MSc Program

Environmental Technology & International Affairs

Regulatory Compliance Management for Technology-oriented Agreements

A transdisciplinary inquiry in managing Radiation Protection Regulations at CERN

A Master's Thesis submitted for the degree of "Master of Science"

supervised by

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Affidavit

I, **PETER JOSEF NISS**, hereby declare

1. that I am the sole author of the present Master's Thesis, "REGULATORY COMPLIANCE MANAGEMENT FOR TECHNOLOGY-ORIENTED AGREEMENTS", 87 pages, bound, and that I have not used any source or tool other than those referenced or any other illicit aid or tool, and
2. that I have not prior to this date submitted this Master's Thesis as an examination paper in any form in Austria or abroad.

Vienna, 08.06.2010

Signature

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to my family

It is my opinion that everything must be based on a simple idea. And it is my opinion that this idea, once we have finally discovered it, will be so compelling, so beautiful, that we will say to one another, yes, how could it have been any different.

John Archibald Wheeler (09.07.1911 – 13.04.2008)
American theoretical physicist

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1. Abstract

This thesis covers intensive multidisciplinary investigations, concerning governance of international technology-oriented agreements in general and regulatory compliance management systems in particular. In this respect the main investigation was conducted at CERN, assessing radiation protection and safety management system and outlining decision-criteria for implementation of a Regulatory Compliance Management System. Moreover it has been clarified what kind of advantages and disadvantages must be anticipated when introducing new managerial standards based on principles of transparency and good governance.

Operating various accelerators and dealing with crucial duties, as well as organisation of human resources and delegation of responsibilities require a strong and reliable systematic approach. In that respect an integrated and comprehensive management system for administrating requirements, responsibilities, reminding, documenting, reporting and tracing of checks, audits, deviations, corrections, improvements in respect of radiation protection and safety rules/regulations and its status of compliance at CERN have been outlined.

Regulatory compliance management is not a static stand-alone activity that is separate from the main activities and processes of an organization. It is part of the responsibilities of senior management and also an integral part of overall risk management including all organizational processes, strategic planning for future projections and all project management processes. Also it will also help decision

makers making better strategic decisions regarding the increasing public awareness and continuous "new media" presence.

Accordingly, a structured and methodical basis for compliance management has been derived from own experiences and various industry standards (ISO 9001, 14001 and 31000). The recommendation for a general Regulatory Compliance Management System for CERN comes with a customized implementation strategy, comprising system and user requirement, and also an implementation timeframe.

Finally, various synergetic issues and impacts regarding the implementation are being discussed. Other departments, e.g. occupational health and safety, might also gain from the implementation (spill-over effect). The following up inspections and measures would get more effective and efficient when using the computer-based integrated management system linked with legal requirements. In addition to that, risks could be much easier discovered and also assessed within their electronic database of requirements.

Organizations also have to decide on basic principles of governance and conduct before implementing management systems for their processes, activities and assets. The concept of good governance provides appropriate ethics for discussion, highly suitable for efficient and effective management of public responsibilities.

However, organizations also need to consider possible critical circumstances related to the implementation. For instance, over-compliance might slow down efficiency of processes, especially if requirements are too extensive. But it could also work out quite the opposite. In this respect it might act a strategic tool to avoid the government to choose a new or tightening the existing regulatory framework.

In any case, knowing the exact status of compliance with already agreed requirements at any time will help acting more accurate and confident in negotiation situations, also promising to make better decisions.

Keywords: Regulatory Governance, Compliance Management, Technology-oriented Agreement, Environmental Management, Risk Management, CERN, Radiation Protection & Safety

2. Purpose, motivation & methodology

2.1. Introduction

We live in a very exciting but constrained world. Our knowledge about the universe or even our own origin is very vague. Moreover our daily life is influenced by countless parameters and unknown conditions, in a way that we always look for simplification (by theories, conventions and rules or even pragmatic regulations) to deal with our various life situations and to manage our daily want, need and risks[1].

In this respect every unknown operation comes with uncertainties and risks. For this reason, humans or organizational entities design and introduce special procedures, methods and systems to meet related circumstances and to avoid dangerous situations, serious incidents with severe consequences, at last providing safety and security. It is even more sophisticated to guarantee safety if there are different views or expectations on it. The following up of safety procedures e.g. for protecting man and environment is sometimes pure intuitive (e.g. fear of danger by fire) or rather systematic if the danger of a situation is not that obvious (e.g. radiation exposure).

[1] According to ISO 31000 (2009) risk is described as an effect of uncertainty on objects wheras effects mean deviations from something expected (positive or negative). An objective can have different aspects (like safety) and can be applied at different levels (concerning strategic, organization, project, products and processes). Risk is also often characterized by reference to potential events and consequences and the associated likelihood of occurence.

As a result a systematic approach has to be established to deal with all inadequateness in running procedures or risks in operating processes and facilities.

This systematic approach starts with defining a normative discussion, meaning how things ought to be, how to value them, what things are good and what are bad, what actions are right or wrong. Various interest groups and institutions, e.g employers, employees, labour unions, governments, NGOs, specialists and many more, drive the initial phase. According to that, standardisation and legislation bodies usually support that procedures and come out with related binding and non-binding requirements, in the sense of conventions, norms, rules, laws and other regulations.

Thus various management systems and processes have been designed and developed, dealing with all that operational and regulative requirements mentioned before.
For example, keeping the product quality at the highest possible level and at the same time keeping the losses due to low quality small, a quality management system should be introduced. So meeting the maximum protection level of workers and staff, an occupational health and safety management system will bring success. Also in cases of anthropogenic or natural emissions, integrative environmental management systems can contribute to a higher level of protection of men and the environment.

All management systems have in common the description of certain procedures within the system, the control of the functionality of the system and the evaluation of the effectiveness of the system.

CERN

Nuclear and particle physics research at CERN is one of mans' attempts to get a deeper insight in this quite unknown area of creation and conditions, in order to finally derive conclusions about how scientific findings and practical experiences fit into theory and presumptions. Several thousands physicists, engineers and other experts from various countries, nationalities and beliefs come to CERN to investigate in those issues since the 1950's, operating enormous complex processes, systems and facilities. They act on behalf of their educational training, practical experiences and

personal understanding. A lot of procedures dealing with all aspects of quality, safety and environment are in place and have to be followed by CERN users and operators to keep both things safe and risk as low as reasonable achievable.

2.2. Purpose

This thesis is dealing with several issues concerning radiation protection and safety management at CERN, the European Organization for Nuclear Research located in Geneva, Switzerland. CERN provides a special case of international research collaboration, which got recent scientific attention with the restart of the Large Hadron Collider (LHC). An additional purpose of CERN is to lower costs in operating complex research facilities and to reduce cooperation barriers to enhance technology progress. The institution operates a number of accelerators which are used by different research collaborations from all over the world for experiments in natural science, with main focus on particle physics. The facilities are operated under special radiation protection and safety requirements, based on international standards (IAEA, ICRP, ISO), bilateral host-state agreements (Switzerland and France) and internal specific rules of conduct.

Legal Compliance Management in Radiation protection

Operating various accelerators or related facilities requires compliance with a huge number of diversified rules and regulations, also regarding safety and radiation protection. Therefore it is obvious that dealing with crucial duties needs a clear and precise organisation of human resources and delegation of responsibilities. Furthermore the question of transparency regarding responsibilities and the definition of aspect, narrow or broader, has to be examined.

Based on observation and interviews conducted directly at the pit-face, it can be derived that there are heterogenic management systems and software applications already in operation dealing with that purpose. Given this evidence, one has to consider what kind of structure and characteristics an idealistic regulatory compliance management system for radiation protection and safety requirements should imply. Moreover it should be also clarified what kinds of advantages and

disadvantages have to be anticipated when implementing a legal compliance management system.

Technology-oriented Agreement

Newly published literature classifies CERN as a so-called "Technology-oriented Agreement" (TOA). This inquiry should find out the degree of relevance of what this categorization may imply for CERN.

Regulatory Compliance

More than that the conceptual framework for regulatory compliance should be discussed, especially regarding the CERN venture, projecting on regulatory governance for pursuing international technology-oriented collaborations (in this case as TOA) in other multinational and transnational scientific and non-scientific undertakings.

2.3. Motivation

In general, the momentum of success of multinational projects (especially in fundamental research) strongly depends on several factors[2]:

- Good regulatory governance promoted, implemented and executed by national or international entities;
- Rule of law (national law, bilateral agreements or international conventions)
- Participation by and consensus with interested and concerned stakeholders
- Transparency in decision taking and compliance with agreed requirements
- Strong commitment and responsiveness by the project management board
- Effectiveness and efficiency in organisation and operation
- Accountability by all stakeholders

It is stressed by CERN that the regulative dimension in its projects is crucial. Even more if there are any constraints in safety, related to these projects. Following the

[2] derived from PUNYARABANDHU (2004)

responsibility for human integrity and safety, radiation protection and safety issues are of important significance within the scientific projects at CERN.

For this reason CERN is committed to having a high quality radiation protection and safety programme. The related "Standards of Care" will be the applicable regulations from both host states, Switzerland and France, as well as international standards, IAEA and ICRP, and "As Low As Reasonably Achievable" (ALARA) will be the guiding principle.

The Radiation Protection Group (RP Group)

The Radiation Protection Group (RP Group) will support the Director General by helping to achieve the scientific and technical goals and by protecting members of CERN, the public and the environment from ionising radiation exposure due to CERN activities and facilities.

The RP Group in particular is responsible for monitoring all ionising radiation and for the control and management of all radioactive sources, materials and waste related to all operations. The group is in charge of establishing an interim storage facility and a conditioning centre for radioactive waste. They also carry out radiation measurements via a permanent monitoring system for the accelerators and the sites in general. The group develops the new radioactivity and environmental site-monitoring project (RAMSES) for the Large Hadron Colider (LHC). Additionally it performs radiological risk assessments and shielding calculations for new projects, including compliance assessments to INB rules. As a result, the group performs high-level dosimetry measurements for materials used in accelerators. The Individual Monitoring Section monitors the radiation doses received by CERN staff, users and industrial support personnel, who work in radiation-controlled areas (CERN, 2010a).

Due to that load of responsibility and obligations under several regulatory norms coming from different levels of legal frameworks, a systematic approach of dealing with all requirements, subject to regulatory governance, has to be investigated.

Accordingly a legal compliance management system for radiation protection and safety requirements has to be examined and described.

2.4. Methodology

The main goal of the investigation is to evaluate the Legal Compliance Management System (LCMS) actually in place at CERN (survey of history and development); identification of common elements and differences to other management systems (ISO, IAEA); exploring and discussing of advantages and disadvantages of implementing an LCMS; and finally to come up with a description of a state-of-the-art system to manage and control compliance concerning radiation protection and safety requirements and developing basic requirements for the implementation at CERN.

To address the defined goals the author has outlined a working programme. This programme includes field investigations, document screening and expert interviews directly at CERN, as well as comprehensive literature research by using scientific publications (electronic papers and expert literature), international standards (ISO[3], IAEA[4], ICRP[5], NCRP[6], EU/EURATOM[7]), CERN document services, cost-free legal databases (RIS[8], EUR-LEX[9]), national radiation safety bodies (BAG[10]), and internet search engines.

Structure of the thesis

Chapter 3 introduces the history of CERN and the recent LHC project by examining background information about the development, but also concers radiation safety issues and explores complications in communicating and experiences in managing risks. Moreover explicit description of relevant terms und subjects (stakeholders,

[3] International Organisation for Standardization, http://www.iso.org/iso/home.htm
[4] International Atomic Energy Agency, http://www.iaea.org
[5] International Commission on Radiological Protection, http://www.icrp.org
[6] National Council on Radiation Protection & Measurements (US), http://www.ncrponline.org
[7] European Commission & The European Atomic Energy Community, http://ec.europa.eu/energy/nuclear/euratom/euratom_en.htm
[8] Austrian Legal Information System, http://www.ris.bka.gv.at/Bundesrecht
[9] European Union law access point, http://eur-lex.europa.eu/de/index.htm
[10] Swiss Federal Office of Public Health FOPH (BAG), http://www.bag.admin.ch

international law, technology-oriented agreements, governance and compliance) is done for better understanding of the basic interrelations and special implications of introducing a compliance management system concerning regulatory issues at CERN.

