EFCOG Best Practice # 248

Facility: Energy Facilities Contractor Group, Nuclear and Facility Safety Subgroup, Hazard Analysis Task Group

Best Practice Title: Management and Control of Less Than Hazard Category-3 Nuclear (Radiological), Non-Nuclear, and Industrial Facilities

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Brief Description of Best Practice: This Best Practice supports the management and control of less-than hazard category 3 nuclear (radiological), non-nuclear, and industrial (i.e., chemical, explosive, biological) facilities, activities, and/or operations. The framework presented reflects a systematic approach including a formal hazard analysis and change control process. The framework presented verifies all hazards are systematically identified and evaluated in support of the overall hazard classification and documentation process.

Why the best practice was used: Implementation of these Best Practices ensure all hazards are identified and evaluated; hazard classification is appropriately assigned; and the appropriate level of safety basis documentation is prepared, and maintained for those facilities, activities, and/or operations not covered by a traditional Documented Safety Analysis or Accelerator Safety Envelope /Safety Assessment Document.

What are the benefits of the best practice: The Hazard Analysis Task Group supports a formalized approach to management and control of less than hazard category-3 nuclear (radiological), non-nuclear, and industrial (i.e., chemical, explosive, biological) facilities, activities, and/or operations consistent with DOE-HDBK-1163-2020, *Integration of Hazard Analyses*.

What problems/issues were associated with the best practice: The fundamental expectation described within this Best Practice is to implement a consistent approach for determining hazard classifications, based on conservative methods to assess credible events with the potential to significantly impact workers, onsite personnel/workers, and members of the public.

How the success of the Best Practice was measured: This Best Practice provides the framework for implementation of a formal classification process for the management and control of less-than hazard category 3 nuclear (radiological), non-nuclear, and industrial (i.e., chemical, explosive, biological) facilities, activities, and/or operations.

Description of process experience using the Best Practice: See Attached.

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Energy Facilities Contractor Group
Nuclear and Facility Safety Subgroup
Hazard Analysis Task Group

Best Practice Paper

Management and Control of Less Than Hazard Category-3 Nuclear (Radiological), Non-Nuclear, and Industrial Facilities

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Abstract

This Best Practice Paper provides best practices for the management and control of less-than hazard category (HC)-3 nuclear (radiological), non-nuclear, and industrial facilities (i.e., chemical, explosive, biological). Implementation of these best practices ensure hazards are identified and evaluated; hazard classification is appropriately assigned; and the appropriate level of safety basis documentation is prepared, reviewed, approved, maintained, and routinely updated.

A fundamental expectation is to implement a consistent approach to determining hazard classifications, based on conservative methods to assess credible events with the potential to significantly impact workers, onsite personnel/workers, and members of the public.

Introduction

Safety basis documents (e.g., DSA[1], HA[2], SHA[3], SA[4], SAD[5]) are the input used to determine if risks are acceptable and the operations can be authorized. Once approved, the safety basis for any operation represents the documented acceptance of risk associated with a facility or operation. Depending on the hazard level of the facility, Department of Energy (DOE) may choose to delegate or retain authorization authority. For facilities and activities where DOE has delegated authorization authority, safety basis documentation may be prepared by the facility or line organizations, submitted for review/concurrence to the overarching centralized safety basis group for the site, and approved by the facility or line organization management.

For facilities and activities where DOE retains authorization authority, as with high-hazard industrial facilities, accelerators regulated under DOE-O-420.2C, *Safety of Accelerator Facilities*, and HC 1, 2, and 3 DOE nuclear facilities regulated under 10 CFR 830, *Nuclear Safety Management*, safety basis documentation is prepared by facility or line organizations, submitted for review/concurrence by the overarching centralized safety basis group for the site, approved by the facility or line organization management for DOE submittal, and finally submitted to DOE for final approval.

The safety basis process for less-than HC-3 nuclear (radiological), non-nuclear, and industrial facilities may also include the documented review of "readiness" for a facility or line organization to start (or restart) operations as described in the facility or activity within the authorization documentation. As with HC-1, 2, and 3 nuclear facilities, the readiness review process typically occurs following completion of the

[1] Documented Safety Analysis
[2] Hazard Analysis
[3] Stand-Alone Hazard Analysis
[4] Safety Assessment
[5] Safety Assessment Document

authorization documentation but prior to the start or restart of operations.

