situation is further complicated by the fact that requirements dealing with a particular issue or environmental media (air, water, etc.) are often scattered throughout many different laws, decrees and regulations, which in turn may replace, amend or suspend certain provisions of the other. According to Italy's Environment Minister Edo Ronchi, "There are something like 3,000 laws regarding the environment in Italy and no one knows which ones to follow."

The country's environmental regulatory regime has been changing, largely due to a 1984 Constitutional Court judgment (Judgment No. 170 of June 8, 1984) that paved the way for the implementation of EU (previously EC) directives into national law. Previously, the Italian legal system assumed the position that EC directives did not take precedence over national laws. As a result, Italy implemented few EU directives. Since the early 1990s, much of the environmental legislation in Italy has been in response to EU legislation.

In the past few years, the central government has repossessed many of the functions and powers involving environmental matters, all of which had been previously transferred to regional and local authorities as a result of constitutional decentralization. As

a result, there is a certain degree of confusion in the interpretation of SH&E legislation as well as coordination problems with regard to the various enforcing authorities.

At the moment, national SH&E policy is managed by the Ministry of the Environment, the regions, the provinces and the municipalities. Notwithstanding the constitutional principle of the decentralization of the functions relating to the environment, it is not possible to draw a definite line between the competencies of the above entities. Currently, the Ministry of the Environment, the parliament or the government issues laws or legislative decrees to implement EU directives. Such laws (or legislative decrees) normally grant local entities the powers to issue specific regulations as well as specific powers to enforce the national legislation.

Occupational Health & Worker Safety

The structure of the Italian model for protection at work, set out before World War II, was characterized by a lack of systematic legislation. Only recently has the conclusion been reached that a systematic consideration of the prevention of accidents and illnesses in the workplace can result in better protection.

The d.lgs. 626/94 constitutes a fundamental change from the past in that an employer was previously obliged to observe formal prescriptions which lacked substance. The employer must now activate an entire series of actions concerning safety and health in the workplace where employees, government and unions are involved.

Recent SH&E Legislation

Legislation enacted during the past 10 years has focused on implementation of many EU directives that still require transposition into Italian law. Among the outstanding directives that apply to manufacturers are the following:

- 91/271/EEC on the treatment of urban wastewater;
- 93/88/EEC, which amends Directive 90/679/EEC on the protection of workers from risks deriving from exposure to biological agents during work;



- 94/45/EEC regarding the establishment of a European Company Board or a procedure for informing and advising workers within enterprises or groups of enterprises with a European dimension;
- 95/63/EEC, which amends Directive 89/655/EEC on minimum health and safety requirements for use of work equipment by workers;
- 96/59/EEC concerning disposal of PCB/PCT;
- directive 96/61/EEC on the prevention and integrated reduction of pollution;
- 96/62/EEC on the evaluation and management of air quality;
- 96/82/EEC on the control of risk of serious accidents connected with defined dangerous substances;
- 94/67/EEC on incineration of dangerous waste;
- 95/30/EEC regarding the adaptation to technical advancement of Council Directive 90/769/EEC relating to the protection of workers from risks deriving from exposure to biological agents during work;
- 96/94/EEC, which establishes a second list of indicative limits in the application of Council Directive 80/1107/EEC on the protection of workers against risks deriving from exposure to chemical, physical and biological agents during work;
- 97/10/EEC, which adapts Attachment I of Council Directive 76/769/EEC concerning the approach of legislative, administrative and regulatory provisions by the member states relating to restrictions on the introduction to the market

continued on page 6

Country Profile: Italy

continued from page 5

and use of some dangerous substances and preparations;

•97/16/EEC concerning the restriction of use and the introduction into the market of some dangerous substances and preparations.

Enforcement of SH&E Regulations

Administrative Actions

Environmental laws frequently provide for the intervention of the administrative authorities and more particularly of the local authorities, who are vested with various powers related to protection of the environment. The provinces and the municipalities, in particular, have the power to impose fines where a violation has occurred. Fines can amount to up to 100 million lira for the more serious offenses.

Moreover, the law gives local authorities—the mayor as a rule—the right to order parties who have committed an environmental offense to fulfill certain requirements. For example, Article 14 of Law No.22/1997 relating to contaminated sites allows the mayor, in the case of waste dumping or unauthorized deposit of waste, to order the perpetrator, jointly with the proprietor and the holders of the real or personal rights to the area (e.g., the landowner), insofar as they may be held responsible for the violation, to remove the waste and to clean up the site. If this party does not take action, the town council may proceed with the cleanup operation at the expense of those responsible.

According to the general principle of administrative law in Italy, it is always possible to challenge an act of the administrative authority before the local administrative court (i.e., the regional T.A.R.).

Civil Liability

Administrative regulations leave open the question of protection of those who suffer damages to their property caused by the polluting activities of third parties.

This matter is covered by Section 844 of the Civil Code, whereby the right of the owner of land to prevent the emission of smoke, heat, fumes, noise, vibrations or similar emissions from the land of his neighbors is recognized only if such emission exceeds normal levels of tolerability.

Civil liability is relevant to recovery of damages for harm caused to the environment. Section 18 of Law No. 349/1986, provides that “any fraudulent, malicious or negligent act in breach of any laws or regulations, which causes damage to the environment, altering, modifying or destroying it in whole or in part, obliges the person who has committed the act to pay damages.”