Chapter 4 describes the findings within the working programme described above at CERN, by concentrating the investigation on safety issues, especially at the Radiation Protection Department, and its defined requirements subject to regulatory compliance management of radiation protection and safety rules and regulations.

In Chapter 5 the author is sketching features and functions of an ideal regulatory compliance management system to be introduced at CERN. Moreover strategic thoughts about implementing and administrating such a system are presented. Within this chapter, requirements and tasks for processes and stakeholders are also outlined as well as related strengths and weaknesses.

Chapter 6 discusses spill-over effects within CERN after implementation and appliance of some major principles of good governance aspects. Furthermore, some critical thoughts about over-compliance are outlined.

3. Background

The very special and applied topic of this master thesis requires a brief description of the history and background situation at CERN and a short examination of the main terminology used in the investigation in chapter 4.

3.1. CERN

CERN is the abbreviation for "European Organization for Nuclear Research". The name is derived from the French acronym "**C**onseil **E**uropéen pour la **R**echerche **N**ucléaire". The convention that established CERN in 1954 clearly laid down the main missions for the Organization (HERMANN, KRIGE, MERSITS, & PESTRE, 1987).

Primarily the Convention states:

> *"The Organization shall provide for collaboration among European States in nuclear research of a pure scientific and fundamental character (...). The Organization shall have no concern with work for military requirements and the results of its experimental and theoretical work shall be published or otherwise made generally available".*

Moreover the Convention declares that CERN shall act in collaborating amongst nations by organizing and funding international co-operation in research, promoting contacts between scientists and interchange with other laboratories and institutes. This also includes distribution of information and the provision of advanced training for researcher (CERN, 2010b).

Meanwhile, CERN with its laboratory site in the surroundings of Geneva has become the world's largest and most respected centre for scientific research in fundamental physics. The primary goal is finding out what the universe is made of and how it works. The instruments used at CERN are particle accelerators and detectors. Different sized accelerators boost beams of particles to high energies before they collide with each other or with stationary targets. Special designed and developed detectors, run by multinational science collaborations, observe and record the results of these collisions. Currently the mayor investigation is done with the so-called Large Hadron Collider (LHC) to accelerate particles to be collided and detected in different detectors allocated within the accelerator ring.

What is really fascinating is the fact that CERN is driven within more than five decades by 20 European member states[11]. But there are many more, different in status and divided in observer states[12] and organisations and non-member states[13], which are also involved in the projects, according to the spirit of the initial Convention.
CERN employs just around 2.500 people. The laboratory's scientific and technical staff designs and builds the particle accelerators and ensures their smooth operation.

[11] Currently: Austria, Belgium, Bulgaria, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Italy, the Netherlands, Norway, Poland, Portugal, the Slovak Republic, Spain, Sweden, Switzerland and the United Kingdom; CERN. (2010b). *CERN's Mission*. Abgerufen am 10. February 2010 von http://public.web.cern.ch/public/en/About/Mission-en.html
[12] Currently: European Commission, India, Israel, Japan, the Russian Federation, Turkey, UNESCO, USA; CERN. (2010b). *CERN's Mission*. Abgerufen am 10. February 2010 von http://public.web.cern.ch/public/en/About/Mission-en.html
[13] Currently: Algeria, Argentina, Armenia, Australia, Azerbaijan, Belarus, Brazil, Canada, Chile, China, Colombia, Croatia, Cuba, Cyprus, Estonia, Georgia, Iceland, Iran, Ireland, Lithuania, Mexico, Montenegro, Morocco, New Zealand, Pakistan, Peru, Romania, Serbia, Slovenia, South Africa, South Korea, Taiwan, Thailand, Ukraine and Vietnam; CERN. (2010b). *CERN's Mission*. Abgerufen am 10. February 2010 von http://public.web.cern.ch/public/en/About/Mission-en.html

They also prepare, run, analyse and interpret the data from complex scientific experiments.

Additional to the permanent staff about 8.000 visiting scientists, representing half of the world's particle physicists, come to CERN for their research. They represent 580 universities and 85 nationalities (CERN, 2010b). What also come with that huge number of people actively involved in several scientific project are high requirements for all different management processes.

3.2. Stakeholders

A large endeavour such as CERN has considerable impacts on people and their environment. Accordingly, individuals are always driven by considerations and assumptions concerning these impacts and therefore form specific interest groups with a common sense.

Scholars from the Stanford Research Institute have already outlined the concept of "stakeholders" in 1963. According to FREEMAN & REED (1983) it is stated that stakeholders are "those groups without whose support the organization would cease to exist."

What comes with that is the necessity to define and examine exactly who is included by the term and why. Therefore every undertaking has the responsibility to identify its stakeholders. This can be accomplished by a comprehensive analysis of all individuals or groups that are likely to be affected by a proposed action. Additionally it has to be examined how much they can affect the action and the other way round how much they are affected by the action itself. Finally the outcome is assessed how the interests of those stakeholders should be addressed in a project, policy, programme or in any other action.

A broader mapping of a company's stakeholders may include employees, the management board, neighbours, shareholders, creditors, suppliers, investors,

government, customers, labour unions, government regulatory agencies, industry trade groups, professional associations, NGOs and other advocacy groups, prospective employees and customers, local communities, national communities, public at large (Global Community), competitors, political parties. A more closer look will identify variation in stakeholders in terms of age, gender, ancestry, education and experience.

Thus both understanding of perception, attitude and intention of every individual stakeholder/interest group and establishing good communication between them and the concerned project-owner, are crucial for any project conducted, whether in business or science.

This is why CERN is following an open information policy[14] doing frequent assessment of dangers concerning its experiments (subject to reality assessment, probabilistic appreciation and severity classification) according to reducing any possible negative effects on people and the environment.

3.3. International Law

CERN is an international intergovernmental organization established by the Conventions signed in Paris on 01.07.1953[15]. Due to additional agreements, between the Swiss Federal Council and CERN, it enjoys international legal status in Switzerland. Moreover it is also established in France, where it is also granted international status in terms of the Agreement signed on 13.09.1965[16] between the French Government and CERN (CERN, 1999).

During the time when the predecessor of LHC, the Large Electron-Positron Collider, was planned, tunnelling and different legal status of private property in France and

[14] Cern is using several communication platform intranet (www.cern.ch), "Le CERN dans la vie local" http://project-voisins.web.cern.ch/project-voisins/ (retrieved on 12.02.2010), guided tours, permanent exhibition, and also by microblogging via twitter (http://twitter.com/cern_fr/) and RRS-feeds (http://twitter.com/statuses/user_timeline/15234407.rss)
[15] revised on 17.01.1971
[16] revised on 16.06.1972

Switzerland turned out to be problematic. For example in Switzerland the rights of a private property extend to a depth of only 30-50 m, whereas in France the owner of a property owns it all the way down to the earth centre. This became more complicated when it was the case that France provided the land underneath for free without paying compensation to the property owner (SCHOPPER, 2009). According to site agreements between Switzerland and France[17] and by application of the rule-of-law principle, a governmental organization subject of international public law cannot simply be sued like a national entity. So the complainant had to follow a complex procedure going through different levels of jurisdiction, going hand in hand with negative consequences for project management and realisation.

Back in that time, CERN management had to apply for a so-called "declaration d'utilité publique"[18] to be issued by the French "Conseil d'État"[19]. It was necessary to obtain a legally binding judgement to finally clarify the undertaking. Additionally CERN had to compile an "etude d'impact"[20] that had to be submitted to the authorities. Yet before submitting, the procedure presumes public hearings where all concerned stakeholders could express their objections (SCHOPPER, 2009).

To avoid time delaying procedures based on complaints and lawsuits, communication between all stakeholders involved in projects and good public relation with each other is absolutely crucial, even more for any further established or upcoming international technology-oriented endeavours. Therefore knowing its own internal processes and check-status of all requirements is one key element for supporting the external communication.

[17] Agreement with France from 13.09.1965 (rev. 16.06.1972) and with the Federal Swiss Council from 11.06.1955
[18] French; translated in the meaning: declaration of public interest
[19] original French; translated in the meaning: Supreme Court
[20] original French; translated in the meaning: Environmental Study

3.4. Technology-oriented Agreements (TOA)

Interestingly this term was formed only recently within the development of international climate change policy. Beside introduction of market-based approaches (like CDM[21] and Carbon cap & trading) new mechanisms, more technology–based, were examined, such as governmental research funding, technology transfer, standardisation and knowledge sharing with respect to climate change negotiations.
According to DE CONINCK *et al.* (2008), "the scope of TOAs is defined as those international agreements that are aimed at advancing research, development, demonstration, and/or deployment of technologies." This engineering perspective of TOAs typically focuses on the potential of technology, whether it comes to development of new game-changing reliable technology or introduction of well-coordinated, efficient and reasonable technology standards.

TOAs are fairly new to the international relations and policy floor. Most of them are related to environmental issues, but few like CERN or ITER (eventually DESERTEC and a highly anticipated convention[22] on Geoengineering together with creating an international organization for Geoengineering Research) demonstrate the power of engineering and technology development to deal with global challenges, which can only be coped on the international and transnational level.

Furthermore, multinational agreements on the international level, like TOAs, are considered by international relations literature as a consequence of rational choice by signature countries (STEIN, 1990). This view mainly relies on game-theoretic assumptions that states can gain more from strategic cooperation than from acting isolated.
What generally makes TOAs difficult to apply is the fact that the participating actors (states) are supreme authorities, acting within their own sovereignty and without

[21] Clean Development Mechanism (CDM) is defined in the Kyoto Protocoll and was introduced by the United Nations Framework Convention on Climate Change fighting global warming.
[22] The Royal Society (2009). *Geoengineering the climate - Science, governance and uncertainty* . The Royal Society London.

recognition of a superior authority forcing them to comply with concluded agreements.

Despite these difficulties some scholars in international relations suppose that TOAs show a lot of incentives to be considered when it comes to fostering international technology progression. BARRETT (2003) states that once the aggregate scale of economies of joining a hypothetical technology-oriented agreement reaches a critical mass (in the sense of general acceptance and application and/or compliance), supported technologies could become international standards. Hence it could be concluded that joining agreements and following standards would be a better strategy than the exclusion by non-participation (e.g. especially in cases of cost-sharing, risk-sharing aspects coming within research and development of new technology). Additionally BUCHNER & CARRARO (2005) showed by applying game-theory methods that international cooperation on Research & Development has some positive effects for the participating parties.

Based on the criteria for assessing TOAs four types of TOAs have been evaluated and defined (UENO, 2006):

Table 1 Technology-oriented agreements

Knowledge sharing and coordination	Carbon Sequestration Leadership Forum (CSLF) and the International Partnership for the Hydrogen Economy (IPHE) Methane to Markets Partnership Task sharing in International Energy Agency Implementing Agreements (IAE-IA) Asia-Pacific Partnership on Clean Development and Climate (APP) Energy Star bilateral agreements
RD&D Research, Development & Demonstration	**European Organization for Nuclear Research (CERN)**[23] ITER fusion reactor Cost sharing in International Energy Agency Implementing Agreements (IEA-IA) The Solvent Refined Coal II demonstration Project (SRC-II) International Organization for Geoengineering Research[24][25]

[23] CERN is not motivated by environmental concerns, but highly related to environmental issues within obligations in radiation protection

[24] Fictive RD&D agreement on common research in Geoengineering. The legal framework and governance of Geoengineering research and development has to be further developed within existing regulations and conventions, e.g. by an international body such as the United Nation Commission for Sustainable Development, proposed by the Royal Society (2009).