The safety basis process is prescriptively described for HC-1, 2, and 3 nuclear facilities and accelerator facilities through various DOE standards, orders, guides, and supplements. However, hazards associated with less-than HC-3 nuclear (radiological), non-nuclear, and industrial facilities are managed using a graded approach. This Best Practice Paper provides best practices for the management and control of less than HC-3 nuclear (radiological), non-nuclear, and industrial facilities across the DOE complex.

Framework

The framework for management and control of less than HC-3 nuclear (radiological), non-nuclear, and industrial facilities reflect a systematic approach including a formal hazard analysis (HA) and change control process. The HA process includes a formal hazard identification (HI) and hazard evaluation (HE). Based on the level of rigor of the facility, activity, and/or operation the analyst may elect to include various screens, control evaluation, and qualitative risk analysis in association with the documented hazard analysis process.

General expectations for safety basis documentation in association with the management and control of less than HC-3 nuclear (radiological), non-nuclear, and industrial facilities reflect a formal hazard classification system and graded approach to HA documentation. Hazard classification documentation for each level increases in complexity and rigor based on potential unmitigated consequences of non-nuclear hazards. All radiological hazards must remain below DOE-STD-1027, *Hazard Categorization of DOE Nuclear Facilities*, HC-3 thresholds to be considered under this methodology. Expectations and safety basis documentation expectations may be outlined as follows:

- Perform and document formal HI, hazard classification, HE, and HA for facilities, activities, and/or operations identified in quantities greater than standard industrial hazards[6] (SIH).
- Prepare a general HA and/or Stand-Alone Hazard Analysis (SHA) for new and existing less than HC-3 nuclear (radiological), non-nuclear, and industrial facilities classified as "low-hazard[7]."
- Prepare a safety assessment (SA) for new and existing less than HC-3 nuclear (radiological), non-nuclear, and industrial facilities classified as "moderate-

[6] A SIH is routinely encountered and accepted in general industry; a consensus standard typically exists.
[7] A Low-Hazard Facility, Operation, and/or Activity has the potential for only localized significant non-nuclear consequences.

hazard[8]" or "high-hazard[9]."

- The safety basis document (i.e., HA, SHA, SA) addresses, at a minimum, the following key features:
    - Site/facility description,
    - Process operation and/or activity description,
    - HA; including a formal HI and HE (including screening as applicable),
    - Accident analysis (as needed),
    - Summary of safety controls (including safety management programs (SMPs) and safety envelop), and
    - Change control process.
- As a Best Practice, the preliminary SA for a new moderate-hazard or high-hazard less than HC-3 nuclear (radiological), non-nuclear, and industrial facility may be submitted to the DOE Site Office for approval prior to construction. Once complete, the final safety basis document (i.e., HA, SHA) for a low-hazard less than HC-3 nuclear (Radiological), non-nuclear, and industrial facility may be submitted to the DOE Site Office. Note: DOE Site Offices may elect to delegate approval authority for moderate-hazard or high-hazard less-than HC-3 (radiological), non-nuclear, and industrial facilities to the site contractor.
- Perform an internal technical review and obtain management approval of a final safety basis documents (i.e., HA, SHA, SA).
- Unless otherwise approved by the DOE Site Office, safety basis documents for facilities, activities, and/or operations classified as moderate-hazard or high-hazard may be revised annually. For low-hazard facilities, activities, and/or operations, a five (5)-year revalidation cycle for safety basis documentation (i.e., HA, SHA) may be sufficient. For other unique facilities, activities, and/or operations (i.e., firing ranges, Emergency Operation Centers) it is suggested HA revision intervals be established consistent with governing procedures.
- Maintain the status of safety basis documents as "current" and reflect any changes in the facility, the work, and the hazards as they are analyzed in the safety basis documentation (i.e., HA, SHA, SA).
- Develop, document, and implement a USQ[10]-like change control process. The change control process may be managed by the centralized safety basis group for the site and approved by the facility or line organization management. For

[8] A Moderate-Hazard Facility, Operation, and/or Activity has the potential for significant onsite non-nuclear consequences (unmitigated).
[9] A High-Hazard Facility, Operation, and/or Activity has the potential for significant offsite non-nuclear consequences (unmitigated).
[10] Unreviewed Safety Question

those facilities, activities, and/or operations with high-hazard or moderate-hazard classification, initial approval (and approval of any changes thereafter) may be required by the local DOE Site Offices.

