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Licensing of digital Instrumentation & Control in Radioisotope Production Facility

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ABSTRACT

In spite of the rapid development of digital I&C systems in all major industries, it has for several reasons been slower in nuclear power plants. The most important reason is that only a few new plants have been ordered worldwide during the last ten years. A second reason is connected to the efforts needed in providing adequate evidence that the digital I&C system can be used in safety and safety related applications. This issue is connected to the effort needed in obtaining adequate assurance that the digital I&C will fulfill its intended function and contain no unintended function in all possible operational states during its entire life cycle. This paper presents an acceptance criteria for licensing a digital instrumentation & control system in a Radioisotope Production Facility[1], which is under commissioning. The acceptance criteria ensure that the I&C systems are designed to reach the highest degree of reliability with respect to the function they perform, operators will have clear and accessible availability to data on every plant parameter, and also ensure that the safety objectives have been covered.

Key Words: Radioisotope Producrion Facility/ Digital I&C Systems.

INTRODUCTION

The requirements for licensing a system depend on the safety importance of the system to be licensed, or qualified. Requirements may be placed even on non-safety systems when they are interfaced to safety or safety-related systems. With respect to requirements applicable to I&C systems we can separate between deterministic, probabilistic and human factors requirements. Due to the complexity of an I&C design process it is necessary to define requirements on the final product, intermediate products and the processes used to generate these products. Deterministic requirements are usually placed on solutions with limited design complexity, solutions for fault tolerance, spare capacity and quality control processes. Probabilistic requirements are often established to ensure that assumptions made in the probabilistic safety assessment [PSA] are valid both with respect to sequence models and reliability estimates. Human factor requirements are formulated to ensure that operators will be able to understand and operate the systems and that the first rapid state changes after the onset of an accident are automated. Requirements are also placed on the process of generating evidence that the licensing requirements are fulfilled. The phases in a licensing process depend on legislation and regulatory practices. Early interaction between utility and regulator can be helpful. Typically, system architecture and design principles set the stage. Already at this phase, the regulator may require plan with descriptions of major project milestones and the quality systems to be used in the project. An assessment of specifications is often the next step in process. When testing is initiated, it is usual to require a comprehensive test plan. This includes both factory and site acceptance testing, which often are carried out in the presence of a representative of the regulator. A modern software quality control

system includes several design reviews be carried out when certain stages in the design have been completed. Some of those reviews may be performed by independent reviewers to ensure that also difficult questions can be brought into the open. If the software development process relies on the use of various tools such as code and documentation generators it may be necessary to license them in a separate process.Typical software quality assurance procedures monitor process compliance more than direct product quality. The structure and implementation of these procedures represent one component in the compilation of evidence. Various intermediate products can also be assessed and reviewed in the course of the design project. Inspections [(2)] of specifications, documentation and code can provide evidence that the underlying processes have been producing required quality. Special V&V (verification & validation), tools such as machine code dis-assemblers, automated tools for inspection of assembly programs, tools for static and dynamic analyses of the software, etc. may be used to get evidence that the coding has been performed according to standards. The completeness of test programs can be assessed using various tools for instance to investigate sensitivity to artificial errors in the code. Statistical testing, either with random test inputs or inputs mimicking a certain usage profile can be used to collect quantitative evidence for the reliability of the software. Operational experience can provide some evidence, but the problem is to prove that the usage profiles of two different applications are similar enough.

To make the licensing process transparent it is important to have the conditions for accepting or rejecting certain solutions documented in a clear way. Regulatory requirements are not stable over time, because new experience may bring in needs for stricter acceptability criteria. Still, it is necessary to maintain consistency in the regulatory approaches. The safety importance for functions and components are reflected in the safety classification, but this is usually too crude to give clear guidance on the acceptability. Deterministic requirements can be checked by inspections, but the probabilistic requirements are more difficult. One possibility is to anchor acceptability conditions to a plant specific PSA where a certain reliability is required. Statistical testing can be used to collect evidence at some reliability level, but it becomes impractical for systems with a very high reliability requirement. For such systems it may not be possible to provide reliability estimates without relying on expert judgment. It is often beneficial to model software errors using some method like the Failure Modes and Effects Analysis (FMEA)[(2)]. A controversial issue in this context is requirements for diversity, since it can be very hard to verify the actual degree of independence. The U.S. Nuclear Regulatory Commission (NRC)[(3,4)] experiences in licensing I&C systems show that the appropriate regulatory guidance found in the NRC Standard Review Plan (NUREG-0800) regulatory guides (RGs), and branch technical positions (BTPs) should be reviewed in the following areas:

* main control room design reviews
* human system interfaces
* displays and soft controls (RG 1.47)
* post-accident instrumentation (RG 1.97)
* alarms
* system isolation and cyber security
* system architecture
* network communications
* software common-cause failures
* redundancy, diversity, and defense in depth
* sensors
* information and data management
* software tools, including change control and security
* system reliability

* commercial off-the-shelf (COTS) systems

This paper introduces an acceptance criteria for licensing the digital I&C system (hardware only) in Radioisotope production facility.