Technology transfer	Multilateral Fund under the Montreal Protocol Global Environment Facility (GEF) DESERTEC[26]
Technology mandates and incentives	International Convention for the Prevention of Pollution from Ships (MARPOL) European Union Renewables Directives Comprehensive Test Ban Treaty (CTBT)[27]

Source: DE CONINCK *et al.,* 2008)

3.5. Governance

There is an overwhelming literature available, mainly invested by scholars in public law, international relations and political science. By Governance is meant the policies, structures and processes that enable control and coordination of stakeholder decision-making (STEWART & JONES, 2003). But the definition should be described in a much broader sense. According to BENN, DUNPHY & MARTIN (2009) Governance is not meant being only accomplished by a superior entity with given authorisation to perform and execute rights and duties to a sublimated legal addressee. Moreover the processes should also include interactions between all stakeholders enabling sustaining coherence in every decision and undertaking.
Regarding CERN and its unique situation of multilevel coordination of radiation protection and safety requirements, Governance means: the process of decision-making and the process by which decisions are implemented, controlled, complied and evaluated.

For that reason the practice of decision-making, implementation and controlling of radiation protection & safety issues at CERN needs to be investigated before designing a management system to support those processes of Governance.

[25] Regarding Geoengineering newly research and development affords in Carbon Dioxide Removal (CDR) and Solar Radiation Management (SRM) have to been taken. BROECKER & KUNZIG (2009) and VICTOR *et al.* (2009) suggested forming an international consortium and other international scientific collaborations following the example of CERN!
[26] The DESERTEC concept describes the perspective of a sustainable supply of renewable electricity (wind, hydro, geothermal and solar power) for Europe, the Middle East and North Africa. It is mainly driven by an industrial initiative consisting of big german enterprises operating in the energy business (http://www.desertec.org). (Added by the author)
[27] Added by the author

What always comes with this is the question of value how Governance ought to be. International scientific literature provides the principles of good Governance. According to leading international organization[28] good Governance is defined and represented by special characteristics, as followed[29]: The rule of law, transparency, accountability, effectiveness, equity, inclusiveness, responsiveness, sustainability and freedom of corruption (CZETTL, 2009). Its primary focus is on traditional government action to enforce compliance on societally agreed and accepted rules subject to human interaction and gregariousness. However now the term is not purely occupied by the state and the civil society but rather a new multi-level mechanism for other "partnerships" too, like international technology-oriented agreements (TOA).

3.6. Compliance

Generally spoken, compliance describes the voluntary or involuntary obligation that private corporations, public institutions or individuals have to comply with relevant and defined specifications, standards, rules, laws and regulations. Accordingly, compliance management means that executive officers or responsible representatives to operate under a systematical approach which the personnel is aware of and take steps to comply with relevant defined requirements. In addition, compliance management system is a special tool, mostly based on written manuals, computer databases and/or charting applications that link public regulation (e.g. international/national laws and regulation) and private rules (such as standards, instructions, specifications) to the organization's processes, devices and buildings.

CHAYES & CHAYES (1993) proposed that the level of compliance within international agreements in general is inherently unverifiable by empirical procedures. That international entities (like nations or international organisations)

[28] Defined and used by several international entities like United Nations (UN), World Bank (WB), Organization of Economic Cooperation and Development (OECD), European Union (EU)

[29] The enumeration is not sufficient and selected by the author in accordance with the requirements for technology-oriented agreements (specially CERN). A deeper examination will be made in the following chapters.

generally comply with their international agreements on the one hand, or that they violate them whenever it is in their interest to do so, on the other, are not statements of fact or even hypotheses to be tested. It is assumed that a variety of reasons why states may deviate from treaty obligations and why in many circumstances those reasons are properly accepted by others as justifying apparent departures from treaty norms. An international treaty regime as a whole need not and should not be held to a standard of strict compliance but to a level of overall compliance that is "acceptable" in the light of the interests and concerns the treaty is designed to safeguard.

Regarding the legal situation of CERN, as a subject to international law, compliance with any public regulation is rather comparable to nation states. Accordingly a systematic approach applied within regulatory compliance management can be very relevant to senior management (CERN Director general, department and group leaders[30]) for the purposes of validation and regulation of consistency, transparency, completeness or compliance with defined regulatory requirements (rules and legal obligations from public and private law).

Concerning requirements in radiation protection, many practices utilizing radiation sources in medicine and industry are well established by national regulators. Practices within research and development operation, especially in case of technical-oriented agreements based on international agreements, show a highly diverged and complicated picture. The legal implications associated with some of these scientific and technological practices are sophisticated and complex.

A systematic management approach that adresses the complex framework of regulatory requirements in radiation protection and their application within the regulated technologies will also help to overcome ineffective processes and also inappropriate measurements. A liable way how such a management system may work and look like will be examined in the following chapter.

[30] The Organigram of CERN will show in following chapters.

4. Results

In this chapter the basic results and findings from the inquiry regarding regulatory management of radiation protection and safety requirements at CERN will be described. It will start with a comprehensive overlook about the present situation how to deal with radiation protection management at CERN today, by describing policy, organisation structure, responsibilities and processes already in place. It will be followed by an examination of inherent and essential elements of a customized regulatory compliance management system for radiation protection requirements, completed by comprehensive discussion of advantages and disadvantages of implementation. Differences to the management system already in place will be appointed. Finally both key elements and success factors for implementing and operating a state-of-the-art system in managing compliance with radiation protection requirements at CERN will be assessed.

4.1. Safety at CERN

Due to its international legal status and its unique activities in scientific fundamental research, CERN has its own specific safety regulatory system. It is mainly based on safety rules and regulations of both host states, Switzerland and France, and recommendations from international bodies like IAEA and ICRP.
Binding regulations are set up by official documents between CERN and host states.

To quote the document CERN/DSU-DO/RH/9335 from October 1999:

„CERN draws up its own safety regulation for following reasons:

i) to standardise regulations throughout its site, which is located on the territories of two Host States;

ii) to cover fields of activity for which no regulations exist;

iii) to remain neutral in its choice of Member States' firms in the context of calls for tenders;

iv) to meet the need for safety regulations in field of activity that are unique to CERN.

In drawing up its own safety regulations, CERN takes the most advanced regulations even if they are not the most stringent.

However, CERN's regulations comply with public policy provisions in force on the territories of the Host States and must ensure, as a general rule, a level of safety not inferior to that offered by the regulations of the Host States. Where there are no specific CERN regulations or where CERN's regulations are incomplete, the applicable regulations are those of the Host State concerned."

It is stressed by CERN that the regulative dimension of all safety issues is crucial. Generally spoken, CERN is required to comply with the rules in force on the territory of the host states and to ensure that a level of safety is maintained that is at least equivalent to that provided by the latter's own regulations.

4.1.1. Organisation

CERN like any other organisation has to define at first special roles and responsibilities to deal with its organisational tasks and procedures.

The Department Directors, the Safety Commission and several special Safety Committees assist the Director-General (DG), who is responsible for all safety matters.

The Safety Commission (SC) has the following functions (CERN, 2006a):

- Providing everyone working at and for CERN with the advice and information they need to maintain the Organization's high safety standards;
- Ensuring application of industrial standards;
- Performing executive safety functions in the following areas:
    - Radiation protection
    - Fire fighting and fire prevention
    - Environmental protection
    - Mechanical and electrical inspections
    - Chemical and pollution risk control
    - Occupational health & medicine
    - Medical prevention & emergency medical assistance

Several Safety Committees support the Safety Commission and play an important advisory and controlling body on safety policy and related matters at CERN: the Departmental Safety Officers Committee (DSOC), the Flammable Gas Safety Officers Committee (FGSOC), the Radiation Safety Officers Committee (RSOC), the Cryogenics Safety Officers Committee (CSOC), the Radiation Protection Committee (RPC), the CERN Environment Protection Committee (CEPC), the Accident Board, and the Committee for Examining Firms' Safety Conditions at Work (CECSTE).
According to CERN Safety Policy (CERN, 2006a), the Department Leaders (DL) who are answerable to the Director-General for all safety matters concerning the activities falling within their competence, have to organise and manage their department in such a way that ensures that CERN's safety regulations are fully implemented.

Department leaders may appoint special Safety Officers (SO) to assist them in meeting their safety responsibilities. These officers may be appointed in one of the following capacities:

- Departmental Safety Officer (DSO), who acts on the department leader's behalf in matters of safety;

- Radiation Safety Officer (RSO), answerable to the department leader, via the DSO, for all matters of radiation safety in the department;
- Cryogenics Safety Officer (CSO) Flammable Gas Safety Officer (FGSO), answerable to the department leader via the DSO;
- Territorial Safety Officer (TSO), who is answerable to the DSO for the safety and good order of the area for which he is responsible.

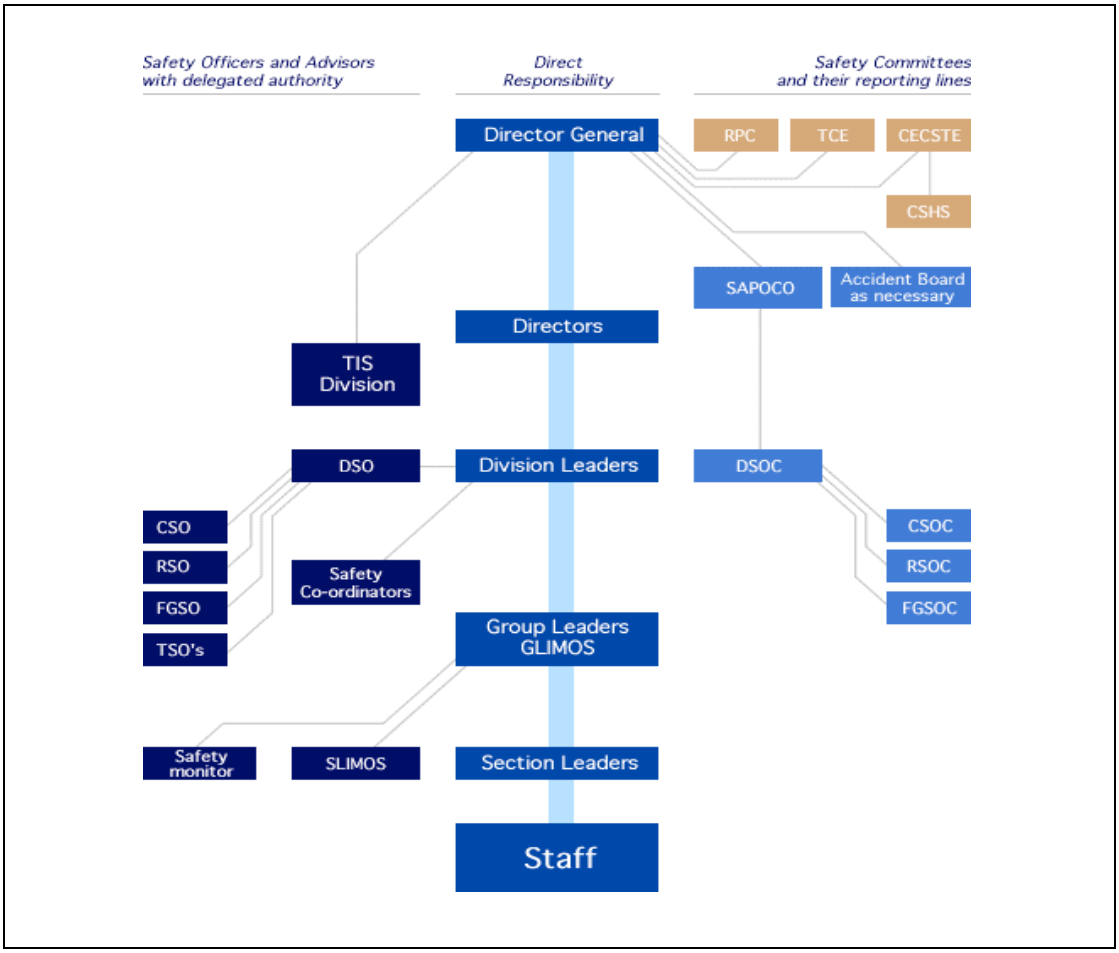
Down in the organisation chart, the Group Leaders (GL), Section Leaders (SL), Heads of Service (HS) and Workshop Foremen (WF) are answerable to their respective Department Leader for all safety and accident prevention matters related to the work under their supervision. If necessary, a so-called Safety Linkman will be appointed to assist them, and they all get support by Safety Officers responsible for their individual facilities.