- Ensure a Contractor Assurance System requirement is in place to assure continuing acceptable performance, management, and control of less than HC-3 nuclear (radiological), non-nuclear, and industrial facilities.

The safety basis documentation for low-hazard less-than HC-3 (radiological), non-nuclear, and industrial facilities, activities, and/or operations includes some type of general HA documentation. For low-hazard industrial operations, managers ensure a more rigorous HA is performed for the facility, activity, and/or operation in the form of a SHA. Documentation for a SHA may resemble a process hazard analysis as outlined within 10 Code of Federal Regulations (CFR) 1910.119, *Process Safety Management of Highly Hazardous Chemicals*. For moderate-hazard and high-hazard facilities, activities, and/or operations the HA process may be performed to a higher-yet level of rigor in the form of a SA. Documentation for a SA may resemble a Documented Safety Analysis or Accelerator Safety Envelope/Safety Assessment Document as outlined within DOE-STD-3009, *Preparation of Nonreactor Nuclear Facility Documented Safety Analysis*, or DOE-O-420.2C.

A general HA will identify the hazards, as well as the controls necessary to mitigate or prevent the impacts of the hazards. A SHA is used to analyze hazards in greater detail and may be required to verify or confirm facility, activity, and/or operation hazard classification. If a SHA will be used to support hazard classification, a risk-based assessment may be used to identify hazards and corresponding controls. If a SA is necessary to support facility, activity, and/or operation hazard classification, a risk-based assessment may be used to identify hazards and corresponding controls along with surveillance requirements. The set of controls within both the SHA and SA will be the safety envelope for the facility, activity, and/or operation.

All safety basis documents for less-than HC-3 facilities (radiological), non-nuclear facilities, and industrial facilities (i.e., HA, SHA, SA) are prepared by qualified analyst. The analyst may be assigned based on individual areas of hazard-specific expertise and the use of various HE techniques, as defined in the Center for Chemical Process Safety (CCPS), *Guidelines for Hazard Evaluation Procedures*, 3rd Edition (i.e., Redbook). Additional guidance on the HA process for DOE facilities, activities, and/or operations can be found in DOE-HDBK-1163-2020, *Integration of Hazard Analyses*.

Over-arching requirements for performing an HA are found in DEAR, 48 C.F.R. Section 970.5223-1, *Integration of Environment, Safety, and Health into Work Planning and Execution*, which requires the identification and evaluation of hazards associated with work as part of an overall documented safety management system. This requirement is expanded upon in various DOE directives, standards, and guidance documents.

DOE O 413.3B, Chg. 6, *Program and Project Management for the Acquisition of Capital*

Assets, provides project management directives to deliver every project at the original performance baseline, on schedule, within budget, and fully capable of meeting mission performance, safeguards and security, quality assurance, sustainability, and environmental, safety, and health requirements and introduces critical decision (CD) points. DOE O 413.3B, Chg. 6, puts forth expectations for facilities that are below HC-3 thresholds. These expectations include the requirement to prepare a Preliminary Hazards Analysis Report (HAR) (i.e., HA, SHA, SA) to identify and evaluate all potential hazards and establish a preliminary set of safety controls.

