

# American Board of Toxicology, Inc.

Candidate Handbook

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# ABT Certification Handbook

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# Introduction

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## About ABT

The American Board of Toxicology, Inc. was incorporated in the District of Columbia on April 17, 1979, as a self-sustaining not-for-profit corporation. The purpose of the ABT is:

- to encourage the study of the science of toxicology,
- to stimulate its advancement by establishing standards for professional practice,
- to prepare and administer procedures including tests for the implementation of such standards, and
- to confer recognition by certificates or otherwise upon those members of the profession who, measured against such standards, demonstrate competence.

The Board awards certificates to persons who have met the eligibility requirements for admission to the Certification Examination and who have met the Certification Examination requirements within a three-year period of eligibility.

## What is Certification?

Certification is the process by which an organization grants recognition to and validates the qualifications and competence of individuals meeting predetermined criteria.

The ABT Certification examination is based on a practice analysis study of the knowledge required for general toxicology.<sup>1</sup> The practice analysis is updated periodically and was last completed in 2021.<sup>2</sup> A profile of the domains and tasks used in toxicology practice was developed by subject-matter experts and an on-line survey of toxicologists confirmed the delineation. The exam questions test the knowledge and/or skills needed to perform these tasks. The domains and tasks are provided at the end of this manual, along with the percentage of questions devoted to each domain.

## Benefits of Certification

The following benefits of ABT certification should be considered by all toxicologists and their employers.



## Benefits to Toxicologists

- Certification recognizes broad expertise in general toxicology for those with formal training in toxicology, as well as those trained in related disciplines.
- ABT certification provides personal satisfaction and intellectual stimulation.
- ABT certification often offers an advantage in the job market and career development, and has been associated with higher levels of compensation.<sup>3</sup> ABT certification enhances credibility in consulting and legal testimony.
- Diplomates have access to a job listing service via the Diplomate area of the ABT website.