Other safety responsible roles are defined, when experiment collaborations need special advice and support. They are represented in safety matters by a Group Leader in Matters of Safety (GLIMOS), who is responsible for the safety of the experiment from its design to dismantling, including its installation and operation phases. Moreover Shift Leaders in Matters of Safety (SLIMOS) ensure safety during shift work overnight and at weekends.

And finally all members of the CERN staff like personnel, fellows, associates, registered visitors, students, apprentices and temporary labour personnel are accountable for the observance of the safety rules to their immediate supervisors or to other persons specifically appointed to be responsible for safety issues relating to their visit or work at CERN.

As shown in the diagram below, safety responsibilities are an inseparable part of a hierarchical organisation:

Table 2 Safety organisation chart at CERN



Source: Safety Commission at CERN

4.1.2. Safety rules

As it is defined in CERN's Safety Policy the safety organisation is established to initiate, maintain, control and execute defined safety rules and requirements. As indicated in the document SAPOCO (CERN, 2006a), which defines the Safety Policy at CERN, Safety rules have mandatory force. They apply to all persons under the Director General's authority, including external contractors and users.

Safety rules follow a classification based on four types of documents:

- Safety Regulations (SR);
- Safety Plans and Safety Procedures (SP);
- General Safety Instructions (GSI);
- Specific Safety Instructions (SSI).

4.1.3. Classification of safety rules

The diagram below shows safety rules classified by domain and comes with briefly described tasks:

Table 3 Safety rules by domain

Occupational Safety and Site Policies		
Access to CERN	Health and Occupational Safety	Safety organisation
Access, visits and special events (extended meetings, conferences, exhibitions...), on-site policies.	Safety at workplace, rules on smoking and alcohol addiction, road traffic, ergonomic, occupational medicine, etc.	Procedures for establishing and updating Safety rules, organisational charts, emergency procedures, etc.
Safety for Accelerators and Experiments		
Design, installation, commissioning, operation, maintenance and decommissioning of accelerators and experiments.		
Radiation Protection		
Ionizing radiations, radiation protection procedures, radiographic inspections, radioactive waste management, radiological risks, etc.		
Technical Safety		
Work organisation	Worksites, Buildings and other Construction	Safety Systems	Fire Safety
General work organisation rules: individual protection equipment, personnel and material transport, material storage, etc.	Civil engineering, buildings, workshops, laboratories, worksites, etc.	Design, installation, commissioning operation, maintenance, decommissioning	Fire prevention systems and rules, new projects, fire fighting systems, etc
Electrical and Optical Safety	Chemical, Cryogenic and Biological Safety	Machines, Tools and Equipments	Mechanical Safety
Electrical installations, electric, electromagnetic and optical risks.	Dangerous fluids/materials, biological agents, asbestos, etc	Design, installation, commissioning operation, maintenance, decommissioning	Rules for mechanical, cryogenic and pressurized equipment.
Environment			
Industrial and domestic waste fluids, consequences of normal and degraded functioning on workers and environment.			
Accidents and Near Misses			
Response to accidents and near misses, internal emergency procedure			

Source: Safety Commission at CERN

The classification of safety rules sub-classifies safety rules in different levels: regulations, procedures, instructions and provisions. Thereby Safety Regulations (SR) translate CERN's Safety Policy into applicable and binding requirements for the purposes of occupational health and safety, environmental protection, safety of equipment and installations, and operational safety. Moreover Safety Plans and

Safety Procedures (SP) include main schemes, organisational charts, or programmes having binding effect in matters of Safety.

For that reason instructions, concerning General Safety (GSI) and specific Safety (SSI), determine, for defined fields of activity or defined types of equipment, how Safety Regulations as well as Safety Plans and Procedures must be implemented at CERN sites.

4.1.4. Actual safety management system

Several expertises and tools are used for monitoring, evaluation, documentation and control of compliance with all requirements matter of radiation protection and safety, as following:

SOS - Safety Officer's Support

This is an interactive list of Safety Officers at CERN (DSO, TSO, CSO, FGSO, GLIMOS) available via Internet.

EDH - Electronic Document Handling

This electronic databank service serves to manage personnel data and tasks like training catalogue, purchases, and transfers. Access is only possible by personalized and secured password.

EDMS - Electronic Document Management System

All CERN safety related documents and engineering & equipment data for users are administered within this electronic database system. Like the EDH before, access is only possible by personalized and secured password.

CERN document server

The CERN document server is kind of a document management sub-system managed also by an electronic database. There any kind of articles, books, proceedings, presentations, periodicals, reports and media files are administered. Like the data management systems before, access is only possible by personalized and secured password.

SIM - Safety Inspections

Special safety inspection reports (kind of comprehensive compliance checks) are available within EDMS. Again, access is only possible by personalized and secured password.

Compared with an integrated compliance management system, the tools listed above are more or less isolated solutions, being not yet fully integrated and interlinked with each other. Furthermore, monitoring and controlling regulatory compliance within projects and experiments by using those tools need quite extensive insight in processes, knowledge and practise in right searching technique and actually is very time consuming.

SMS - Safety Management System

For that reason an integrated Safety Management System (SMS) was started to being implemented. It consists of several processes: planning, implementation, operation, checking, correction/improving and finally a management review. The system is still under construction and lacks an integrated approach.

Findings

An integrated and comprehensive management system for administrating requirements, responsibilities, reminding, documenting, reporting and tracing of checks, audits, deviations, corrections, improvements in respect of radiation protection and safety rules/regulations and its' status of compliance is not yet in place.

4.2. Radiation Protection and Safety at CERN

As we have seen in the previous chapters radiation protection and safety issues are part of a holistic safety management structure at CERN. Within the Safety Commission a specialised division, the Radiation Protection Group, is responsible for operational matters concerning ionising and non-ionising radiation protection. The following Paragraphs will outline their very special role, operational work and responsibilities.

4.2.1. Mission statement

CERN is committed to having a high quality Radiation Protection and Safety Programme (FORKEL-WIRTH, 2010). The „Standards of Care“ will be the applicable regulations from both Host States, Switzerland and France, as well as international standards, IAEA and ICRP, with the guiding principle "As Low As Reasonably Achievable" (ALARA).

4.2.2. Mission mandate

The task of the Radiation Protection Group (RP) is to assess the hazards correlated with radiation and radioactivity, to ensure the safety of persons and installations in this field, and to advise and assist all those people working at CERN in protecting themselves from such hazards by complying with rules according to Preface Safety Code F. (CERN, 1996).

The leader of the Radiation Protection Group is entrusted with the technical interpretation of the rules in the field of radiation protection. He is responsible for providing the authorities of the Host States with the information specified in the agreements made between CERN and their radiation protection services, according to Preface Safety Code F. (CERN, 1996)

The staff of the Radiation Protection Group forms part of the Safety Commission (TIS). They help in the interpretation and application of the general rules in order to resolve the often complex and constantly changing problems encountered around the accelerators and in the experimental areas, according to Chapter 1 Art 1.2 Safety Code F (CERN, 1996).

4.2.3. Mission implementation strategy

The Radiation Protection Group supports the Director General by helping to achieve the scientific and technical goals and by helping to protect workers, public people and the environment from unnecessary ionising radiation exposure due to CERN activities and facilities. Other specially trained staff members assist the group in certain routine activities. The main responsibilities and work lie in training,

workplace monitoring, radiation work controls, radioactive materials control and environmental monitoring.

The Radiation Protection Group makes recommendations to senior and line organisation on radiation safety, conducts radiation surveys, directly monitors personnel and radiation-related work activities, evaluates the effectiveness of controls and processes and ensures that work is conducted in accordance with all applicable requirements.

Within its responsibility to monitor activities and compliance subject to radiation protection regulation the Radiation Protection Group has to use a systematic management approach.

4.2.4. CERN radiation protection regulations

On the basis of what was stated in sub-chapters 3.3 and 4.1 it may be inferred that applicable regulatory framework in radiation protection at CERN is composed of two sources, internal CERN Safety Rules and subsidiary provisions from regulations of the Host-State concerned.

CERN Safety Rules are written and executed by the Radiation Protection Group with support of several committees and commissions[31]. With respect to interviews with radiation experts (FORKEL-WIRTH, 2010), CERN's own regulations are composed in accordance with relevant Host-States acts[32], European directives[33], international conventions[34] and international standards[35]. Whenever there is no own CERN's rule or regulation concerning a special situation, procedure or process subject to radiation protection, Host State regulation is the alternative applied (EDER, 2010).
The actual CERN Safety Rules concerning and related to radiation protection at CERN are listed below:

[31] see sub-chapter organisation (4.1.1)
[32] among others: SrahlenschutzVO 1994
[33] among others: EU Council Directive 96/29/EURATOM, EU Council Directive 2008/231
[34] among others: IAEA Safety Guide RS-G-1.4, Safety Series No. 115
[35] among others: ICRP-75 (General principles for the radiation protection of workers), ICRP-103 (Recommendations of the International Commission on Radiation Protection)

Safety Code F Rev. - Radiation Protection (2006)

The code sets out the basic principles of radiation protection and the rules for protection of occupationally exposed persons at CERN and for protection of the public and the environment. These rules include exposure limits for occupational exposure and exposure for members of the public, classification of areas, optimisation (ALARA) including job planning, management of radioactive waste and management of radioactive materials and sources (CERN, 2006b).

Safety Code F - Radiation Safety Manual (1996)

This code is superseded by code "Radiation Protection (2006)". However, safety instructions for radiation protection contained in this manual remain valid for a transition period (CERN, 1996).

Safety Code U1 - Procedure for the control of Basic Nuclear Materials on the CERN domain (1994)

This code aims at establishing regulations for the control of depleted uranium, deuterium, enriched lithium, thorium, etc., and applies to all activities concerning import, export, transfer and use of fissile materials by the Organisation for purposes of scientific research (CERN, 2010a).

Safety Note NS 7 - Recommendations for the safe use of uranium at CERN (1979)

Within these requirements properties of uranium and of the radiation hazards (external or internal irradiation) are described. It is a kind of reminder of the procedure to be followed before any order of uranium pieces (CERN, 2010a).

Safety Note NS 16 - Rules concerning the transport of radioactive material (1997)

These rules are intended to minimize the amount of ionising radiation, for the benefit of anyone applying for transport and of those responsible for the supervision.

Safety Procedures (various)

Accordingly for any work or other purpose concerning radiation protection, special procedures are formulated, based on CERN's own safety rules and relevant Host-States regulations (e.g. „Working rules for the medical X-ray equipment", „Rules for

industrial radiography“, „Use of radiation protection instruments by other groups than RP“, „Working rules for the treatment and storage of radioactive waste at CERN“, „Emergency procedure in case of fire for the radiation areas of the SC Division“, „ Periodic calibration of Radioprotection instruments“ etc.).

Findings

Due to the very unique situation of an organisation for research, development and demonstration (as it is defined for technology-oriented agreement) and being a subject of International Law, CERN follows a teleological approach[36] in dealing with its responsibilities. It has the possibility to create its very own regulatory framework upon its' own intrinsic needs and individual special applications. Nevertheless, this framework cannot be defined arbitrarily. It is based on the most advanced regulatory requirements derived from bilateral agreements, international conventions, worldwide standards and national laws.

The major aim of CERN radiation protection safety rules and regulations is to provide comprehensive protection for every person working at and for CERN, protection of the environment and safety for all installations, facilities and experiments conducted at CERN. It achieves these goals very successfully not by application of one lonely national standard but with an integrated overarching approach by applying related and interlinked legal norms from different legal frameworks.

[36] Derived from philosophical study of telos i.e., of purpose, aim, end (SANDEL, 2009)

5. Outlining a solution

In this section the author will examine an adequate solution for a regulatory compliance management system at CERN. The author will examine standard procedures concerning compliance management systems already available (ISO standards and IAEA standards). Necessary functionality and special features of the system will be outlined. Differences compared to the system actually in place will be described. Intended users will be defined and their needs, roles and responsibilities will be discussed. Additionally any expectations by stakeholders towards the system, related benefits and drawbacks, will be explored. And finally criteria will be specified in order to provide comprehensive information for a final decision-making process of implementing a suitable and sustainable solution at CERN.