CASE STUDY

The radioisotope production facility (RPF) [1] is built to maintain and improve the health care benefits to the community, ensuring the supply through local production of the necessary amount of therapeutic and diagnosis radioisotopes to meet the requirements of medical professionals in the immediate future The RPF provides a strengthen and expand the experience in the field of nuclear sience & technology, it also provides industrial isotopes to meet agricultural and industrial needs.

The plant processes the following isotopes:-

1- Molybdenum 99 produced through the fission of low enrichment uranium. This radioisotope is the source of technetium 99m, used for medical diagnosis. The weekly production of Mo-99 may reach 1000 Ci. The final product comprises generators with degree of purity that makes it applicable for human.
2- Iodine 131 produced through the fission of low enrichment uranium..This radioisotope is used in nuclear medicine as therapeutic or diagnosis agent, and to label other compounds of interest. The final product has a degree of purity that makes it applicable for human use.
3- Iodine 125 produced through the irradiation of xenon gas. This radioisotope is used in nuclear medicine as therapeutic or diagnosis agent. The final product has a degree of purity that makes it applicable for human use.
4- Chromium 51 produced through the irradiation of potassium chromate targets. This radioisotope is used as injectable medical product. The final product has a degree of purity that makes it applicable for human use.
5- Iridium 192 wire produced through the irradiation of iridium-platinum-alloy targets, this radioisotope is used in brachytherapy. The final product has a degree of purity that makes it apt for use in human.
6- Iridium 192 produced through the irradiation of natural iridium sheets. This radioisotope is used in sealed sources for industrial gamma radiography.

The plant requirements for system operations and safety analysis are summarized as follow:-

1. **Site**
2. **Plant Building**

The Plant is divided into three main sectors, namely:

- Free Area
- Supervised Area
- Controlled Area

The building has a dynamic confinement system that forms the final barrier to prevent the uncontrolled release of radioactive material towards the environment in the event of an accident.

3. Hot Cells

Hot cells are used to handle radioisotopes. The facility is equipped with the following hot cells:

a) Molybdenum 99 (Fission) Production Hot Cells
Four hot cells where Mo-99 sodium molybdate solution is produced.

b) Iodine 131 Production Hot Cell
One hot cell for the production of carrier-free 1-131 solutions of high activity concentration that allow their further fractionation and capsulation for use in nuclear medicine as therapeutic and diagnosis agent, and to label other compounds of interest.

c) Iodine 125 Production Hot Cell
One hot cell for the production of 1-125 solution for use in nuclear medicine as therapeutic and diagnosis agent, and to label other compounds of interest.

d) Chromium 51 Production Hot Cell
One hot cell for the production of aqueous Cr-51-enriched sodium chromate solution for use as injectable medical product.

e) Iridium 192 Production Hot Cell
Two hot cells to obtain Ir-192 wires for use in medicine and Ir-192 sealed sources for use in industrial gamma radiography.

f) Assembly and Loading of the Technetium Generator
One hot cell dedicated to the loading of the Molybdenum 99 - Technetium 99m (GENTEC) generator.

g) Multi-Purpose Production Hot Cells
One multi-purpose hot cell (compound labeling or production of other radioisotopes).

h) Activity Control Hot Cell

This cell allows radionuclide calibration and activity control prior to dispatch. Hot cells are airtight boxes fitted with a ventilation system with air filters at its inlet and outlet, connected to the central ventilation system.Process equipment, glove boxes, laboratories, and radiochemical hoods are distributed inside the facility with a view to ensuring comfortable working conditions and minimum personnel circulation. Moreover, teletongs and master-slave manipulators are supplied, as may correspond. The hot cells have auxiliary services such as compressed air, vacuum, and liquid effluent collection.

4. Ventilation and Air Conditioning System

The ventilation system serves the following purposes:

- To treat the air released into the environment surrounding the Plant, minimizing the release of radioactive products.
- To provide the necessary air renewal to bring down radioactive concentration in supervised and controlled areas to levels as low as reasonably achievable.
- To maintain the airflow between areas connected towards others with higher radioactive contamination potential.
- To condition the air for personnel comfort.