Definitions and Classification Criteria

In order to establish the criteria for the management and control of less than HC-3 nuclear (radiological), non-nuclear, and industrial facilities several "baseline" hazard classification definitions are established. All radiological hazards must remain below DOE-STD-1027, HC-3 thresholds to be considered under this methodology. The minimum definitions include, but are not limited to, the following:

- "High" hazard has the potential for significant offsite non-nuclear consequences.
- "Moderate" hazard has the potential for significant onsite non-nuclear consequences.
- "Low" hazard has the potential for only significant localized non-nuclear consequences.
- "SIH" are routinely encountered and accepted in general industry; a consensus standard typically exists.
- "Localized" signifies the area within 100 meters (m) of the facility or within the exclusionary area for explosives and airborne objects.
- "Onsite" signifies the area beyond 100 m from a facility to which the general public does not have uncontrolled access.
- "Offsite" is the area beyond onsite, to which the general public has uncontrolled access.
- "Public" is a member of the public at the nearest site boundary location.

In addition to hazard classification definitions, significant non-nuclear consequences for each hazard type may also be defined for a given site and based on input from the local DOE Site Office.

Additional points for consideration with respect to the management and control of less than HC-3 nuclear (radiological), non-nuclear, and industrial facilities are as follows:

- A qualified analyst assesses the impacts of multiple hazards.

- HA/SHA/SA development follows a graded approach.
- A USQ-like change control process is established, documented, and implemented.
- Local DOE Site Office approval is required for facilities, activities, and/or operations for which there is a potential for significant off-site non-nuclear consequences to the public.
- Facility management approval may be required facilities, activities, and/or operations for which there is not a potential for significant non-nuclear consequences to the public.

Guidelines may be established for unmitigated non-nuclear consequence calculations that credit material form and separation, initial conditions, and assumptions, and/or credible release sequences of material, as follows:

- Take no credit for active safety systems.
- Take credit for passive safety features that are assessed to survive accident conditions, where that capability is necessary to define a physically meaningful scenario.
- Take no credit for passive safety features producing a "leakpath" reduction in the source term/hazard.
- Assume the availability of passive safety features that are not affected by the accident scenario.

Less Than Hazard Category-3 Nuclear (Radiological), Non-Nuclear, and Industrial Facility Classification Process

Facilities, activities, and/or operations are divided into either nuclear facilities or industrial facilities. Nuclear facilities are classified as HC 1, 2, or 3 nuclear facilities. Non-nuclear, and industrial facilities are classified as either business occupancy (office), SIH, low-hazard, moderate-hazard, high-hazard, or accelerator. An additional "radiological" designation may be given to facilities with radiological material or radiological generating devices below the HC-3 threshold limits. Less than HC-3 radiological facilities are considered nuclear facilities and must meet the quality assurance requirements in Subpart A of 10 CFR 830, *Nuclear Safety Management*.

Typically, business/office occupancy, SIH, and low-hazard classifications can be assigned at the lowest level of rigor, although SIH and low classifications may require additional analysis prior to final hazard classification determination by an analyst. All moderate-hazard and high-hazard classifications assigned by the analyst are based on documented screening criteria. Example SIH screening criteria can be found in DOE-HDBK-1163-2020. Moderate-hazard and high-hazard classifications are determined based on thorough analysis in addition to

applicable screening criteria.

Business/office occupancy classification may be assigned to facilities, activities, and/or operations with hazards limited to:

- Common to any work environment (e.g., tripping, slipping, falling).
- Consumer products and tools that do not require personal protection equipment (e.g., toner cartridges, paper cutters).
- Building systems and utilities managed and maintained externally by facility support organizations (e.g., building electrical panels).
- Conditions outside of the manager's control (e.g., natural phenomena, adjacent unrelated operations).

A SIH classification may be assigned to facilities, activities, and/or operations with hazards of the type and magnitude routinely encountered and/or accepted by the public in everyday life. Unless in quantities or situations that could significantly impact large numbers of people, SIH classifications may include but not be limited to:

- Hazardous materials or operations encountered in general industry.
- Applications adequately controlled by Occupational Safety and Health Administration regulations.
- Applications covered by one or more national consensus standard (e.g., ASME[11], ANSI[12], NFPA[13], IFC[14], IBC[15], IEEE[16], NEC[17]), where these standards are adequate to define special safety requirements.

Equipment considered SIH cannot have been modified or used outside of manufacturer's specifications. An SIH classification may be used for hazards that can affect only those workers involved in a specific activity and may not have the potential to cause injury to onsite personnel involved in other activities.