5.1. Regulatory framework at CERN

Like it was outlined in chapter 4.2.4, CERN has got his own regulatory framework for radiation protection requirements in place. This regulatory framework is not static but rather dynamic to meet the necessary requirements by applying European and national legislation[37], but also deploying developments subject to international recommendations and standardisation (FORKEL-WIRTH, 2010).

[37] see also chapter 4.2.4

This framework[38] consists of various policy, management and technically related documents; explicitly „Codes“, „Notes“ and „Instructions“[39]. All these documents provide specific content, like general principles, organisational arrangements, management measures, as well as specific instruction and mandatory orders regarding radiation protection and safety issues.

5.1.1. Adapting the regulatory framework by self-assessment

The point of concern is that following the dynamic alteration and development of “external” radiation protection regulations just-in-time is somewhat slowed down by inertia. Even though there is some procedure[40] available, the evidence seem to indicate that CERN human resources are limited and time-constrained due to highly sophisticated and intense work-load for the radiation protection experts, additionally accompanied by lack of manpower.

In case of new regulation rising from the international or national realm, the implementation process into the actual CERN regulatory framework takes time. The time-constraints evolve due to various reasons:

First, the new regulation or recommendation has to be identified. This requires an ongoing monitoring of the various regulatory and advisory bodies (e.g. EU/EURATOM, IAEA, ICRP and national laws) investing in radiation protection issues and extended knowledge as well as vast experiences about internal concerned and applicable processes.

[38] Often also called „Code of Conduct“ within several CERN documents
[39] The new classification at CERN is devided into “Safety regulations”, “ Safety Plans and Procedures”, “ Generaly Safety Instructions” and “Specific Safety Instructions. Radiation Protection rules are not transfered yet.
[40] Safety rules are regularly reviewed and revised. The general revision process follows the procedure *„Safety rules preparation and issuing“* and the internal document *„SP-R1 - Safety Procedure for establishing, updating and publishing CERN Safety rules“*

Second, if the already identified regulation or any other normative rule is considered relevant for some applications within CERN, it has to be introduced into the existing and regulatory framework (regarding rulemaking bodies and procedures).

Third, the identified and relevant regulation has to be compared with the existing internal regulations. That could be rather difficult because an indication system is neither available within the regulatory framework itself nor in the safety management system. Every safety document has to be reviewed by assessing relevance or connection to the newly identified and relevant regulation. In that respect, this is highly time-consuming and will result in a delay for the next steps.

Fourth, before implementing the identified and relevant regulation (even only some parts or somewhat altered content) in all considered internal codes, rules and procedures is possible, the issue has to undergo an extensive discussion and decision-making process, passing several bodies concerned with internal policy but also regulatory issues (like Safety Commissions (SC), Radiation Protection Committee (RPC)).

Finally, after a decision has been taken to adapt the regulatory framework to a new safety regulation (containing either the whole identified and relevant regulation or only parts of it), all the safety documents have to be revised. More to come, it has to be officially announced to everyone concerned and has also to be trained to people, in particular to those who need it for immediate protection and safety issues.

Therefore it must also be considered that only announcement and sporadic training is not sufficient for a proper implementation of new safety regulations. Compliance with the introduced rule has to be guaranteed continuously, too. This comes with controlling problems and rises the main question: how to ensure compliance and to control it efficiently?

5.1.2. Adapting the regulatory framework by external interference

Beside the self-assessment of relevant radiation protection regulations developed and established by national and international regulatory bodies, CERN has some customary legal obligations to apply certain regulations imposed by the competent bodies of the Host States. This was done previously by several bi-lateral Host-state-agreements and recently by a newly installed committee, called the *Tri-Parti Committee in Radiation Protection*, which is considered a platform between both Host States and CERN to discuss and develop CERN's regulatory framework in radiation protection issues in a more integrated and transparent way[41].

In case of a new adapted regulation, introduced by the *Tri-parti Committee*, the procedure of implementation in CERN's regulatory framework is the same like under the self-assessment procedure mentioned above.

5.2. Regulatory Compliance Management System

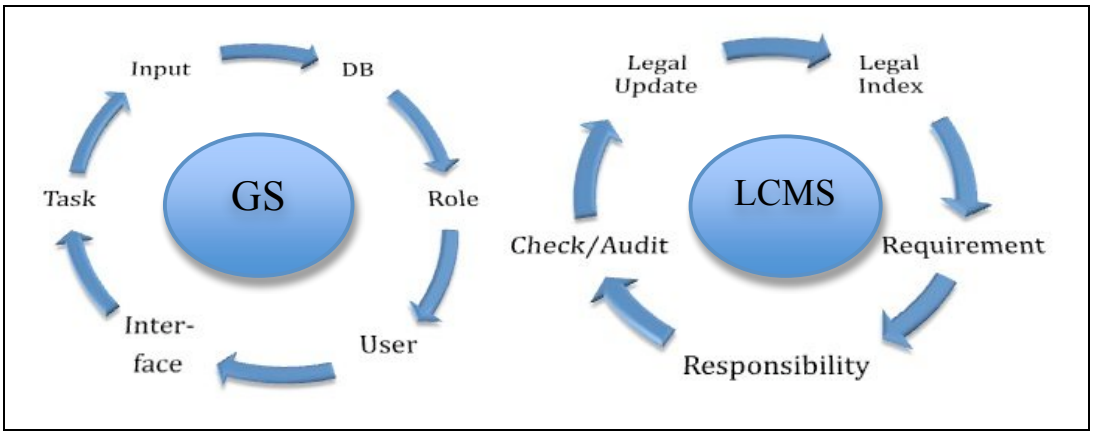
The procedures sketched in chapter 5.1 now have to be systematically administered by an integrated software based management system.

A management system in general is the framework for procedures and processes used by an organisation to meet their requirements. It is driven by the very simplified steps "PLAN – DO – CHECK – ACT" already introduced by Sir Francis Bacon in 1620. More or less any management system which has to meet convenors' aims by making improvements to the related processes has to keep track on that simple steps, also in case of an advanced regulatory compliance management system.

[41] The committee consists of CERN and the competent bodies of Switzerland and France. It has the objective, that best practices established in the field of radiation protection and safety - subject to legislation and regulation of the Host States, European laws and directives, to international recommendations and standards, which have been prescribed by IAEA, WHO, and ILO - are being used within the organization of CERN where ionizing radiation is used (FORKEL-WIRTH, 2009).

Every system consists of several compartments, defined by their composition, characterisation/behaviour and interrelations/interconnections to fulfil a certain function (v. BERTALANFFY, 1949). Given this evidence, it can be seen that a regulatory management system also consists of certain sub-parts, like every common system, to fulfil its intended function. This function means to guarantee compliance with any concerned requirement, no matter if they are mandatory or voluntary:

Table 4 Basic components of General Tasks Management Systems (GS) & Legal Compliance Management Systems (LCMS)



Source: Own illustration; Copyright 2010

These very basic components could be found in nearly every task management system. A quite good source of well discussed and elaborated management systems dealing with general and organisational requirements can be found in several industrial management standards.

5.2.1. Industrial Standards

With years of experience gained since the publication of the International Regulatory Standards (e.g. ISO 14001, ISO 31000), one of the mayor objectives remains to improve the organisation's regulatory performance with respect to its management of direct and indirect governance aspects and associated impacts, whether or not they are linked to legal requirements.

Interestingly, there is no industry standard available for regulatory management like for example in quality management (ISO 9001 series), in environmental management

(ISO 14001 series) or risk management (ISO 31000 series). But within these standards you can find at least some hints dealing with compliance procedures and duties.

ISO 14001

ISO 14001 requires an organisation to make a commitment in its environmental policy to comply with applicable (environmental) legal requirements. This commitment includes establishing, implementing and maintaining procedures for periodically evaluating compliance with applicable legal requirements that are consistent with realising this commitment.

But in ISO 14001 you will only find some single chapters concerning legal compliance within an organisation or any related undertaking. The specific clauses of ISO 14001 which are most important with respect to legal compliance are the following elements:

- Public environmental policy commitment to legal compliance (sub-clause 4.2);
- Identification and having access to applicable legal requirements and other requirements related to their environmental aspects (sub-clause 4.3.2 a);
- How those legal requirements apply to the organisation's environmental aspects (sub- clause 4.3.2 b);
- Objectives/targets/programmes (sub-clause 4.3.3)
- How legal obligations are routinely managed and monitored (sub-clauses 4.4.6 and 4.5.1);
- Evaluation of legal compliance (sub-clause 4.5.2);
- Corrective and preventive actions where necessary (sub-clause 4.5.3);
- Internal audit (sub-clause 4.5.5);
- Management review (sub-clause 4.6).

According to these chapters, the European co-operation for Accreditation (2007) has finally defined “legal compliance” related to ISO 140001 as:

"Full implementation of applicable environmental legislation. Compliance occurs when requirements are met and desired changes are achieved."

It has to be stressed that the understanding and implementation of legal (or in sense of international bodies, in the more broader meaning of "regulatory") compliance may vary from country to country and depends on the regulatory background and governance culture of the organisation.

ISO 31000

Systematic risk management is a rather new branch in strategic management of organisations. Although the consciousness about risk has ever been to any operation and its objective, the adaption of a systematic management process dealing with risks in a transparent and credible manner is becoming high attention to concerned stakeholders and risk owners[42].

Countless requirements[43] based on legal permissions, technical standards, company policy, expert recommendations, internal orders and stakeholder claims, pose a risk on company processes but also to responsible officials and representatives. Therefore managing these requirements is a primary goal within responsible organisations and are strongly embedded in their overall risk management.

The ISO 31000 (2009) Standard provides principles and general guidelines on risk management. There is a strong relationship identified between managing risks and the legal or regulatory framework in which it occurs. The Standard explicitly lists some positive consequences of organisational managed risks related to regulatory issues:

[42] According to ISO 31000 (2009) a *risk owner* is a person or entity with the accountability and authority to manage a risk

[43] According to ISO 31000 (2009) also called *risk criteria*. Risk criteria are based on the external and internal environment (cultural, social, political, legal regulatory, financial, technological, economical environment whether international, national, regional or local) in which the organisation seeks to achieve its objectives (operation, projects, products and services, assets, practice, relationship with stakeholders, governance, organisational structure, resources and knowledge capabilities) and can be derived from standards, laws, policies and other requirements.

- Complying with relevant legal and regulatory requirements and international norms
- Improve overall governance
- Improve stakeholder confidence and trust
- Improve controls
- Effective allocation and use of resources
- Enhance health and safety performance and environmental protection
- Improve loss prevention and incident management
- Minimisation of losses
- Improvement of operational effectiveness and efficiency
- Improvement of organisational learning
- Improvement of organisational resilience
- Establishing a reliable basis for decision making and planning

Accordingly, it is stated in the ISO 31000 standard:

> *„(...) risk management contributes to improvement of performance in, for example, human health and safety, security,* ***legal and regulatory compliance****, public acceptance, environmental protection, product quality, project management, efficiency in operations,* ***governance and reputation****."*

Findings

Regulatory compliance management is not a static stand-alone activity that is separate from the main activities and processes of an organisation. It is part of the responsibilities of senior management and an integral part of overall risk management including all organisational processes, strategic planning for future projects and all project management processes. A systematic approach can help management and decision-makers to meet with an overwhelming growth of legal requirements, increasing public awareness and perpetual media presence. Moreover, risk management recognizes the capabilities, perceptions

and intentions of external and internal stakeholders that can facilitate or hinder achievement of the organisation's objectives.

A clear and concise policy along with full commitment by senior management will ensure that risk management remains relevant and up-to-date. Therefore, the integrated application of standards like ISO 9001, ISO 14001 and ISO 31000 to CERN regulatory compliance management in radiation protection and safety is highly recommended.