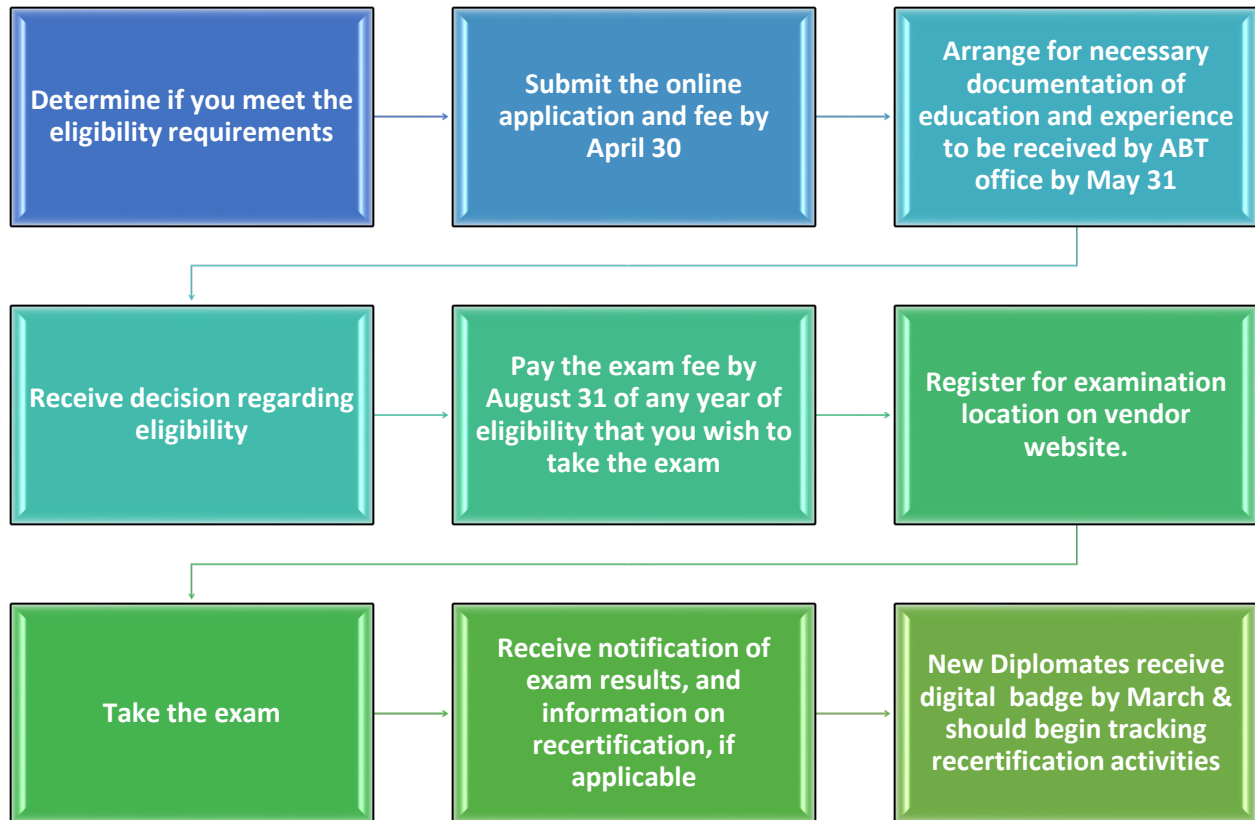
## Benefits to Employers

- ABT certification provides an objective demonstration of a toxicologist's breadth and currency of knowledge and supports scientific credibility.
- Certification by the ABT facilitates access to other certified colleagues who can provide expertise in diverse areas.
- ABT certification is recognized by the national registries in several European countries, and thus, by the EuroTox.
- ABT offers a job listing service whereby employers can advertise openings to all Diplomates via the Diplomate portion of the ABT website.

## Benefits to Society

- The ABT certification is recognized as the standard for competence in general toxicology based on demonstration of appropriate educational background, active practice of toxicology and examination.
- ABT Diplomates are required to demonstrate currency with respect to new developments in toxicology through recertification at 5-year intervals, thus, providing timeliness in the assessment of toxicological issues of concern to society.
- The ABT's certification process is recognized world-wide, thus providing a consistent international standard of competence and expertise on toxicology issues.

## Certification Process



### Contacting the ABT office

Candidate inquiries are handled by the ABT office located in Raleigh, North Carolina. Inquiries can be made via telephone, mail, or email, though the best method is via email. The ABT office contact details are below.

American Board of Toxicology, Inc.

P.O. Box 97786

Raleigh, NC 27624

(919) 841-5022

[info@abtox.org](mailto:info@abtox.org)

Website: [www.abtox.org](http://www.abtox.org)



## Quick Reference for Requirements and Deadlines

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This is an overview of the items necessary for application, the fees and the deadlines associated with each. For complete details, please see the sections below regarding each item.

Requirement	Deadline
Online application completed	April 30 <sup>th</sup>
Application fee due (\$325)	April 30 <sup>th</sup>
Confirmation of degree (transcripts) received by ABT office (sent from institution)	May 31 <sup>st</sup>
Confirmation of professional work experience (supervisor letters) received by ABT (sent directly from supervisor via email or post)	May 31 <sup>st</sup>
Application withdrawal for \$275 refund	June 1 <sup>st</sup>
Exam fee due from eligible candidates (\$400)	August 31 <sup>st</sup>

## ELIGIBILITY REQUIREMENTS

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### Education and Experience Requirements

One of the following three combinations of education and experience are necessary to meet the eligibility requirements for admission to the Certification Examination.

1. An applicant must possess an earned doctoral degree in toxicology or related field and have at least three (3) years of full-time professional post-degree experience (or part-time equivalent thereof) in toxicology after official conferral of the doctoral degree. The three years of experience must be after the date on which the doctoral degree was awarded officially. Having completed all requirements for the degree, but not having received the degree will NOT suffice.
2. An applicant must possess an earned master's degree in an appropriate field and have at least seven (7) years of full-time professional **post-baccalaureate** experience (or part-time equivalent thereof) in toxicology.