Low hazard classification is given to facilities, operations, and/or activities with the potential for only localized significant non-nuclear consequences. Moderate hazard classification is given to facilities, operations, and/or activities with the potential for significant onsite non-nuclear consequences. High hazard classification is given to facilities, operations, and/or activities with the potential for significant offsite non-nuclear consequences.

Hazard classification is based on the highest level of hazard determined within the safety envelope for any hazard type. For example, if a facility, activity,

[11] American Society of Mechanical Engineers
[12] American National Standards Institute
[13] American Fire Protection Agency
[14] International Fire Code
[15] International Business Code
[16] Institute of Electrical and Electronics Engineers
[17] National Electric Code

and/or operation would be classifiable as a low-hazard for use of certain chemicals and moderate-hazard for its use of explosive materials, the facility, activity, and/or operation is classified as a moderate-hazard.

In addition, a radiation-generating device (RGD) employing electrostatic or electromagnetic fields to impart kinetic energy to molecular, atomic, or sub-atomic particles, and capable of creating a radiological area accessible to individuals is classified as an "accelerator." Accelerators may be exempt from meeting the requirements of the DOE O 420.2C, *Safety of Accelerator Facilities*, based on criteria listed in the order.

Site Boundaries

The terms "localized," "onsite," and "offsite" define non-nuclear low, moderate, and high hazard classifications, respectively. Localized is generally defined as the area within 100 m of the facility/activity. Onsite and offsite are defined by site boundaries where the public has uncontrolled access. Site boundaries are typically defined by property boundaries, which may or may not have permanent fence lines, gates, or signage, but are controllable by the direction of the site if an abnormal event occurs. On government installations, control may be achieved by using site contractors or federal government security, and/or emergency response organizations.

Given the diversity of the many facilities, a single definition for "site boundary" may not be appropriate to apply to all facilities. For facilities located outside of the defined areas, hazard classification may be determined on a case-by-case basis by a qualified analyst. This variability emphasizes the importance for the hazard classification of facilities, activities, and/or operations to be formally documented.

Receptors

For low-hazard, moderate-hazard, and high-hazard facilities, activities, and/or operations classifications and potential unmitigated non-nuclear consequences are analyzed for multiple receptors, including, but not limited to workers, onsite personnel, and the public. Personnel within the defined localized area are designated "workers." Personnel located beyond the defined localized area (e.g., beyond 100 m), but within the site boundaries are designated "onsite" or "collocated/co-located" workers or personnel. Personnel located beyond the site boundaries are designated the "public." Additional receptors, such as environment, facility, mission, public perception, etc., may also be included in the analysis process.

Hazard Specific Consequences

The hazard specific non-nuclear consequences in association with less than HC-3 nuclear (radiological), non-nuclear, and industrial facilities, activities, and/or operations tend to encompass a broader scope of hazards than those considered

in the traditional nuclear approach. In addition to the radiological hazard, the analyst also focuses the HA process on potential non-nuclear hazards, such as chemical, explosive, laser, non-ionizing radiation, airborne objects, use of equipment outside the manufacturer's recommendations, non-commercial equipment, biological, and other potential hazards. All receptors (i.e., worker, collocated worker, public, environment, facility, mission) are evaluated with respect to each hazard identified. If certain receptors will not be evaluated, justification may be presented to support this decision. Typically, hazards such as chemical reactions/incompatibility, combustible materials (non-chemical), confined space, electrical, hot work/open flames, internal flooding, mechanical hazards, noise, physical impact, pressure, thermal, vehicles, and standard wastes are considered either SIH or low, because these types of hazards have the potential to impact only the worker and therefore do not impact the facility, activity, and/or operation hazard classification determination.

For low-hazard, moderate-hazard, and high-hazard classifications, "significant" consequences are based on hazard-specific non-nuclear consequences. Hazard-specific threshold criteria may be evaluated on a case-by-case basis. An example Qualitative Consequence Matrix for multiple receptors is provided in DOE-HDBK-1163-2020.