5.2.2. International Standards

When dealing with radiation protection and safety issues within processes there will always be a strong dependence of regulatory frameworks and technical recommendations by international governance bodies and committees. According to the Department of Nuclear Safety & Security, the International Atomic Energy Agency (IAEA) provides *„a strong, sustainable and visible global nuclear safety and security regime that provides protection of people and the environment from effects of ionizing radiation, minimization of the likelihood of accidents or malicious acts that could endanger life and property, and effective mitigation of the effects of any such events.“*[44]

IAEA

The IAEA has already published various guidelines dealing with management systems for safety requirements concerning facilities and activities. IAEA Safety Requirements GS-R-3 (IAEA, 2006a) define the requirements for establishing, implementing, assessing and continually improving a management system that integrates safety, health, environmental, security, quality and economic elements that are properly taken into account in all the activities of an organisation. Regarding regulatory management, the publication also explicitly covers not only nuclear facilities but also radiation protection activities and any other practices or circumstances in which people may be exposed to radiation from naturally occurring or artificial sources and the regulation of such facilities and activities.

[44] Derived from http://www-ns.iaea.org on April 26th 2010

Generally the IAEA stresses that senior management shall always demonstrate its commitment to the management system and shall allocate adequate resources to carry out these activities. It shall communicate its commitment to any stakeholder.[45]

The IAEA also states that the management system shall identify and integrate the requirements according to statutory, regulatory and any other requirements[46] formally agreed on with concerned stakeholders[47]. Moreover it is also mentioned by the IAEA that the management system shall include descriptions which explain how work has to be prepared, reviewed, carried out, recorded, assessed and improved, similar to compliance checks mentioned in the previous articles. According to sub-clause 5.18 (IAEA 2006a), controls shall be used to ensure that requirements do not bypass the required verification activities. Additionally it can be derived from the IAEA document[48] that any record shall be specified in the process documentation and shall be controlled. All records shall be well administered, by being readable, complete, identifiable and easily retrievable. In case of non-compliance[49] to specified requirements, the circumstances shall be identified, segregated, controlled[50] and recorded[51].

Interestingly, the IAEA document[52] also suggests some kind of organisational unit with the responsibility of conducting independent assessments, which is quite comparable to the proposed[53] compliance management officer (CMO).

And finally the IAEA also recommends a frequent management system review to ensure the continuing suitability and effectiveness of the management system and its ability to enable the organisations objectives set to be accomplished.

[45] also sub-clause 3.12 (IAEA, 2006b)
[46] also sub-clause 3.9 (IAEA, 2006b)
[47] also sub-clause 3.8 (IAEA, 2006b)
[48] in sub-clause 5.21 (IAEA, 2006a)
[49] also sub-cluases 6.50 until 6.58 (IAEA, 2006b)
[50] also sub-clauses 6.59 until 6.65 (IAEA, 2006b)
[51] also sub-clauses 5.35 until 5.49 (IAEA, 2006b)
[52] in sub-clause 6.4 (IAEA, 2006a)
[53] see chapter 5.2.4

Findings

The IAEA Safety Requirements GS-R-3 (IAEA, 2006a) and Safety Guide GS-G-3.1 (IAEA, 2006b) are by and large consistent with the requirements of industrial management systems concerning the management of general safety issues. The principles of planning, assessment, communication, monitoring and controlling organisation's requirements are generally the same, like they are in ISO 9001, ISO 140001 and ISO 31000, but of course more related to radiation protection and safety issues.

On this basis it has to be concluded that the IAEA management system requirements of both documents are considered as state-of-art processes. Its assessment and occasional appliance at CERN with regard to implementing a monitor system for compliance with radiation protection and safety issues is highly recommended.

5.2.3. System requirements

Any system to monitor compliance of operations, processes, products, practice and assets with related rules and regulations, mainly consist of basic parts as listed below:[54]

- Procedures (e.g. Input/Output, right/wrong)
- Function Logic (for correct data processing)
- Structures (e.g. processes, facilities, roles, interconnections)
- Input data (e.g. text, symbols, pictures)
- Content
    - Index (List of rules, laws, requirements, procedures, orders, tasks, controls)
    - Provisions (text/pic information, derived from rules and laws in the register)
- Audit/check procedures (Verification of the information and provisions on-site)

[54] List without claim to completeness. Derived from www.gutwin.at on 18.02.2010

  - Commenting results
  - Documentation[55]
- Output (e.g. alerts, reminders, information, listings)
- User (e.g. roles, individual access, password security)

For that reason, computer processing data based software is the most advanced and capable solution[56]. Basically it contains an electronic database (e.g. SQL based systems) and specific software application with graphic interface (e.g. html, webbrowser).

Moreover the database and software system should have special aesthetical[57] competences, besides its basic functionality and data processing. It must have at least a simple user interface, invisible redundant procedures, good design and high usability. It should also be easy to upscale, to adjust and to extend to users' needs.

All these qualities are not yet system immanent, but they will help to improve the acceptance and the overall performance and reliability of the system a lot[58].

A comprehensive market search in software based regulatory management systems available on the European/world-wide market is not in the main scope of this thesis. It will be one of the initial planning steps within the management implementation process. However, one well recognised provider is mentioned in the annex.

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[55] According to IAEA (2006b), an electronic document management system consists of *„the computer hardware, software and databases that allow for the integrated preparation, input, distribution, storage, location and retrieval of electronic documents, whether initially created electronically or produced from paper documents."*

[56] also Annex II and Annex III IAEA (2006b)

[57] *Aesthetics* is kind of a senoric-oriented science examine ways of seeing and perceiving the world.

[58] The implemenation of an integrated legal complinace management system at Treibacher Industry AG turned out to become a great success because of the investment in better interface design and usability to be as clear, precise and simply as possible. Within the recertification process for ISO 14001 by Lloyds of London, the lead auditors mentioned in their final report, that the new legal complinace management system shows great acceptance among users, because of the simplicity, clarity in structure, unambiguity to the user and uniqueness of its functionality. It was also regarded as best-practice in the Austrian chemical and nonferrous metal industry.

Software procedures

Functionalities are various in their aims, structure and procedures. Some main and necessary functionalities of the database system in an LCMS are listed below[59]:

- Organisation (of internal safety rules, relevant external safety regulations – global legal register for all kind of "Safety Rules"),
- Tracking (in case of changes in national/international regulations),
- Transferring (input of identified and relevant requirements into the database, transfer of data via man-machine interface),
- Administration (structuring different processes/facilities/responsibilities according to the real situation; frequency of checks, alarms, deviation analysis, documentation, reports),
- Linking (all relevant data within all assigned facilities, processes, requirements and all allocated persons, checks and reports)
- Compliance (by individual authorized check procedures),
- Controlling (status of compliance by assessing the input-data quality and quantity)
- Effectiveness (input-data evaluation just-in-time; only occasional random audits needed)
- Efficiency (less time-consuming random spot-checks based on web and browser based software)

Software benefits

Every software based management system comes with a certain intend to improve a given process or organisation. A systematic approach of dealing with any kind of regulation (tasks and orders, mandatory or voluntary, legally binding or non-binding, laws or recommendations) within a software based management system brings benefits. Just to mention some of the most important[60]:

[59] List without claim of completeness
[60] derived from the authors own experiences

- Structured and comprehensive list of all new and modified regulations with link to the original text
- Follow up of changes in laws and regulations with a direct link to relevant audit/checks already set up in the system
- Clear and unambiguous distribution of tasks and responsibilities within any task, procedure or operation
- Centralised and timely coordination of appointments, reviews, audits, checks
- Automatic notification of by email for assigned reviews, audits, checks
- Filtering and analysis functions ("who, what, when, where")
- Support information for human resource planning
- Easy adaptation of procedures and processes within the operational structure
- Complete documentation and data availability

5.2.4. User requirements

Every management system has his users and other stakeholders, with their special needs and perceptions. It is necessary to understand the internal context, like the organisation's culture, the relationship between the internal stakeholders, information flows, decision-making processes, resources and knowledge. Within those experienced factors, it is known as a golden rule, that a successful management system has to follow its users and their needs, not vice versa. But needs are generally neither easy to assess nor are they the same for everybody. Internal and external stakeholders want to satisfy their very own needs to meet their obligations or perception. In the same way they share some common interest like keeping the undertaking safe; meaning to protect people, property and the whole acting environment from disruption, damage or losses. So the information being managed in the regulatory management system needs to be well defined according to the users' needs. Generally spoken the system should only be used within the organisation whereas information needed by external stakeholders should be derived and composed by internal responsible users according to the external stakeholder concerned.

Below some crucial stakeholders are described and examined in detail.

Management board

The senior management[61] should be fully committed to the compliance management system. Its commitment has to be communicated to employees and other persons working for or on behalf of the organisation. The data collected by the compliance management system should be accessible to and processable for them, in matter of periodic management reviews of its suitability, adequacy and effectiveness.

Staff

Considering the fact that personnel, workers and clerks (so-called "verifiers") are those people who ultimately perform compliance checks (e.g. in radiation protection and safety), the data input and the use of the interface have to be easily trainable, understandable and operable.

Moreover the person in charge of compliance-checks (subject to radiation protection and safety rules/regulations) concerning a facility, object, machine, waste or any other process must be fully aware and confident with his task. Every data input to the compliance management database has to match exactly with the discovered real-life situation.

Transparency within all processes and responsibilities will help to increase awareness in everyone's effort and contribution to the common mission and its values. It will bring people up to a higher level of skills, competences and attentiveness subject to their tasks and responsibilities. Hence it will strengthen organisational credibility, trust and value.

Compliance Management Officer (CMO)

It has been shown[62] that planning, introduction and maintenance of a compliance managing system require additional resources. Therefore it is highly recommended to appoint a special person in charge of implementing and running the regulatory

[61] *Senior management* means the person who, or group of people which, directs, controls and assesses an organization at the highest level, for example: director general, executive team, department leader, section leader, laboratory director

[62] The author was responsible for implementing a legal compliance management system in chemical industry (project had to cover over 500 legal permits with over 5000 provisions)

compliance management system. Within planning, implementing and maintaining the system the CMO has to take care about several important tasks:

- Conducting the planning and design phase of the implementation procedure,
- Supervising the compliance management system (maintenance and optimisation),
- Ensuring that only duly authorized[63], unambiguous, realistic and measurable compliance checks are established within the system,
- Supervising amendments and changes to the system (e.g. adding new requirements and frequent checks and also changes in organisation, structure and procedures).
- Reviewing reliability and correctness of compliance checks regularly, at least annually (by random audits).
- Ensuring that adequate capabilities (education, training, knowledge) are given to the "verifier" for safely carrying out any (radiation protection and safety) compliance checks[64].
- Ensuring that adequate authority is given to the "verifier" for correct transacting (radiation protection and safety) compliance checks.
- Ensuring that the "verifier" understands the task of compliance checks without misconception. Fundamentals of the radiation, its risks, and their role in minimizing exposure are needed for basic understanding of compliance checks within radiation protection rules and regulations.
- Ensuring to identify deficiencies and concerns in conducting radiation protection compliance-checks. Prompt action should be taken to address and eliminate identified issues and prevent recurrence.
- Ensuring that "verifier" of compliance checks (in radiation protection and safety control) is familiar with the design features and operations of the

[63] The authorization for adding a new requirement to the system, should be made jointly with those who are responsible for compliance.
[64] Training, in cases of radiation protection checks, should be provided by the Radiation Protection Group but the responsibility for effective translation to check practice rests with line organization

facility that affect the potential for exposures of persons to danger or risks (e.g. radiation) within the checks.

Based on results of monitoring and reviews, the CMO together with the senior management should decide on the improvement on the compliance management framework, policy and plan according to the organisation's overall strategy.

Other (external) stakeholders

In principle, the regulatory compliance management system is and should be exclusively accessible by the organisation. It is first and foremost an internal tool that is intended for use and optimisation of internal processes. It allows the management both an overview of the status of overall compliance and control and optimisation of associated processes.

Like it is the case in other public related management processes (e.g. quality and environment management) stakeholder satisfaction should be derived by the positive impacts and results of the system. The organisation's performance may be audited by independent bodies (certification organisation), published and communicated to external and internal stakeholders.

5.2.5. Implementation Strategy

As a general advice, the regulatory compliance management process should be an integral part of CERN's senior management, embedded in the culture and practices, and tailored to the organisation processes and needs of the stakeholders. The major implementation tasks can be transferred and applied directly from clause 4.4 in ISO 31000:

First, defining timing and strategy for implementing the management framework for radiation protection and safety issues.

Second, applying the compliance management policy and process to the organisational specified radiation protection and safety processes.

