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Assessing Public Health Risk Associated with Chemical Hazards of Licensed Material Under 10 CFR Part 53

**Comment On:** NRC-2026-3334-0001

Draft Regulatory Guide: Assessing Public Health Risk Associated With Chemical Hazards of Licensed Material

**Document:** NRC-2026-3334-DRAFT-0002

Comment on FR Doc # 2026-17093, NRC-2026-3334-0001, from The Breakthrough Institute

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## Submitter Information

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## General Comment

Please find the Breakthrough Institute's comment attached. We appreciate the work of NRC staff and the opportunity to comment.

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## Attachments

Breakthrough Institute Comment on Draft Regulatory Guide DG-1444

September 21, 2026

**Subject: Breakthrough Institute Comment on Draft Regulatory Guide DG-1444, "Assessing Public Health Risk Associated with Chemical Hazards of Licensed Material Under 10 CFR Part 53" [Docket ID NRC-2026-3334].**

The Breakthrough Institute (BTI) appreciates the opportunity to comment on Draft Regulatory Guide DG-1444, proposed Regulatory Guide 1.264, "Assessing Public Health Risk Associated with Chemical Hazards of Licensed Material Under 10 CFR Part 53." BTI is an independent, nonprofit 501(c)(3) research center that focuses on energy, environmental, and innovation policy, including the regulation and governance of nuclear energy technologies. BTI conducts analytical research in the public interest and does not receive funding from nuclear developers or operators.

BTI supports the NRC's development of RG 1.264. The draft guide describes one methodology that the NRC staff considers acceptable for implementing 10 C.F.R. § 53.440(k).<sup>1</sup> Section 53.440(k) establishes a distinct public-health requirement for the chemical hazards of licensed material, and DG-1444 provides a useful three-step structure for identifying relevant hazards, comparing offsite consequences against Protective Action Criteria (PAC) Level 2, and defining design features or programmatic controls where additional protection is needed. The draft draws on existing Part 70 chemical-hazard practice rather than creating an entirely new toxicological framework.<sup>2</sup>

## I. SUMMARY OF RECOMMENDATIONS

BTI recommends retaining DG-1444's overall three-step structure and making targeted revisions at the decision points that control whether an applicant must perform additional analysis or impose additional regulatory controls. The recommendations below are ordered by implementation significance.

1. **Define an explicit bounding-analysis pathway and stopping criterion.** If an applicant demonstrates that the calculated offsite concentration bounds the applicable conditions and remains below the applicable PAC Level 2 value, Step 2 should be complete.

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<sup>1</sup> Nuclear Regulatory Commission, Draft Regulatory Guide DG-1444: Assessing Public Health Risk Associated with Chemical Hazards of Licensed Material Under 10 CFR Part 53, Proposed RG 1.264, [ML25043A094](#), August 2026.

<sup>2</sup> 10 C.F.R. § 53.440(k); Nuclear Regulatory Commission, DG-1444, Sections B-C, [ML25043A094](#); Nuclear Regulatory Commission, NUREG-1513, Integrated Safety Analysis Guidance Document, May 2001, ML011440260.

2. **Explain how the applicable event-frequency category and PAC Level 2 consequence criterion together demonstrate the § 53.440(k) requirement for a low risk of permanent injury.** For health criteria with exposure-duration-specific values, require the comparison to use the appropriate duration or demonstrate that the one-hour value is bounding; retain the one-hour comparison where the underlying criterion is defined on that basis.
3. **Clarify the accepted path when a chemical is absent from the DOE PAC database and the data available to apply DOE-HDBK-1046-2016 are insufficient to derive a defensible Level 2 value.** The guide should identify acceptable alternatives or an early staff-coordination pathway rather than leave the issue to case-specific RAIs.