Radiological Hazards

Hazard classification for accelerators is based on the applicability of DOE O 420.2C and the listed exemptions. Hazard classification for radioactive material is based on the thresholds defined in NA-1 SD G 1027, *Guidance on Using Release Fraction and Modern Dosimetric Information Consistently with DOE STD 1027-92, Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 548.23, Nuclear Safety Analysis Reports, Change Notice No. 1.* Radioactive material falling below the HC-3 thresholds results in a "low hazard" classification versus a SIH classification because of the inherent risks in association with radiological hazards. Additionally, this philosophy elevates the level of rigor in HA documentation for less-than HC-3 nuclear facilities to that of a SHA.

Chemical Hazards

Hazard classification for chemical facilities, activities, and/or operations may be dependent on various screening criteria. The chemical criterion for moderate-hazard and high-hazard industrial facilities classification is typically based on a chemical consequence analysis to determine significant onsite or offsite impacts. A hazard classification review by the analyst is generally be triggered by:

- Inventories of flammable gases exceeding 1000 standard cubic feet released from a single container, manifolded series of containers, or house gas system.

- Inventories of highly hazardous chemicals exceeding Process Safety Management (PSM) threshold quantities.
- Inventories of toxic and highly toxic chemicals exceeding threshold quantities based on Protective Action Criteria (PAC)-2 values.

Based upon input to screening criteria, the analyst may verify the inventory of chemicals to address potential credible release events. Typically, the quantity of chemical used to evaluate a given release event is based on the potential for release from a single, common event. Chemical dispersion modeling may be required as a part of the hazard classification review. Standard modeling protocols may be further defined within programmatic documentation for each site. Dispersion modeling completed by analyst is for safety basis purposes only. Results of dispersion modeling may not be used for other purposes without disclosure of the modeling parameters.

For toxic and highly toxic chemicals, significant chemical consequences are determined by the potential to exceed the PAC-2 thresholds at 100 m; onsite, and offsite. For flammable gases, significant chemical consequences are a determined by the potential to cause an energetic event or thermal impact at 100 m, onsite, and offsite. For process safety management quantities (per 29 CFR 1910.119, Appendix A) of highly hazardous chemicals (, significant chemical consequences are determined by the potential to exceed PAC-2 thresholds, an energetic event, or a thermal impact at 100 m, onsite, and offsite.

Explosive Hazards

Hazard classification for explosive facilities, activities, and/or operations may be dependent on various screening criteria. Hazard classification for explosive facilities, activities, and/or operations reflect the quantity-distance (QD) arc identified in the DOE explosives safety documents, explosives site plan (ESP), and/or explosives building license (EBL) required by the Department of Defense (as applicable). A hazard classification review by the analyst is triggered when the QD arc extends beyond the documented access control area. The access control area may be defined as a physical boundary or spacial designation. Although a QD arc may have the potential to extend beyond the documented access control area, the QD arc by definition cannot exceed the facility boundary.

For explosives, significant explosive (i.e., overpressure) consequences are typically based on the explosive type, QD arc, and access control for a credible event with the potential to cause an overpressure outside of the facility, activity, and/or operation boundary. Generally, operations (e.g., storage) that perform activities with energetic materials that could **not** result in a detonation may be given a low hazard classification. Conversely, operations that do perform activities with energetic materials that could result in a detonation and/or projectiles are evaluated further to determine if

there are compensatory measures identified in the ESP/EBL that would prevent onsite or offsite explosive consequences. Potential explosive consequences may be calculated based on overpressure at a distance from the detonation/deflagration site and are typically considered "significant" at pressures greater than 0.25 pounds per square inch and/or 140 decibels.

Lasers

Hazard classification for facilities, activities, and/or operations with lasers[18] may be dependent on various screening criteria. Hazard classification for lasers reflects whether onsite personnel or the public could be exposed to any class of visible laser (400-700 nanometers), or to any Class 3B or Class 4 laser directed into navigable airspace or with unenclosed beams. Laser classes are formally defined within American National Standards Institute (ANSI) Z136.1-2014, *Safe Use of Lasers*, based on wavelength and power. Typically, facilities, activities, and/or operations using Class 1 and Class 2 lasers may be considered SIH, while those using Class 3 and Class 4 lasers may be classified as low-hazard, moderate-hazard, or high-hazard based on the specific application, receptors, and unmitigated consequence potential.