It comprises two main systems, namely:

- Conventional Ventilation: It services the rooms corresponding to the free-circulation area.
- Active Area Ventilation: It services the rooms located inside the supervised and controlled areas, as well as the production cells, and the glove boxes within the installation.

5. Instrumentation and Control System

The Instrumentation and Control System comprises the Instrumentation of the Radiological Protection and Physical Safety System and the Operation Supervision System.

5.1. Operation Supervision System

The Plant has adequate instrumentation to supervise the ventilation system and the auxiliary process systems during operation by means of a Data Acquisition System DAS which in turn comprises a Programmable Logic Controller and two operation stations with PC-type-desktop-computer support.
Visual and sound alarms are supplied in the DAS to provide immediate warning on any modification of plant operating conditions that could pose any radiological hazard.

5.2. Radiological Protection System

Radiological protection is guaranteed through an adequate plant design, appropriate operating procedures and training and a radiation and contamination monitoring instrumentation system.
The different plant areas are classified in accordance to the degree of radiological risk they pose. Each area has adequate shielding and restricted access for operator protection. The radiation and contamination monitoring instrumentation provides early warning and alarm should habitability conditions or dose rate exposure exceed the preestablished limits.

5.3. Physical Safety System

The Physical Safety System includes the Physical Safety Center and the Access Control System. At this centre, the safety personnel are in charge of access control and the supervision of safety in all buildings and surrounding environment. The safety centre concentrates all safety information and is in charge of initiating the corresponding response.The Access Control System - ACS - allows circulation of authorized personnel and material along normal routes, and detects the circulation of unauthorized personnel.

6. Electric Power Supply System

The electric power supply system comprises different sources to increase the reliability and availability of the system:
a) Main source
b) Essential source
c) Uninterruptible source

The main source has sufficient capacity to starts-up the plant and manage the electricity demand as a whole.The essential source supplies sufficient electricity to run the ventilation system, the relevant equipment, and essential Plant services during a main power cut-off. The uninterruptible source (UPS) supplies electricity to feed the loads of relevant equipment without interruption during the transition

from the cut-off of the main source until the connection of the essential source.

7. Fire Protection System

The Plant has a fire detection and extinction system based on protection measures, detection and extinction systems, and adequate barriers to prevent the spreading of an eventual fire.

The Structure of the I&C system

The instrumentation and control system comprises the following main elements:-

I- Data acquisition system (DAS).
II- Security centre and Access control system.
III-Radiological protection system instrumentation.

I- <u>The Data Acquisition System:-</u>

The Data Acquisition System comprises two supervision computers, each is located in a different room, so they are redundant and independent. The computers supervise the operations of the ventilation and auxiliary systems during normal and maintenance operation. Visual and sound alarms are provided in the DAS to give warnings if necessary.

II- <u>Security centre :-</u>

The Security Centre comprises the following elements:-

- The Fire alarm panel.
- The closed circuit television (CCTV) system and the video matrix. The closed circuit television system provides the necessary means for alarm verification, as well as general video monitoring of the inner and outer perimeter of the building.
- The Access Control Station. A set of sensors is placed in possible access routes to sensitive areas to provide early warning of unauthorized personnel. Rooms with glass openings also have glass break detectors.
- The Alarm System Station. Which concentrates the signals of the intrusion or non authorized access detectors, and alarm states of fire, CCTV and access systems.

<u>III- Radiological Protection System Instrumentation:-</u>

This system performs all the radiation monitoring related to liquid effluent, gases, area and personnel supervision inside the RPF. It is composed of fixed and portable instruments. The portable instruments are redundant, independent, and diverse for the fixed instruments. These instruments are:-

- **Gaseous Effluent Monitoring System**

This system is used to detect the presence of Iodine, Aerosols and/or noble gases active elements in the gaseous effluent of the plant.

- **Fixed Area Monitoring System**

Provides local and remote warnings to the personnel exposed to excessive radiation levels. Contains several microprocessor based detection modules that are connected to a central processing unit.

- **Fixed Aerosols and Iodine Collector Heads**

Each collector head has a filter for aerosol and cartridge for Iodine. There are many collector heads in the different rooms and one outside the plant.

- Portable Beta/Gamma Survey Meters.
- Portable Contamination Survey Meters.
- Hand, Feet and Clothes Monitors.
- Manual sample changer system.

For measuring and dispose the Aerosol retention filters and the Iodine retention cartridges.

- Spectrometry System.
- Iodine Monitors (Thyroids).
- Liquid and Particulate Sample Spectrometer. It is used to measure samples coming from the fixed Aerosols Collector Sampler and from the Liquid Monitoring System.