This provision only entitles the government and the local entities (on whose territory the damage has been produced), as well as some environmental associations, to commence legal proceedings against the person who caused the damage to the environment. This type of action has been rare in the past, but it is becoming more common. Recently, environmental associations have set in motion many legal proceedings.

Criminal Sanctions

Government intervention in protection of the environment is centered around the prescriptions of the government rather than on the enforcement actions of criminal courts. The Italian environmental regulatory system is composed of a series of penal sanctions, part of which are set forth by the criminal code and others included in the regulation related to water, air and land protection.

Criminal sanctions for environmental crimes may vary depending on the violation's severity, from a minimum of a few weeks to a maximum of 2 years in prison.

The current tendency of the Italian governmental environmental policy is toward a transformation of the criminal offenses into administrative violations. This does not mean that environmental violations will only be punished with administrative sanctions but that criminal sanctions will be reserved for the more serious violations.

Strict Liability

According to some Supreme Court decisions, business activities that involve the production of hazardous waste must be treated as “dangerous activities,” and as such, must be ruled by Section 2050 cod. civ., whereby any environmental damage is deemed to constitute a case of strict liability. According to such provision, “Whoever cause injuries to another in the perform-

Public Holidays

National holidays are noted as follows. This is a working guide only; dates should be verified prior to undertaking any visit. When holidays fall on a Saturday or Sunday, commercial establishments may be closed the preceding Friday or the following Monday.

New Year	Jan. 1
Epiphany	Jan. 6
Easter Monday	April 13
Liberation Day	April 25
Labor Day	May 1
Anniversary of the Republic	June 2
The Assumption	Aug. 15
All Saints Day	Nov. 1
Immaculate Conception	Dec. 8
Christmas	Dec. 25

ances of an activity dangerous by its nature or by reason of the instrumentalities employed, is liable for damages, unless that he has taken all suitable measure to avoid the injury.”

Enforcement Practices

Enforcement of environmental regulations is effected through the application of administrative and criminal sanctions. In addition to the traditional financial penalties and to the criminal sanction of imprisonment, other sanctions are addressed to the restoration of the original status quo (for example, the order to destroy a building).

In the event of violation of the prescription contained in administrative permits, the administrative authority can issue a notice containing a warning and an order to comply within a certain term with such prescriptions. In other cases, the permits can be suspended.

Audit Privilege

If an audit is conducted to meet a specific license or permit condition, these findings are public information and must be made available for discovery. However, if an audit is self-initiated, there is no obligation to report the findings to the regulatory authorities. Attorney-client privilege is available in Italy. Therefore, any audit report prepared by an attorney would not be subject to discovery.

Information Access

Environmental information about a specific facility theoretically is available through governmental authorities upon request. In fact, the right of public access to environmental information is provided for in three laws:

continued on page 16

Country Profile: Italy

continued from page 6

- Law 349/86 on the Establishment of the Ministry of Environment and Rules about Environmental Damage, establishes in Article 14 the right of every citizen to have access to environmental information held by public authorities upon payment of copying costs;

- Law 142/90 on the System of Local Authorities gives rights of access to administrative documents and the right to obtain copies (articles 6 and 7);

- Law 241/90 on New Rules about Administrative Procedure and the Right of Access to Administrative Documents sets forth the general right of public access to administrative documents in Articles 22-28.

Despite the legal basis for access to information, "inefficient bureaucracy and its traditional secrecy about environmental matters" has made access difficult.

Contaminated Land

Applicable Regulations

Legislative decree No. 22 (Feb. 5, 1997), the Italian framework law on waste (Decreto Ronchi), contains provisions that directly apply to contaminated land. More specifically, Articles 17.1 and 17.2 require that any facility which causes ground contamination, surface water or groundwater contamination must undertake the necessary cleanup and remediation activities. Relevant municipal, provincial and regional authorities must be notified and told of any proposed remediation measures planned to control contamination and to reduce health and environmental risks.

Process Safety Management Standard

continued from page 13

SDS Consulting Corp. (2005). Process hazard analysis leadership training, Alberta, Canada.

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According to Sections 19 and 20 of the Decreto Ronchi, each region must issue its own contamination cleanup plan, while the Provinces are in charge of monitoring the cleanup activities in its own territory. Each municipality must then give its approval to each project to clean up polluted sites. Following satisfactory completion of the cleanup, the relevant authority issues certificates of completion.

Liability for Pre-Existing Contamination

Article 14 of d.lgs. 22/97 provides that whoever deposits waste in the soil is obliged to move, collect or dispose of such waste, in addition to cleaning the area in question and ensuring that it is returned to its original state. Such obligation is on the person liable for the violation together with the landowner as well as the tenant, but only if they effectively contribute with malice or negligence to the violation.

Cleanup Standards

Article 17 of d.lgs. 22/97 states that within 3 months of the decree entering into effect, the Minister for Industry, Commerce and Health must define the acceptable limits of soil and groundwater contamination in relation to the specific use of a site. Currently, authorities in question have not yet issued such cleanup standards.

Key Agencies

Central Government Authorities

- Ministry of Environment
Piazza Venezia, N. 11
Rome
Tel: (39-6) 70361

- Ministry of Labor
Via Flavia, N. 6
Rome
Tel: (39-6) 46831

- Ministry of Health and Safety
Piazza dell'Industria, n. 20
Rome
Tel: (39-6) 59941

Regulatory Information Sources

- Gazzetta Ufficiale
Piazza Verdi, n. 11
Rome
Tel: (39-6) 85081

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