Non-Ionizing Radiation

Hazard classification for facilities, activities, and/or operations with non-ionizing radiation are dependent upon whether onsite personnel or the public could have unrestricted access into an area that exceeds the published exposure limits for radio frequencies, microwaves, optical radiation, and/or magnetic fields.

Airborne Objects

Hazard classification for airborne objects reflect potential significant impacts to onsite personnel or the public specific to aviation activities and other airborne hazards, including projectiles, fragmentation, and unmanned ariel systems. Airborne objects may reflect, but are not limited to:

- Aviation activities that pose a risk greater than those accepted by the general public per 14 CFR 91, *General Operating and Flight Rules*, or contained in corporate-specific procedures.
- Airborne objects with the potential to cause injury or exposure to someone not associated with the facility, activity, and/or operation, or have the potential for offsite impact.
- Activities that involve the carry, use, test, transport, or control of firearms, munitions, or other energetic material.
- Unmanned ariel systems weigh greater than fifty-five (55)-pounds, or not otherwise covered under 14 CFR 107, *Small Unmanned*

[18] Light Amplification by Simulated Emission of Radiation

Aircraft Systems.

Significant onsite or offsite airborne consequences are based on the severity (e.g., fatality, irreversible injuries) of the injury to receptor. Typically, the potential for impact from an airborne object or aircraft would be considered a significant impact and require additional more rigorous analysis.

Equipment Outside of Manufacturers Recommendations

Hazard classification for facilities, activities, and/or operations with equipment outside of manufacturers recommendations reflect whether the equipment, tools, or materials used could cause injury/exposure to anyone not associated with the facility, activity, and/or operation, or have an offsite impact. Significant onsite or offsite equipment consequences are based on the severity (e.g., fatality, irreversible injuries) of the injury to onsite personnel or the public based on use of equipment outside of manufacturers recommendations.

Noncommercial Equipment

Hazard classification for facilities, activities, and/or operations with non-commercial equipment reflect whether the equipment could either cause injury/exposure to someone not associated with the facility, activity, and/or operation, or have an offsite impact. Significant onsite or offsite noncommercial equipment consequences are based on the severity (e.g., fatality, irreversible injuries) of the injury to onsite personnel or to the public.

Biological Hazards

Hazard classification for facilities, activities, and/or operations with biological hazards generally reflect the given BSL and/or type of biological agents. The BSL definitions are established by the Centers for Disease Control (CDC). Typically, laboratories using biological agents associated with BSL-1 and BSL-2 activities are classified as low-hazard based on the CDC definitions and requirements for use of select BSL materials.

An analyst may evaluate hazard classification on a case-by-case basis if the biological activities involve human or primate prions, vertebrate laboratory animals, Risk Group 3 or 4 agents, or BSL 3 or 4 laboratory activities. Hazard classification for these types of facilities, activities, and/or operations may be based on facility location, biological agents, and the BSL capability of the facility, and/or other CDC criteria.

Unique and Other Hazards

Because of the diversity of the different DOE sites, there is a potential for unique and undefined hazards to exist. Unique hazards are evaluated individually for hazard classification by an analyst. Generally, unique hazards will be considered either SIH or low, because these types of hazards have the potential to impact only the worker. Unique hazards with the

potential to impact onsite personnel or public may be analyzed on a case-by-case basis and may require a SHA. Significant onsite or offsite consequences are based on the severity of the injury (e.g., fatality, irreversible injuries) to onsite personnel or public from these unique hazards.

Initial Conditions & Assumptions

In certain situations, use of an Initial Condition and/or Assumption (IC/A) may be appropriate to consider for the hazard classification of a facility, activity, and/or operation. Ideally, the IC/A is a passive engineered control or design feature, but may include administrative controls and/or active engineered controls. A credited IC/A may be evaluated and assigned surveillance requirements, as appropriate (typically through administrative controls and/or procedures) to ensure the IC/A remains valid throughout the life of the facility, activity, and/or operation. Use of an IC/A to keep a facility, activity, and/or operation from jumping to the next level of hazard classification is documented within the HA, SHA, or SA and is protected with controls and/or surveillance requirements. As a good practice, the local DOE Site Office may be notified when an IC/A is credited in the determination of hazard classification.