## II. SECTION C.2 SHOULD DEFINE AN EXPLICIT BOUNDING-ANALYSIS PATHWAY

Section C.2 states that a "simplified conservative analysis may be sufficient" and allows a more detailed analysis if the conservative result exceeds PAC Level 2. The draft contains the elements of a graded pathway, but it does not state what an applicant must show for the first analysis to qualify as acceptably bounding, or what review consequence follows once the bound is below the criterion. The regulatory value of a conservative screen is that the applicant can demonstrate the decision-controlling concentration is bounded over the conditions to which the calculation applies.

The final guide should define that performance objective without prescribing a single method for constructing the bound. Depending on the model and design, an applicant may be able to establish conservatism analytically, through sensitivity studies, through previously accepted calculations, or by exercising the applicable model over the relevant parameter space. The required showing should be the same: the selected source-term, dispersion, receptor, and other material assumptions bound the concentration used for the Step 2 decision.

Models that do not respond monotonically to individual inputs could create suboptimal solutions. Relatedly, BTI has previously shown that ARCON can exhibit non-monotonic response to wind speed because of the model's low-wind treatment and recommended that a bounding condition be established against the behavior of the applicable model rather than inferred from

an input that appears intuitively "worst."<sup>3</sup> DG-1444 itself identifies RG 1.249/ARCON as an acceptable dispersion method. The same principle applies here: where the model response is not demonstrably monotonic, the technical basis should show that the selected inputs actually bound the calculated concentration. Exercising the model over the relevant parameter space is one acceptable way to make that showing; it should not be the only permissible method.

The consequence of a bounding result should also be explicit. If the demonstrated bound remains below PAC Level 2, additional site-specific or best-estimate refinement cannot change the Step 2 conclusion and should not be required merely to make the analysis more realistic. Conversely, a bounding result above PAC Level 2 should not be treated as a finding that § 53.440(k) is not met. It should trigger the next level of the graded process: refinement of conservative assumptions, a more realistic consequence analysis, or Step 3 controls. This is consistent with the performance-based Part 53 approach BTI has supported elsewhere: define the safety outcome and permit applicants to use appropriate methods to demonstrate it.<sup>4</sup>

## Recommendations

| Affected Provision   | Recommendation                                                                                                                                                                                                                                                                                                                                                  |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Section C.2 - Step 2 | Define an explicit bounding-analysis pathway and stopping criterion. If an applicant demonstrates that the calculated offsite concentration bounds the applicable conditions and remains below the applicable PAC Level 2 value, Step 2 should be complete. A screen above PAC Level 2 should trigger refinement or Step 3, not itself establish noncompliance. |

## III. PAC LEVEL 2 SHOULD BE TIED TO THE § 53.440(k) FINDING AND THE RELEVANT EXPOSURE DURATION

The NRC should retain PAC Level 2 as the guide's principal acceptable consequence criterion, but it should make two points explicit. First, the guide should explain how the event-frequency

<sup>3</sup> The Breakthrough Institute, Comment on Draft Regulatory Guide DG-1463, Meteorological Monitoring Programs for Nuclear Power Plants (Proposed Revision 2 to Regulatory Guide 1.23), Comment ID NRC-2025-0975-0162, August 31, 2026.

<sup>4</sup> The Breakthrough Institute, Comment on 10 CFR Part 53: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors, Comment ID NRC-2019-0062-0463, February 28, 2025.

treatment in Step 1 and the PAC Level 2 consequence criterion in Step 2 combine to demonstrate the regulatory requirement for a "low risk of permanent injury." Second, the guide should specify how the exposure duration used in the concentration calculation must relate to the exposure-duration basis of the selected PAC value.<sup>5</sup>

## **Explain the Relationship Between PAC Level 2 and the "Low Risk" Standard**

Section 53.440(k) requires design features, related functional design criteria, programmatic controls, or a combination of those measures to be defined such that analyses demonstrate a low risk of permanent injury to the public from the chemical hazards of licensed material. DG-1444 translates that qualitative standard into a workable screening framework. It explains that PAC Level 2 represents exposure levels below which an individual would not experience irreversible health effects or symptoms that would prevent protective action. It then evaluates Anticipated Event Sequences (AESs) and Unexpected Event Sequences (UESs), while excluding Very Unexpected Event Sequences (VUESs) on frequency grounds.<sup>6,7</sup>