And third, ensuring that decision-making (e.g. within SAPOCO), including the development and setting of objectives is aligned with the outcomes of the compliance management processes.

These processes should be supported by both information meetings and training sessions and communicating and consulting with stakeholders, to ensure that its compliance management framework will be accepted.

Organisational structure

It has already been outlined in former chapters that regulatory compliance management is or should be part of risk management. Nevertheless it affects CERN in different areas, functions and responsibilities. Therefore it is highly recommended that its management responsibility should be embedded in the upper management organisation and closely related to policy and decision-making processes; like SAPOCO and/or Safety Commission. The assignment of a Compliance Management Officer (CMO) for efficiency reasons is highly recommended.

New Section „Regulatory Compliance Management“

From own experience the author recommends a pooling of competences in a new organisational unit. Reason for that is the simplification of communication during implementation process and higher efficiency within operation of the management system. Moreover, several tasks like safety policy support, risk management support, compliance reporting, ongoing regulatory development with public stakeholders, regulatory communication/representation in standardisation bodies and/or International Organisations and also internal governance optimisation will gain from centralisation. According to current organisation systems, the regulatory compliance management department could be established under the Directorate General and/or subsidiary to Risk Management Department.

Monitoring the system

Like mentioned before in chapter 5.2.5 the main objectives may be extracted from corresponding clauses in ISO 31000 as well as from IAEA Safety Requirement GS-R-3 (IAEA, 2006a) and Safety Guide GS-G-3.1 (IAEA, 2006b).

In order to ensure that regulatory compliance management system works effectively, the organisation should assess periodical performance tests by reviewing the management plan and its appropriateness, according to the basic compliance strategy and the requirements of the regulatory framework.

5.2.6. Implementation Timeframe

In any case, the planning phase within the implementation procedure is of high importance. As in every strategic management process, the system must be tailored to the organisational framework subject to the result to be achieved. Especially in complex research projects such as CERN, personnel and time expenditure can easily be compared with the implementation of environmental and quality management systems in complex industries like automotive, pharmaceuticals and space endeavours like ESA for example. One approach for implementation can be found described in detail within the relevant standards ISO 9001, ISO 14001 and ISO 31000 and also in recommendations concerned by the IAEA.

Generally spoken the whole implementation phase should be subdivided into a short-term, a mid-term and a long-term perspective. Every stage in these processes goes along with specific workloads and special organisational impacts and also comes with defined milestones and intermediate results.

The person responsible should be experienced in management systems, especially ISO 9001 or ISO 14001. Hence, he or she should work out a clear and concise work programme (e.g. the CMO together with concerned department leaders, senior management, radiation protection specialists and CERN's risk management officer) under consideration of recommendations mentioned in chapter 5.2.

6. Discussion

The introduction of a Regulatory Compliance Management System at CERN will be a challenging undertaking. It may not only require a multidisciplinary approach with respect to technical and legal aspects but also a deep understanding of the internal and external context framework of the organisation (policies, cultures, values, stakeholders). On the other side synergetic benefits of an implementation are expected being brought to other departments and applications of CERN. This kind of a spill-over effect will be outlined.

Moreover, to achieve compliance with all relevant requirements concerning radiation protection and safety regulation by implementation of an integrated regulatory compliance management system at CERN some fundamental aspects about "good" governance of requirements and occasionally "bad" over-compliance with requirements have to be considered as well.

6.1. The spill-over effect

Introducing a regulatory compliance management system will certainly have several further positive effects on general management and organisation at CERN.

Integrated risk management

According to MEULBROEK (2002) "Integrated risk management" is "the identification and assessment of the collective risks that affect firm value and the

implementation of a firm-wide strategy to manage those risks". In former times persons in charge have always practised some kind of risk management, but it was not often undertaken in a systematic and integrated way across an undertaking. Integrated risk management has only recently become a practical possibility, mainly based on the efficient computer applications and other communication technologies.

A systematic listing of any requirement, which has to be followed within CERN and also its compliance status, will have great benefit for integrated risk management. Risks could much easier be discovered and assessed within its electronic database of requirements. Regulations concerning technical equipment, processes and procedures, especially in radiation protection and safety, are inducing some kind of risk for health and environment. Most of them have been introduced to protect man and environment from being endangered or even harmed, just by complying with the requirements of concerned regulations. There is already a strong relationship identified in ISO 31000 between managing risks and the framework in which it occurs. Defining the management framework by structuring the elements and organising the key procedures will help competent responsible dealing with risk evaluation to make management more accurate and efficient.

General safety management

According to the SAPOCO document (CERN, 2006a) Safety management includes several duties, which have to be under permanent supervision and evaluation. Within these duties, there are obligations of frequent compliance checks with safety regulations at CERN. The Safety Commission at CERN is responsible for compliance with checks and tracking of inspections conducted. Safety experts also have to keep themselves properly informed of national and international Safety standards and regulations. Moreover they have to draw up and issue safety codes and other instructions to relevant departments, facilities and experiments. In this respect, following up inspections and measures for improvement but also complete documentation procedures will become more effective and efficient when using the computer-based Regulatory Compliance Management System.

Inspection and equipment monitoring

At CERN the General Infrastructure Service (GS) department provides and supports all experiments with technical services. Their main mandate includes infrastructure and services to ensure the preservation of health and safety of any person at CERN e.g. by access control, construction and maintenance management or safety system engineering. It is absolutely obvious that a Regulatory Compliance Management System, already applied within the structures of CERN, would also complete and improve overall procedures in any subdivision of GS, too. As an example, the GS/ASE department, responsible for Access, Safety and Engineering data management tools, already provides the Engineering Data Management System (EDMS), the Equipment Data Management System (MTF), the Job Management Tool (JMT) and many more. Any requirement managed in RCMS can be made fully accessible and evaluable to GS departments and management systems in place to be used and supplemented on demand.

In best case LCMS and GS based technical management systems result in an integrated and comprehensive database, supporting competent management in decision-making processes.

6.2. The Good Governance aspect

Good Governance was initially invented by International Organisations (e.g. United Nations and World Bank) and further developed by scholars in International Relations and National Administration. According to CZETTL (2009) the concept is to stimmulate the interaction between different stakeholders, driven by different socio and political forces.
In that respect it has extended from its original focus on traditional government action of utilizing power to enforce compliance, to now focus on addressing different stakeholders in a more co-operative and communicative sense.

The generial intention for applying a management system dealing with regulatory issues is managing related risks in a systematic, transparent and credible manner. It

lies in the eye of the beholder, how and to what extent that scope should be met. The workers want full protection and safety regarding their work, the organisation aims to meet protection and safety as low as reasonable achievable within its operations and personal, the authorities want to have the organisation being compliant with their regulatory framework to balance the socio and economic requirements, and finally neighbours and other concerned public want to have full transparency and accountability in the organisations work.

The question raises, what kind of considerations and factors should an organisation take into account when it comes to good practises in managing its processes, activities and assets?

For that reason, one have to look at the basic goals and perspectives of Good Governance to derive some link to good management practise (especially for regulatory issues) within some kind of intergovernmental organisation (like CERN).

Definition of Good Governance

Although there is no agreement on an official definition available (EC, 2003), variable reliable sources can be found in the field of economic development[65], describing principles of Good Governance as follow: Participation, rule of law, transparency, consensus, responsiveness, equality, effectiveness and efficiency, accountability.

According to EC (2003) the term can be associated in general with *"a basic measure of quality and performance of any political/administrative system".*[66]

Regarding a successful integration of regulatory management at CERN, good governance - with respect to the performance of the administrative system and satisfaction of all stakeholders - should be measured on six major principles:

[65] for more details see www.unescap.org, www.undp.org, www.worldbank.org, www.oecd.org
[66] Art. 4 COM (2003) 615

Participation, Rule of Law, Accountability, Transparency, Effectiveness, and Efficiency[67].

Participation in terms of freedom of expression, through-all-level communication and contribution to the objectives and development of the organisation strengthens the relationship between all stakeholders and also contributes to overall trust in policies, systems and processes.

Following the principle *Rule of law*, in respect of the supremacy of regulatory requirements, plays another important role within an organisation's accountability and reliability. It means by and large that only what is written counts. Whether governor or governed, or rulers or ruled, no one can grant exemption to the application of the law. It means also that it has to come with some kind of enforcement animus. Introduction of requirements for a certain process, not communicated and enforceable to everyone and everywhere within the organisation's complex, will immediately result in a washy commitment to the introducing system.

Therefore it may be inferred that *Accountability* is very closely linked to following the Rule of law. Generally spoken, an organisation is accountable to those who will be affected by its decisions and/or activities. Furthermore it stands for continuity and sustainability of all decisions and activities of an organisation.

Judgements, decision-making, monitoring, controlling, communication, management and compliance, all of these terms have to be done on basis of „Rule of law" and in a transparent manner. That means that all information concerned should be distributed or made available to all stakeholders. Hence it will also contribute to the accountability of the organisation.

Finally, any organisation naturally aspires for effective and efficient procedures (management and processes). However there is no contrary opinion on that issue,

[67] The following statements are derived intutively, based on the related work by CZETTL (2009) with no claim on completeness and accuracy. It is meant to serve for an open discussion.

unless humans and the environment are endangered, spoilt, harmed or even damaged. Every procedure has to be carefully balanced between the risks and benefits from improvement towards effectiveness and efficiency.

Applying the concept of „Good Governance“ on organisational behaviour in management and decision-making processes as it was done before, should lead to further discussions, improving and developing the context, for any prospective and sustainable implementation of management systems.

Corporate Governance

When we look at management structures in big companies or other complex organisational entities, then we recognise parts of a Governance system. There are several management systems concerning quality, environmental, safety, risk and knowledge issues with various related IT-databases implemented, to overlook and manage special responsibilities of cooporations.

According to BLANCHARD & DIONNE (2003) „Corporate Governance“ can be defined as a system consisting of processes, customs, policies and rules to monitor and control operations of an organsiation aiming at mitigating possible conflicts of interests between different stakeholders[68] and to achieve long-term strategic goals. O'DONOVAN (2003) defines Corporate Governance as an internal system encompassing policies, processes and people, which serves the wants and needs of stakeholders, by controlling and directing management activities by objectivity, accountability and integrity. Nevertheless Corporate Governance remains ambiguous and is an often misunderstood phrase, only confined to corporate management. But the concept is something much broader, for it must include a transparent and efficient administration and has to meet well defined and also written objectives.

Key principles of Corporate Governance include honesty, trust and integrity, openness, performance orientation, responsibility and accountability, mutual respect and commitment towards the organisation.

[68] The principal stakeholders are the shareholders, management and the board of directors. Other stakeholders include e.g. employees, customers, regulators and the community at large

Therefore sound Corporate Governance has already been defined by scholars very closely to the new concept of „Good Governance“, as it was examined in chapter 6.2.

6.3. The over-compliance aspect

Over-compliance is a very interesting outcome of governmental regulatory legislation and execution. WU (2009) examined the question why firms choose different levels of compliance within their regulatory framework and why some firms even undermine it.

According to the meaning of compliance, some private corporations, public institutions or individuals voluntary over-comply with relevant and defined specifications, standards, rules, laws and regulations. Within theories which already have been recommended by academic scholars the strategic behaviour theory offers the most reasonable explanation. It states that over-compliance could be a strategic tool to induce government either by choosing a new or tightening the existing regulatory framework, which is more suitable for the compliant, just to gain competitive advantages against non-compliant.

But what in case of scientific research, lacking well-known market mechanism? And even more provocative, what in case of lacking well-known state mechanism like legislation, jurisprudence and enforcement? Is there any case of over-compliance feasible when you are working within the limits of technology, on forefront of fundamental research?

Regulatory pressure

All questions raised in the latter paragraph do address the very special case of CERN. Although CERN is subject to international law and generally may act outside conventional national restrictions, it may not and even does not want to act without conventional regulations. Safety and security are highly important for any upcoming experiment. Man, machine and environment are the assets to be well considered and strictly protected. In any case of accidents or incidents where these key principles have been compromised, key stakeholders such as host states or member states might

act on behalf of a supra-national authority by introducing stricter requirements and increasing overall regulatory pressure. In this respect, no scientific investigation has been carried out yet.

