The National Institutes of Health | Division of Technical Resources | Office of Research Facilities

Design Requirements Manual **News to Use**

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The formulae $\frac{\partial \bar{u}_i}{\partial t}+\frac{\partial}{\partial x_j}(\rho \bar{u}_i \bar{u}_j)=-\frac{\partial \bar{p}}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu \frac{\partial \bar{u}_i}{\partial x_j}\right)+g_i(\rho-\rho_0)$ *for building* $\frac{\partial}{\partial x_j}(\rho \bar{u}_i \bar{u}_j)=-\frac{\partial \bar{p}}{\partial x_i}+\frac{\partial}{\partial x_j}\left(\mu \frac{\partial \bar{u}_i}{\partial x_j}-\rho \overline{u_i' u_j'}\right)+g_i(\rho-\rho_0)$ *state of the art* $\frac{\partial}{\partial x_i}(\rho \bar{u}_i \bar{H})=\frac{\partial}{\partial x_i}\left(\lambda \frac{\partial \bar{T}}{\partial x_i}-\rho \overline{u_i' h'}\right)$ *biomedical research facilities.*

Risk Assessment Tools for Critical Facilities

Facility Risk Assessment (RA) is the process of identifying and analyzing potential future events that may negatively impact a facility, how likely each sort of risk is, and how much of an impact a risk may have on the facility operation, and in turn on end user's operation. NIH has a variety of critical facilities, including Animal Research Facilities (ARFs), Biosafety Level-3 (BSL-3) laboratories, facilities which house equipment such as MRIs or electron microscopes, and those responsible for clinical drug development. While it is impossible to eliminate all risks, many of these risks can be mitigated by incorporating certain elements into the design of the facility.

An RA tool is typically used during the project's design development phase to document project risks, their assessed risk characteristics, and the reduction of those characteristics by engineering and administrative controls. The tool helps stakeholders decide how much of each type of risk can be tolerated. Administrative controls could include frequent maintenance, cleaning, testing, or monitoring. Engineering controls could include use of HEPA filters, biological safety cabinets (BSCs), and compounding aseptic isolators (CAIs). Engineering controls are generally preferred because of their reliability and robustness, but administrative controls can significantly reduce the risks to the facility, scientific research, and people. RA informs the project team, especially the designers, and guides them in the development of mitigations. The assessment is later revisited after construction, and any remaining risks or controls are discussed and assessed for future mitigations.

NIH performs RA for every major Aseptic Processing Facility (APF). These facilities manufacture products in accordance with cGMP for use by clinical patients. Manufacture of these products involves risks associated with facility design and construction, including contamination and cross contamination, cleanability of surfaces, utility system reliability, floods or water leaks, power failure, pests, room pressure reversals, and accessibility for routine maintenance and/or equipment repair. Other risks associated with individual process steps are considered, but the risks exclusive to the process and technique are not considered as part of the facility RA.

Risk Assessment Method

The NIH RA tool uses the Failure Modes and Effects Analysis (FMEA) method. The assessment is carried out by a multidisciplinary team that includes users, quality assurance, engineers, architects, and maintenance personnel. This team considers every facility system and component for potential failure effects as well as the consequences for each failure mode. They assign a value of 1 (low) to 5 (high) for each of several categories – severity, probability of occurrence, and detectability – based on current practices, procedures, facility design, and condition.

Risk Assessment Method Assessment for Severity: The RA tool rates the level of severity (i.e., the impact should failure mode occur) using the following rating scale:

1 (Low) Any failure mode with no adverse health effects to patients or animals, or minimal impact to scientific research.

2-4 (Medium-Low, Medium, and Medium-High) A failure mode which could cause reversible moderate to significant impact to patients, animals, or scientific research.

5 (High) Any failure mode that results in irreversible significant impact to patients, animals, or scientific research.

Assessment for Probability: Like the assessment for severity, this RA tool assesses the probability of occurrence for each failure mode using the following scale:

1 (Low) Any failure mode that is expected to occur no more than once every five years, or where a design/function is standard, simple, or well-known.

2-4 (Medium) Any failure mode that occurs occasionally (every 1-5 years) and where the design/function is reasonably standard, reasonably simple, or well understood (2); any failure mode that occurs occasionally (yearly) or where the design/function is not known to be robust (3); any failure that occurs often (monthly) or where the design/function is not known to be robust (4).

5 (High) Any failure mode that occurs regularly (weekly or more frequently) and where the design/function is not known to be robust.

Assessment for Detectability: This RA tool assesses the likelihood of detection should a failure mode occur.

1 (Low) Any failure mode that will almost certainly be detected.

2-4 (Medium) Any failure mode that has a high chance of being detected (2); any failure mode that has a moderate chance of being detected (3); any failure mode that has a low chance of being detected (4).

5 (High) Any failure mode that has a very remote chance of being detected.

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Risk Assessment Tool

The ratings for severity, probability, and detectability are multiplied together to establish a Risk Priority Number (RPN) for each failure mode. Generally, an RPN≤27 is indicative of an acceptable risk; 27<RPN<64 indicates a medium risk, for which mitigations should be considered; and an RPN≥64 indicates high risk which must be mitigated. After mitigations (e.g., engineering and administrative controls) are identified, the RA team evaluates the net risk reduction these have on the severity, probability, and detectability of a given risk, yielding a net RPN. Additional mitigations will be considered until the RPN for that failure mode is reduced below the user's risk tolerance.

Conclusions

Critical facilities are at risk for disruption and damage from a variety of sources, which can have severe consequences for scientific research, patient and animal health, maintenance workers, and the environment. The RA tool described here focuses on identifying and assessing risk and mitigation strategies to minimize the severity, probability, and detectability of these risks into the design of critical facilities. The RA tool has been developed by NIH for its critical facilities but can be adopted by other institutions.

References

1. ICH Q9, Quality Risk Assessment, 2005
2. FCIS- Template for Risk Assessment

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