- **Portable Personnel Monitoring**

To determine the dose received by people working in or visiting controlling areas.

- **Emergency Equipment**

It is a kit provided to allow personnel to manage emergency situations. It includes: special protection clothing, mask and filter, self-contained breathing apparatus, Lantern, Gloves, and PVC boots.

ACCEPTANCE CRITERIA

The licensing process for digital I&C systems in any nuclear facility should proceed in two phases as shown in Figure (1). The first phase introduces the hardware licensing process which is held during the design and implementation of the facility. During this phase, the evidents are collected to ensure the existence of the safety requirements functions (reliability, validation & verification, diversity ….). The second phase is held after design & implementation and before commissioning for software licensing (3+3 process)[5].

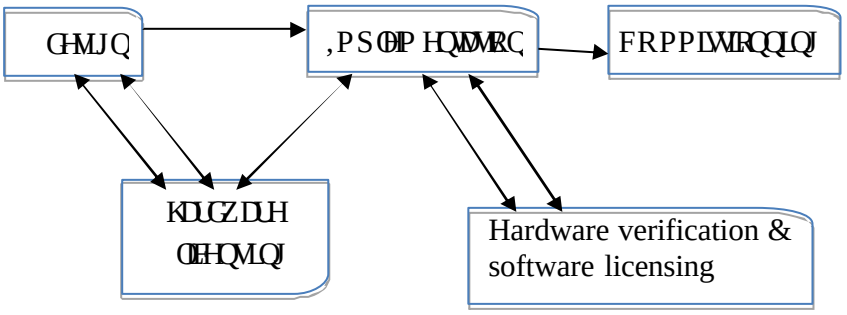

Fig. (1): Phases of digital I&C licensing.

The acceptance criteria for digital I&C (hardware) in a radioisotope facility[s1,2,3,4,6,7,8,9] is as follows:

a- Data Acquisition System (DAS)

- The range of operation of sensor (detector) channels should be sufficient to cover the expected range of variation of the monitored variable during normal operations.
- The sensor channel should be commensurate with the precision and accuracy to which knowledge of the variable measured is required for the control of the RPF.
- The system should give reliable information about the status and magnitude of process variables necessary for the full range of normal RPF operation.
- The RPF control system should be designed for reliable operation in the normal range of environmental conditions anticipated within the facility.
- The subsystems and equipments of the RPF should be readily tested and capable of being accurately calibrated.
- Technical specifications, including surveillance tests and intervals, should be based on Sagety Analysis Report (SAR) analyses and should give the necessary confidence in availability and reliable operation of detection channels and control elements and devices.
- The applicant should plan and discuss how all control elements, their driver and release devices, and display components will be calibrated, inspected, and tested periodically to ensure operability as analyzed in the SAR.
- Annunciators or alarms on the control console should clearly show the status of the systems.
- The control system should be redundant to ensure that a failure could not prevent the system from performing its intended function.
- The control system should show independence and diversity.

b- Radiological instrumentation

- Detector channels and control elements should be redundant to ensure that a single random failure or malfunction could not prevent the instrument from performing its intended function.
- The logic, schematic, and circuit diagrams should be included and should show independence of detector channels.

c- Security system and Access Control

- The designed range of operation of each device should be sufficient for the expected range of variation of monitored variables under conditions of operation.
- The system should be redundant to ensure that a failure could not prevent the system from performing its intended function.
- The system should show independence and diversity.

d- Design Criteria

According to Argentina RPF, the following are the design criteria for the instrumentation and control system:-

a- The system is designed to achieve the highest level of reliability in accordance with the type of operations being carried out.
b- The design guarantees the minimization of any altering failure, i.e. any failure arising from malfunction of any of the components of the system that may alter the correct operation of the system.
c- Potential human error is minimized through the incorporation of fail-proof systems and interlocks during the preliminary design stage.
d- Radiation sensors are placed to cover operational and accident ranges.

CONCLUSION

The safety case for licensing of digital I&C system should describe the safety philosophy and the basic safety principles involved and how I&C equipment comply with these principles. In this paper an acceptance criteria for licensing digital I&C (hardware) for a radioisotope facility had been propsed. The proposed criteria collects the evident for the following safety requirements:

- Provision of alternative elements or systems, so that anyone can perform the required function regardless of the state of operation or failure of the others.
- Probability, that a device, system or facility will perform its intended functions satisfactory for a specified time under stated operating conditions.
- The testing and evaluation of the hardware to ensure compliance with functional, performance and interface requirements.
- The process of determining whether or not the product of each phase of the digital system fulfills all the requirments imposed by the previous phase.
- Existance of two or more different ways or means of achieving a specific objective

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