The logic appears to be that Step 1 addresses the likelihood component of risk through the Part 53 event categories and Step 2 addresses consequence through the PAC Level 2 comparison. That is a sensible structure, and it is more administrable than attempting to force the chemical-hazard analysis into the comprehensive radiological risk metrics that DG-1444 expressly says need not govern the chemical analysis. But the final guide should state the relationship rather than leave applicants and reviewers to infer it. The acceptance basis should explain why the combination of the event category and the PAC Level 2 endpoint is sufficient for the § 53.440(k) finding.

Clarifying the interaction of event category and PAC Level 2 would also distinguish an acceptance criterion from an additional margin requirement. Once an applicant has conservatively or boundingly demonstrated that the controlling concentration remains below a technically supported PAC Level 2 value, the guide should not require an undefined additional margin below the criterion. Uncertainty should instead be addressed through the source-term, dispersion, and

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<sup>5</sup> Nuclear Regulatory Commission, DG-1444, Sections C.1-C.2, [ML25043A094](#).

<sup>6</sup> 10 C.F.R. § 53.440(k).

<sup>7</sup> Nuclear Regulatory Commission, DG-1444, Section C.1, [ML25043A094](#).

bounding basis of the analysis. Regulatory guides already permit justified alternative methods; the principal need here is a transparent technical bridge for the NRC-endorsed pathway.

## Match the Exposure-Duration Basis to the Postulated Release

Section C.2 directs applicants to calculate the concentration of the chemically hazardous material at the exclusion area boundary for a worst-case one-hour period after release. That is a clear default for acute airborne releases, but the final guide should specify how the one-hour averaging period interacts with the exposure-duration basis of the health criterion selected from the PAC hierarchy.<sup>8</sup>

The issue is clearest for Acute Exposure Guideline Levels (AEGs). AEGs are developed for multiple exposure periods, including 10 minutes, 30 minutes, 1 hour, 4 hours, and 8 hours, because the concentration associated with a given health endpoint can vary with exposure duration. Emergency Response Planning Guidelines, by contrast, are defined on a one-hour basis. The guide should therefore avoid treating one hour as universally interchangeable with the duration embedded in every underlying PAC source.<sup>9,10</sup>

For a PAC source that provides duration-specific Level 2 values, the applicant should use the value corresponding to the postulated release and receptor exposure duration, or demonstrate that the one-hour comparison is bounding. For ERPG-2, the one-hour comparison remains appropriate because the underlying guideline is defined on that basis. TEEL-2 values should be applied consistently with the exposure-duration assumptions and derivation method in DOE-HDBK-1046-2016, including any applicant-derived value under Section 3. This approach preserves the guide's simple one-hour atmospheric pathway where it is technically matched to the criterion without forcing a one-hour comparison where another supported duration controls the health endpoint.

The final guide should also state that the one-hour atmospheric calculation is an acceptable default when it bounds the relevant § 53.440(k) consequence, rather than an exclusive analytical

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<sup>8</sup> Nuclear Regulatory Commission, DG-1444, Section C.2, [ML25043A094](#).

<sup>9</sup> National Research Council, Acute Exposure Guideline Levels for Selected Airborne Chemicals, National Academies Press, <https://www.nationalacademies.org/read/13247/chapter/3>.

