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Chapter 18

A Life-Cycle Approach for Development and Use of Emergency Response and Health Protection Instrumentation

Mark D. Hoover and Morgan Cox

Introduction

This chapter presents a "life-cycle" approach to the development and use of emergency response and health protection instrumentation for responding to emergencies involving dispersion of biological, chemical, radioactive, or nuclear materials. The life-cycle approach presented in this chapter is derived from participation in and review of historical experience with health protection and industrial hygiene instrumentation for air monitoring, personal dosimetry, and detection of biological, chemical, and radioactive materials. This includes recent experience in development of new consensus standards for homeland security applications (Cox and Hoover 2004).

The life-cycle approach is generally applicable to the development and deployment of instrumentation for any purpose. In all cases, developing documentation and national and international consensus standards adequate to guide, record, and demonstrate the scientific defensibility of instrument use throughout the life-cycle process is considered essential to success. As described below, the life-cycle approach provides a template for improved understanding and collaboration between all stakeholders in the process. Stakeholders include threat assessment professionals, vulnerability assessment experts, research and development scientists and engineers, instrument manufacturers and vendors, procurement specialists and their technical representatives in first-responder and other user organizations, instrument calibration and maintenance specialists, instrument users, and the workers and members of the public we strive to protect. The approach is relevant to new instrument concepts as well as to refinement or modification of commercially available instruments for specific purposes.

Life-Cycle Phases for Instrument Development

General considerations of instrument life-cycle phases from conception to retirement are shown schematically in Fig. 18.1, described in the following sections, and summarized in Table 18.1.

Mission Evaluation

Mission evaluation is the critical initial phase of the instrument life-cycle process. It defines the objective of the measurement and identifies constraints on when, where, or by whom the instrument is to be used. Clarity of objective can guide the creative selection or

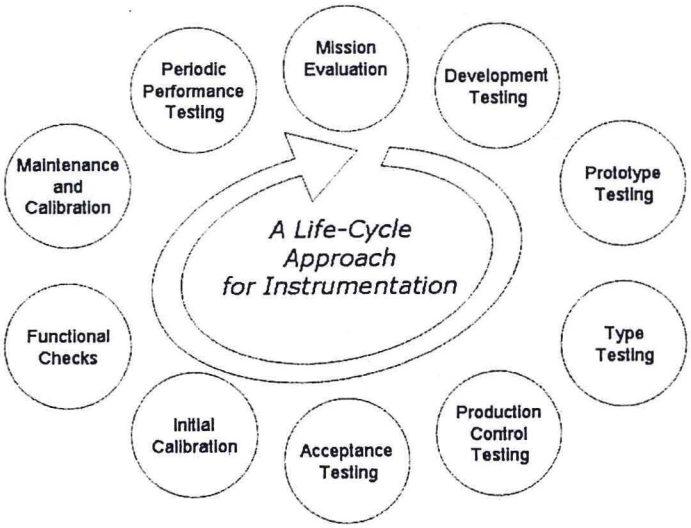

Fig. 18.1. Schematic diagram of a life-cycle approach for development and use of instrumentation.

development of effective approaches for the "how" factor. A traditional feedback loop can be applied, in which changing solution options alter the vision of how the mission can be accomplished. For example, personal alarming dosimeters and detectors began as rather massive devices that were worn in a pack or on the belt. In many situations, an individual doing work was accompanied by a technician responsible for measuring dose or dose rate. Current instrumentation has been miniaturized to the extent that pocket-sized devices can be worn by an individual and used with radiofrequency telemetry to provide remote continuous monitoring of personal dose and dose rate, including geographical positioning.

Development Testing

Development testing is performed by the manufacturer during the design phase to determine the likelihood that a specific instrument design will meet the intended specifications. This includes balancing tradeoffs of user requirements for limits of detection and response time against instrument size, weight, reliability, ease of use, cost, and training requirements. Development tests are normally conducted under "bread-board" conditions, in which subsystem performance is evaluated, without a complete instrument configuration. Understanding the expected conditions of use and monitoring objectives allows the manufacturer to develop an instrument that is likely to pass the other tests described below.

Selection of the polarity for the front face of a solid-state detector in an alpha radiation continuous air monitor is an example of the value of having an early understanding of the expected conditions of use. Detectors with a positive front surface and a grounded back surface are susceptible to radiofrequency interference; the configuration essentially acts as

an antenna. A postdevelopment retrofit might require installation of a Faraday cage around the detector. Such a retrofit might interfere with air sampling efficiency or ease of use. An insightful development precaution would be to design the detector with a grounded front face, so that concerns for radiofrequency interference are "engineered out" from the inception.