Separation

In some cases, the Safety Basis analyst may determine separating facilities, activities, and/or operations is appropriate to consider for non-nuclear hazard classification determinations. Separation of non-nuclear facilities, activities, and/or operations is similar to the principles of segmentation for nuclear facilities. Segmentation may be used per DOE-STD-1027 as part of the hazard categorization process for a nuclear facility, and included rigorous documentation. In some instances, demonstration of segmentation may be used to justify a less-than HC-3 nuclear classification. Separation is intended to prevent excessive requirements needed for one operation from being applied to less-hazardous non-nuclear operations and/or activities in the same facility. Separation may not be applicable to all non-nuclear hazards.

Facility areas may be considered independent if features exist to preclude potential impacts of hazards in one area from affecting the workers or operations in other areas. Independently functioning building systems may be considered to justify separation. Separation may not be considered unless the rationale is justified and clearly documented within the safety basis documentation and analysis (i.e., a reduction in risk is identified). Although not exclusively, chemical, explosive, and non-ionizing radiation hazards are examples of non-nuclear hazards that may provide merit for formal separation justification.

Documentation

Although the safety basis document can vary significantly for each less than HC-3 nuclear (radiological), non-nuclear, and industrial facilities, the HA, SHA, and SA have commonalities. For purposes of discussion the analysis behind the HA, SHA, and SA documents are referred to collectively from this point forward as the HA Process. The HA Process is an analytical effort that systematically identifies facility hazards and accident potentials through HI and HE with an optional control evaluation and/or optional risk analysis.

The initial step of the HA Process is to define the scope of the evaluation. The scope defines the physical and process boundaries of the facility and/or process. The scope is defined in the safety basis documentation together with the defined receptors. Minimally, the HA Process considers the complete spectrum of hazards and subsequent events/scenarios (nuclear and non-nuclear) that may occur with consequences to the receptors.

The next step of the HA Process is to identify hazards of the scoped facility, activity and/or operation. A defined HI Checklist provides a systematic approach reflecting the facility/process design, process, and materials to identify a comprehensive list of hazards. An example HI Checklist is provided in DOE-HDBK-1163-2020. The HI Checklist is field verified with facility walkthroughs.

Screening of hazards and/or screening of hazard events/scenarios may be utilized to support the HA Process. Hazards considered potential initiating events may not screen from further analysis even if they are below the defined screening criteria.

The appropriate HE technique is selected based, in part, on the identified hazards, potential initiating events, and complexity of the process. The HE may be performed using one or a mixture of HE techniques. A broad-brush technique is preferred for the HE with use of additional HE techniques if deemed necessary. Regardless of the HE technique chosen, the technique systematically identifies and assess hazards to evaluate the potential internal, external, and natural events that can cause the identified hazards to develop into accidents as well as support systematic derivation of controls. Additional information on HE technique selection criteria can be found in the Redbook and DOE-HDBK-1163-2020.

The control derivation feeds into the safety envelope, which discusses all of the credited controls. The derived credited controls are be protected throughout the lifetime of the facility, activity, and/or operation. The change control process is established to keep the safety basis document current. As with any safety basis document, it is a best practice to implement a formal peer review process prior to routing for management/approval authority endorsement. Implementation of a formal peer review process helps ensure quality and consistency across a given site. A formal peer review process may identify lessons learned and incorporate best practices.

The change control process may resemble a USQ-like process for evaluating changes to the facility, activity, and/or operation along with different levels of approval. The HA Process output is a living document that is reviewed and updated regularly, on a schedule not to exceed five (5) years.

It is recommended a "readiness-like" activity (i.e., self-assessment and/or an independent validation review) also be instituted as a part of the HA Process. Additional guidance on the HA Process for DOE facilities, activities, and/or operations can be found in DOE-HDBK-1163-2020.

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14 CFR 107, *Small Unmanned Aircraft Systems*.

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U.S. Department of Health and Human Services, *System Safety and Risk Management NIOSH Instructional Manual.*