<sup>10</sup> Federal Emergency Management Agency, Chemical Incident Consequence Management, Appendix A, § 3.3, <https://www.fema.gov/oet-tools/chemical-incident-consequence-management/appendix-a/3/3>.

pathway. If the nature or duration of a licensed-material release makes another supported analysis controlling, the applicant should be able to evaluate that case directly. This should remain a narrow Part 53 chemical-hazard provision, not a general NRC program for industrial chemicals or environmental contamination; DG-1444 itself distinguishes chemical hazards under NRC responsibility from routine occupational and environmental chemical regulation administered under other programs.<sup>11</sup>

The NRC should retain PAC Level 2 as the principal acceptable benchmark, explain how the benchmark and event-frequency treatment together establish the § 53.440(k) finding, and require the exposure-duration basis of the selected PAC criterion to be matched to the postulated exposure or shown to be bounded by the one-hour analysis.

## Recommendations

| Affected Provision                                   | Recommendation                                                                                                                                                                                                                                                                                                                                                                                                                                |
|------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Sections C.1-C.2 - PAC Level 2 and exposure duration | Explain how the applicable event-frequency category and PAC Level 2 consequence criterion together demonstrate the § 53.440(k) requirement for a low risk of permanent injury. For health criteria with exposure-duration-specific values, require the comparison to use the appropriate duration or demonstrate that the one-hour value is bounding; retain the one-hour comparison where the underlying criterion is defined on that basis. |

## IV. THE FALLBACK FOR CHEMICALS WITHOUT PAC VALUES SHOULD BE MORE ADMINISTRABLE

The NRC should clarify the accepted path when a chemical of interest is not in the DOE PAC database and the available information is insufficient to derive a defensible Level 2 value under Section 3 of DOE-HDBK-1046-2016. DG-1444 should identify the expected process (*for example, an applicant-developed toxicological basis, another technically justified health criterion, or early staff*

<sup>11</sup> Nuclear Regulatory Commission, DG-1444, Sections B and C.2, [ML25043A094](#).

*coordination*) rather than leave the issue to be resolved for the first time through application-specific RAIs.<sup>12</sup>

DG-1444 already anticipates chemicals without published PAC values. It directs applicants first to determine, using safety data sheets and other relevant studies or analyses, whether the licensed material presents a significant chemical hazard. If the applicant concludes that a permanent-injury chemical hazard exists but the chemical is absent from the DOE PAC database, the guide directs the applicant to use Section 3 of DOE-HDBK-1046-2016 to determine an associated Level 2 TEEL and then continue to Step 2. That is a useful fallback when the data needed by the handbook are available.

The guide does not explain what happens when that derivation cannot be supported by the available toxicological data or by an adequate analogue. Part 53's technology-inclusive scope makes that possibility foreseeable even if it proves uncommon. A first-time applicant should not have to infer from silence whether the appropriate response is to generate new toxicology data, propose an alternative health endpoint, request a pre-application determination, or wait for a case-specific staff position.

The NRC should therefore supplement Step 1 with a short fallback provision for cases in which no published PAC Level 2 value exists and DOE-HDBK-1046-2016 does not yield a defensible value from the available information.

## Recommendations

| Affected Provision                         | Recommendation                                                                                                                                                                                                                                                                                                                       |
|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Section C.1 - Chemicals without PAC values | Clarify the accepted path when a chemical is absent from the DOE PAC database, and the data available to apply DOE-HDBK-1046-2016 are insufficient to derive a defensible Level 2 value. The guide should identify acceptable alternatives or an early staff-coordination pathway rather than leave the issue to case-specific RAIs. |

<sup>12</sup> U.S. Department of Energy, DOE-HDBK-1046-2016, Temporary Emergency Exposure Limits for Chemicals: Methods and Practice, reaffirmed March 2022.

## V. CONCLUSION

BTI supports the NRC's effort to provide a clear and predictable method for implementing § 53.440(k). DG-1444's basic structure is sound: identify potentially significant chemical hazards of licensed material, apply a health-based consequence criterion, refine the analysis only when needed, and use design or programmatic controls where the remaining hazard requires them.

The NRC should finalize RG 1.264 with the targeted clarifications recommended above so that applicants and reviewers have a common, technically supported basis for determining when the § 53.440(k) finding has been made and when additional analysis or regulatory treatment is actually necessary.

Sincerely,

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