Prototype Testing

Prototype testing demonstrates that the design of an instrument is likely to meet certain specifications. Although prototype testing is not formally required by national or international standards, it is good practice that decreases the possibility that production units will fail to meet requirements. This testing phase also provides opportunities to ensure functionality under any special operational controls that may be required for specific situations and field applications (for example, use with personal protective equipment that may restrict vision, hearing, or touch).

Type Testing

Type testing is the first formal requirement of national and international standards. A review of responsible standards organizations such as the American National Standards Institute (ANSI), the International Electrotechnical Commission (IEC), and the International Organization for Standardization (ISO) can be found in Cox et al. (2003). To fully define the performance characteristics of the instrument, instruments shall be type-tested in accordance with applicable standards. Type testing shall be performed on one or more production models of each instrument to fully characterize the performance and limitations of the instrument. The range of required tests addresses concerns that variation in source or agent characteristics, instrument orientation with respect to the source, temperature, humidity, and instrument stability can affect the accuracy of measurements in the field. Other tests such as vibration and drop tests address the ruggedness of the instrument as well. The instrument characteristics, as defined by results of the type test and the standard-specified interpretation of the test data, will document for the user how accurately the instrument can be expected to detect and quantify the chemical, biological, or radiological agent of concern under a range of expected operational conditions.

Production Control Testing

Although production quality control falls under the manufacturer's requirements covered by the ISO 9000 standards, production control testing has not generally been a formal component of the standards process for individual classes of chemical, biological, or radiological instrumentation. Production control testing represents good practice to ensure that

Table 18.1. Summary of a life-cyle approach to instrument tests and test requirements.

Name of test	Purpose of test	Test frequency	Units to be tested	Specifications to be tested	Responsibility
Mission evaluation	To define mission and measurement objectives and identify candidate technologies	Prior to initiation of the development process, and continuously throughout the life cycle	Conceptual or by analogy with existing missions and technologies	Definition of the specifications that will be evaluated in the subsequent life-cycle phases	Responsible officials, with input from research, development, manufacturing, and user professionals
Development Test	To aid in the development of a prototype that is likely to meet certain specifications	As needed	Individual components and assemblies	As selected by the manufacturer; or requested by the purchaser/user	The manufacturer
Prototype Test	To demonstrate that the design of the instrument is likely to meet certain specifications	As needed prior to start of production	One or more prototype units	As selected by the manufacturer; or requested by the purchaser/user	Generally the manufacturer; occasionally the purchaser/user
Type Test	To demonstrate that the design of the instrument as manufactured meets certain specifications	A minimum of once prior to full production	One or more initial production units	All specifications from the relevant standard, or as agreed upon between manufacturer and purchaser/user	Generally the manufacturer; occasionally the purchaser/user
Production Control Test	To control production, avoid defects, and confirm instrument compliance with selected specifications	Depending on the acceptable failure rate agreed upon between manufacturer and purchaser/user	As determined by the manufacturer or as agreed upon between manufacturer and purchaser/user	As selected by the manufacturer, or requested by the purchaser/user	Manufacturer

Table 18.1. *Continued*

Acceptance Test	To demonstrate compliance with selected specifications	After the units are received and prior to their initial use	As agreed upon between manufacturer and purchaser/user	As selected by the purchaser/user	Purchaser/user
Initial Calibration	To establish a traceable calibration relevant to expected conditions of use	Prior to initial use	Each unit	Selected instrument parameters and responses	Designated calibration staff of the users' organization (or selected vendor)
Functional Check	To provide indications that the instrument is operational	Before each use and periodically during use.	Each unit	As appropriate for the instrument being used	User
Maintenance and Calibration	To provide preventive maintenance, make necessary repairs, and reestablish a traceable calibration	At a frequency, such as annually, based on the design and reliability history of the instrument	Each unit	As appropriate for the instrument	Designated maintenance staff of the user's organization (or selected vendor)
Periodic Performance Test	To verify that the instrument continues to meet relevant specifications	As appropriate based on experience and anticipated modes of failure	A representative number of units	Selected specifications from the type test	As arranged by the purchaser

instruments meet critical requirements. Higher performance and reliability are especially important for homeland security applications. Production control testing is performed by the manufacturer in accordance with documented procedures, and often by agreement with the purchaser.