- An applicant must possess an earned bachelor's degree in an appropriate field and have at least ten (10) years of full-time professional post-baccalaureate experience (or part-time equivalent thereof) in toxicology.

Years of experience shall be determined using the actual date the applicable academic degree is awarded and not the date degree requirements were completed. The degree must have been awarded at least 3, 7, or 10 years prior to June 30 of the year of application.

The following is a quick summary of the combination of degree and work experience necessary and the documentation required pertaining to the verification of the degree.

Degree conferred by June 30	Number of years professional experience as of June 30 in the year of application	Documentation required to confirm degree
<b>Bachelors</b>	10 years full-time or part-time equivalent*	Transcript of Bachelor's degree sent directly from institution
<b>Masters</b>	7 years of full-time or part-time equivalent <b>post-baccalaureate</b> experience (work between Bachelors and Masters can be counted)*	-If only using post-Master's degree experience, then only transcript of Master's degree sent directly from institution. -If using post-baccalaureate experience, then both Masters and Bachelor's degree transcripts are necessary.
<b>Doctorate</b>	3 years full-time or part-time equivalent*	Transcript of Doctorate degree sent directly from institution

\* 3, 7 or 10 years prior to year of application

## Work Experience

The applicant must have full-time involvement in the practice of toxicology within the year immediately prior to the date of application. Experience must have been earned as of June 30 of the year of application.

Scholastic work towards a higher degree is not considered to be professional level experience. Individuals working toward a higher degree while employed full-time in the practice of toxicology will receive credit for the employment as years of experience if full time employment can be documented, but this experience will be applied to the eligibility requirements for the lower degree.

- With respect to experience in the practice of toxicology, a candidate should have carried out one of the following functions: designed and managed toxicological experiments, interpreted results and translated them to identify and solve human, animal and environmental health problems. It is not sufficient that the candidate work with or for

toxicologists. The applicant must be responsible for the professional toxicological work conducted. These experiences should account for the majority of "time in professional practice" used to support the application.

- A candidate need not necessarily actually produce or develop the data that is used in assessing and evaluating toxicity. With an appropriate educational background and/or previous toxicology experience, a candidate may be engaged in interpreting data generated by others and then may use this data and information to synthesize a comprehensive toxicity assessment. With sufficient documentation of educational training and/or specific experience, such a candidate could be eligible to take the examination. Sufficient evidence should be provided that there is an understanding of the evaluation and interpretation of such studies, the best evidence being a prior history of having been personally engaged in the conduct of toxicity studies.
- Being engaged in activities such as environmental monitoring, exposure monitoring, biological monitoring, monitoring of workers, etc., in and of itself does not constitute the practice of toxicology. If the results from these activities are utilized by the candidate in a broader context of assessing toxicity and if the candidate's educational background and/or previous experience indicates appropriate training in toxicology, monitoring activities and application of their results may constitute the practice of toxicology.
- For a candidate engaged in data reviews of existing toxicity information, identification of toxicity data gaps, identification of structure-activity relationships of potentially toxic chemicals, maintaining data bases, development of risk assessment methodologies, preparation of health assessment documents, etc., the application must unequivocally document that the candidate utilizes the information in an integrative fashion in the broad context of a comprehensive toxicology evaluation. Reviewing data and simply preparing warning labels for a product using a "by the numbers" approach does not constitute the practice of toxicology, nor does simply maintaining a data base and publishing the results. Developing risk assessment methodologies by applying the data and then adjusting the mathematical model parameters without demonstrated understanding of the data or the broader aspects of toxicology does not constitute the practice of toxicology.
- Providing managerial guidance or consulting support for specific clients or for purposes of litigation could include defining toxicity, hazard and risk, dose-response evaluation, duration of exposure and evaluation of toxicity data to assess the likelihood of adverse effects associated with exposure to potential toxicants. In these cases, appropriate

educational training and/or experience in previous or other job activities may provide the necessary link to judge that the applicant is engaged in the active practice of toxicology. Merely translating the jargon of the various sciences into layman's terminology does not constitute the practice of toxicology.