Negotiations on the bargain

Every new experiment at CERN comes with uncertainties even in the „right“ or most suitable regulation to apply. Hence, compliance in any (so-called right) requirement at CERN strongly depends on special circumstances, even more regarding radiation protection and safety. Within international projects like CERN, project enquirer are dependent on negotiations and compromises to gain further support in their work by any stakeholder. But finally it is nothing more than a bargain with the competent authority and others issuing the „right“ regulatory requirements.
Knowing the exact status of compliance with agreed requirements at any time, will help these responsible to act more accurately and confidently in negotiation situation but also promise to make better decisions in upcoming projects.

6.4. Legal self-regulation and administration of complex organisation, facilities and activities

A real deep look into future potential of RCMS brings several exciting ideas. When you are able to administrate a complex organisation like CERN with all its legal, technical and organisational requirements in a transparent framework, what about going one step further in self-regulating other multi- and transnational technology-oriented organisations or even more the whole human social interface system?

According to this idea, authorities will only bring in the key principles, the necessary legal framework and provide consulting. Principles are a form of self-regulation. They allow determining what standards are acceptable or unacceptable. They can also avoid over-ambitious legislations that might not be practical.

In case of CERN, system-users themselves may work out the regulatory requirements, adapt the most suitable version according to the legal inclination and will also conduct compliance and legal conformity checks.

This could be made possible by a full transparent RCMS, which could act as a kind of „Web 2.0“[69] intergovernmental panel, that works highly interactive between competent users by applying all available electronic management systems, visualisation social interfaces and networks in a fully integrated manner. Consequently, compliance is not checked just once in a period by governmental random sampling but at almost any time by all users (stakeholders) linked in the RCMS. Requirements are adjusted in best manner according to the technical circumstances and available technologies. Just in case of qualified complaints by users or rigorous and recurring non-compliance within the framework and also reported endangering of men, property and environment, government has the lonely power of enforcement of corrective measures.

The implication and potential that come with this idea are really enormous and have to be investigated and assessed in a much deeper way by further research. In this respect a lot of questions have to be answered for self-regulated upcoming technology-oriented organisations, such as multi-national renewable or fusion energy operations[70] or international geoengineering projects, but CERN may act as a unique role-model and can be studied directly during the implementation and operation of an RCMS.

[69] using current interactive internet technologies and web services
[70] e.g. DESERTEC and ITER

7. Outlook

In this last chapter the author wants to outline some ideas and further research areas related to Technology-oriented Agreements and Regulatory Compliance Management Systems.

7.1. Relevance for other and coming TOAs

The management of climate change mitigation measures turned out to be rather difficult. There are very different approaches already applied or proposed to fight anthropogenic impacts on worldwide climate.

There are technical provisions (like air quality standards or best available techniques), legal instruments (like national or bilateral binding regulations) and, very recent, economic measures like carbon cap & trade. All these current arrangements lack sufficient and effective implementation and additionally imply negative economic burden on the participants. According to the „free-rider“ principle, not to comply with all these measures let you enjoy the benefits without having to bear the monetary burden.

Geoengineering

That is why a wide range of engineering techniques, each more or less capable of influencing the climate, recently have been proposed by scientific scholars to enlarge the methods of climate change mitigation. The methods discussed are quite diverse and vary greatly in terms of their technological characteristics, costs and possible

consequences. Generally spoken they are classified into two groups, carbon dioxide removal (CDR) and solar radiation management (SRM).

The proposals on both sides have advantages and also disadvantages in common. They are usually time consuming, cost-excessive in their implementation and highly dangerous related to their unintended consequences.

The situation is quite comparable with the CERN legacy. In the aftermath of World War 2 the international community had to deal with an increasing worldwide problem, the knowledge in physics especially in nuclear technology spreading out of Europe and nuclear proliferation. Strong institutions like the European Atomic Energy Community (EAEC or today called EURATOM) had to be introduced. It was intended to create a specialist market for nuclear power and to distribute it through the European community and to develop nuclear energy.

Therefore the conceptual framework for an RD&D agreement regarding the CERN venture, could also be projected on regulatory governance for pursuing international technology-oriented collaborations in other multinational and transnational scientific undertakings like Geoengineering.

Newly published literature introduced the mechanism of "Technology-oriented Agreement" (TOA), whereas Geoengineering could also be within its scope by research and development affords in Carbon Dioxide Removal (CDR) and Solar Radiation Management (SRM) techniques. BROECKER & KUNZIG (2009) and VICTOR *et al.* (2009) suggested to form an international consortium and other international scientific collaborations following the example of CERN as another TOA.

The central problem for investigating in Geoengineering is the so-called „control dilemma" (COLLINGRIDGE, 1980). It is stated that the development of new technology leads to the problem to identify disruptions at an early stage. When a technology is widely deployed, it is often too late to stop negative implications

within its application. Therefore the situation will get even worse, especially when entities like countries, firms or individuals start to investigate on the subject by their own. For that reason the dilemma can only be resolved by comprehensive and profound research, development and demonstration of new methods or technologies, on a large scientific consensus.

To overcome this critical call from concerned stakeholders (public, authorities, politicians, individuals) the author suggests to introduce a consortium or organisation on an international level. This organisation should explore the safest and most effective methods on artificial climate change mitigation measures and help to form a common understanding of responsible implementation. For that reason, scientific collaboration should be formed on a virtual and physical background.

Result

If Geoengineering is to have a future role in climate change mitigation and is to be applied responsibly, then highly coordinated and collaborative research is needed to enhance knowledge and also develop governance mechanisms for effective decision-making processes.

In that respect, CERN could act as a role model for founding, legally embedding, implementing and finally operating an international organisation dealing with research, development and demonstration in Geoengineering science. The new geoengineering RD&D organisation should act in collaboration between nations by organising and funding co-operation, promoting contacts between scientists and interchanging with other laboratories, institutes and governments.

Moreover the new RD&D organisation should be set up under an international legal framework, for purpose of a correct and effective regulation of measurements with trans-boundary or even trans-national effects. International agreements founded by the United Nations, European Union and related international bodies have shown[71]

[71] e.g. ITER, MARPOL, CTBT, GEF, CLRTAP, OST, UNCCD, CBD, UNCLOS, European Union Renewables Directives, Montreal Protocol

that they are able to govern proper technology-oriented organisations according to the expectation of all stakeholders.

7.1. Development of a new ISO Standard

One of the factors driving the investigations in this thesis work was a lack in standardisation procedures concerning compliance management systems. Wherease compliance procedures are implied in several existing standards, no common undersatnding or definition for an own standard has been found yet.

Usually the need for a standard is expressed by industry, which communicates its need to a national standardisation body. Accordingly, ISO standards are developed on following principles: consensus among stakeholders[72], global applicability and voluntariness. In this respect CERN and the implementation of its Regulatory Compliance Management System could serve as a model accompanied by further applied scientific research.

[72] manufacturers, vendors and users, consumer groups, testing laboratories, governments, engineering professions and research organisations

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Glossary

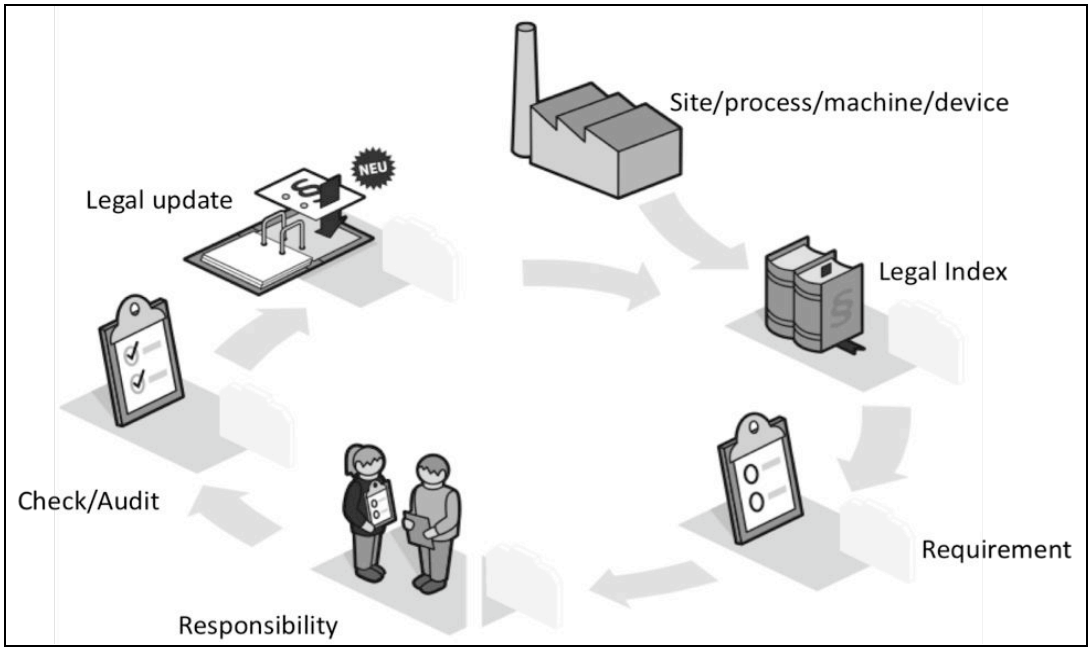
ALARA	As Low As Reasonable Achievable
APP	Asia-Pacific Partnership on Clean Development and Climate
CBD	Convention on Biological Diversity
CDR	Carbon Dioxide Removal
CECSTE	Committee for Examining Firms' Safety Conditions at Work
CEPC	CERN Environment Protection Committee
CERN	European Organisation for Nuclear Research
CLRTAP	Convention on Long-range Transboundary Air Pollution
CMO	Compliance Management Officer
CSCO	Cryogenics Safety Officers Committee
CSLF	Carbon Sequestration Leadership Forum
CSO	Cryogenics Safety Officer
CTBT	Comprehensive Nuclear-Test-Ban Treaty
CTBT	Comprehensive Test Ban Treaty
DG	Director-General
DL	Department Leader
DSCO	Departmental Safety Officers Committee
DSO	Departmental Safety Officer
EAEC/EURATOM	European Atomic Energy Community
EC	European Commission
EDH	Electronic Document Handling
EDMS	Engineering Data Management System
ESA	European Space Agency
EU	European Union
FGSO	Flammable Gas Safety Officer
FGSOC	Flammable Gas Safety Officers Committee
GEF	Global Environment Facility
GEF	Global Environment Facility
GL	Group Leaders

GLIMOS	Group Leader in Matters of Safety
GS	General Infrastructure Service
GSI	General Safety Instruction
HS	Heads of Service
IAE	International Energy Agency
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
ILO	International Labour Organisation
IPHE	International Partnership for the Hydrogen Economy
ISO	International Organisation for Standardization
IT	Information Technology
ITER	International Thermonuclear Experimental Reactor
JMT	Job Management Tool
LCMS	Legal Compliance Management System
LHC	Large Hadron Collider
MARPOL	International Convention for the Prevention of Pollution from Ships
MTF	Equipment Data Management System
NCRP	National Council on Radiation Protection & Measurements
NGO	Non-governmental Organisation
OECD	Organisation of Economic Cooperation and Development
OST	Outer Space Treaty
RCMS	Regulatory Compliance Management System
RD&D	Research, Development & Demonstration
RP	Radiation Protection
RPC	Radiation Protection Committee
RSCO	Radiation Safety Officers Committee
RSO	Radiation Safety Officer
SAPOCO	Safety Policy Committee
SC	Safety Commission
SL	Section Leaders
SLIMOS	Shift Leaders in Matters of Safety

SMS	Safety Management System
SO	Safety Officer
SOS	Safety Officer's Support
SP	Safety Procedure
SR	Safety Regulation
SRM	Solar Radiation Management
SSI	Specific Safety Instruction
TOA	Technology-oriented Agreement
TSO	Territorial Safety Officer
UNCCD	United Nations Convention to Combat Desertification
UNCLOS	United Nations Convention on the Law of the Sea
WF	Workshop Foremen
WHO	World Health Organisation

Annex

Legal Compliance Management System Scheme



Source: Graphics derived from www.gutwin.at; adapted by the author