Acceptance Testing

Acceptance testing should be performed by the purchaser or user on each new instrument before initial use. Acceptance testing should test each instrument against specific characteristics identified as critical or indicative of overall instrument performance. The purpose of acceptance testing is to demonstrate that each instrument meets certain stated specifications and contractual requirements. An acceptance test generally consists of physical inspection, general operational tests, and appropriate response tests.

Initial Calibration

The initial instrument calibration is frequently performed as part of the acceptance test. Some instruments are factory-calibrated and do not require additional calibration. In these instances, calibration checks or verifications may be appropriate. For instruments being held in reserve for future use, the initial calibration may be performed at a later date.

Functional Checks

A functional check is often qualitative and determines that an instrument is operational and capable of performing its intended function. Functional checks may include battery check, zero setting, or source response check. Many modern instruments include automatic diagnostic and self-checking features. For radiation detection instrumentation, functional checks may include response to natural background radiation. For biological or chemical detection instrumentation, checks may include response to ambient materials, or may require the artificial introduction of test materials. All or a subset of these checks are typically performed at least daily, or prior to each intermittent use, whichever is less frequent.

Maintenance and Calibration

Maintenance shall be performed using components at least equivalent to those specified by the manufacturer. Replacement components shall be manufacturer-specified or equivalent. Repairs made using unapproved instructions or components that may affect instrument performance constitute an instrument modification and shall render invalid any type tests made on the instrument model as applied to the specific instrument. Modified instru-

ments shall have their performance tested and documented prior to issuance for field use. If the user can document that the modifications do not affect the instrument's performance, additional testing is not required. For example, modifying the size or shape of a control knob to enable its use with protective gloves might be a valid modification that would not require additional testing. However, if modifications deal with the instrument operating principle, then additional testing would be required.

Periodic Performance Testing

Periodic performance testing is needed to determine whether instruments continue to provide adequate performance under existing or altered conditions of use. Aging and degradation of critical instrument components are also a concern. Based on experience and anticipated modes of failure, the purchaser should test or arrange to test a representative number of units against selected specifications from the type test to verify that the instrument continues to meet relevant specifications. Individual units, models, or families of instruments should be modified or removed from service when they no longer meet operational needs. The life-cycle stage of periodic performance testing should also be viewed as an opportune time to reevaluate mission needs and instrument options. It should also be viewed as an opportunity to adopt or develop improved tests or test-agent characteristics to better reflect instrument performance in the real world.

Benefits of Harmonization

Harmonization Across the Life-Cycle Process

The life-cycle approach to instrument development and use permits an "inception to grave" harmonization and integration of testing and evaluation approaches. Using common tests throughout the life cycle improves the likelihood of understanding when things go wrong and can save time and money by using the same test sources and test facilities. A radiological example is use of the same design and specifications for electroplated radioactivity samples at all test stages. For biological detection systems, an example is use of the same strains or forms of anthrax or anthrax surrogates throughout the development, testing, and application of an instrument. The life-cycle approach will also reduce the costs of conceiving, developing, verifying, and validating instruments and conducting training and documentation for their use.

Harmonization Among Instrument Types or Classes

Different detection methods or configurations of detection methods can give different results. In order to integrate detection results from many locations, under many conditions,

with hand-held, portable, and fixed instrumentation, it is necessary that the life-cycle approach include common tests and calibration approaches to allow comparison and interpretation of all available data. When attempting to make simultaneous comparisons of data from multiple instruments and locations, it is important to be aware of environmental and temporal variability, as well as of differences in instrument configuration or operating principle. Harmonization includes the recognition that several instrument types are frequently needed to cover different phases of incident response. An example involves changing requirements for response to a mixed-radionuclide source with temporal changes in the ratio of alpha-, beta-, and gamma-emitting components. Initial monitoring and protection strategies may rely on the measurement of one radiation type (which may dominate the initial radiological risk) as a metric of concern, but later decisions may require information about other radiation types that assume greater relative importance with time. Events involving multiple agents of biological, chemical, or radiological materials may require an evolving suite of monitoring instrumentation. In other words, simply because one component has been reduced to a "safe" level, it cannot be assumed that all components have been reduced to safe levels.

Conclusion

An integrated life-cycle approach expands the traditional views of standards and testing and will improve our ability to accomplish our missions. It can guide the development of new instruments as well improve the process for adapting or modifying existing instruments to new applications.

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