- Conducting microbiological assays or other *in vitro* laboratory work as a course of regular operations in itself does not constitute the practice of toxicology. However, using such methods in the interpretation of adverse effects as it relates to exposure does.
- Histopathological evaluation of tissues from organisms exposed to substances does not in itself constitute the practice of toxicology; however, contributions to study design, protocol development, and/or interpretation of histological evaluation with other lines of evidence (e.g. clinical chemistry data, gross findings, behavioral changes) related to exposure does.

### Eligibility Periods

Each period of eligibility to take the examination is of three years' duration. An individual who is found by the Board to have adequate credentials may take up to three examinations within that period of eligibility.

Eligible candidates who fail to appear for an examination will lose that year of eligibility. If the applicant does not pass the examination within the period of eligibility, reapplication with forms, fees and supporting documentation is necessary before eligibility can be reestablished.

### Eligibility Extensions

Eligibility extensions will not be granted for any reason during any eligibility period. The only exception is in the third year of eligibility, when an extension MAY be granted by the Board of Directors only because of a medical condition that prevents a candidate from taking the examination, or due to death or serious illness of an immediate family member. Requests for extension must be made in writing and be received by the ABT office either before or within 10 business days after the missed examination. Appropriate corroborating documentation (doctor's letter or copy of a death certificate) must accompany all such requests or they will not be considered. If an extension is granted, the candidate must take the examination in the following year but will not have to pay an additional Application Fee or Examination Fee.

## APPLICATION PROCEDURES

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### Application Deadlines and Fees

Fee Due	Deadline
\$325 Application fee	<b>April 30</b>
\$400 Examination fee	<b>August 31</b>

Applications are only accepted online via the ABT website at [www.abtox.org](http://www.abtox.org). Complete the information required and pay the Application fee of three-hundred (\$325) U.S. dollars. Fees may be paid online via credit card, or a check may be mailed to the ABT office. All fees and costs related to conversion of foreign currency to U.S. dollars are the responsibility of the applicant. The application and fee must be submitted to the ABT office no later than April 30 of the year in which the applicant first wishes to take the examination. There will be a \$30.00 processing fee charged for returned checks. If a candidate withdraws his/her application by June 1 in the year of applying for eligibility, \$275 of the application fee will be refunded. The fee is non-refundable in any other circumstance.

### Documentation Required with Online Application

The Eligibility Committee of the ABT must have a complete dossier to review. The applicant must describe his/her experience as a toxicologist, including full job description(s) and bibliography that includes a list of publications with full bibliographic citations. **A full curriculum vitae is required.** A listing of related toxicology activities can also be included on the CV. To aid in the preparation of complete documentation describing the applicant's experience in toxicology, several suggestions are listed below. These suggestions should be regarded as guidelines. The applicant may wish to provide additional relevant information.

#### Suggestions

- Simply providing the job title will not suffice. Duties and responsibilities can be described in terms of time allocated to specific activities, types of studies or functions performed, reporting relationships, toxicology personnel supervised, students or postdoctoral fellows trained, numbers and types of technical reports prepared and role played in the preparation of such reports, etc. Thoroughness is essential. Provide specific and detailed descriptions of each aspect of present and past employment activities in toxicology.
- Many scientists with newly acquired degrees have a training period for the conduct of toxicological studies, or apply a previously acquired skill as a part of an overall team effort to toxicological studies. At what point within their scientific contribution and growth has "skilled technical work" changed to "full-time professional

experience in toxicology"? For purposes of defining eligibility criteria, "full-time professional experience in toxicology" will begin when the individual has demonstrated the capability to conduct a toxicological study in an independent manner, to prepare a valid report of the results and to understand the interpretation of a toxicological study for professional use.

- This definition will apply to post-doctoral as well as post-baccalaureate experience in toxicology. It will be incumbent upon the applicant, and particularly upon the sponsors of applicants, to provide adequate documentation to satisfy the definition.
- A formal position description may be attached, but may not be sufficient by itself.
- List the name(s) of the supervisor(s) who will provide a supporting letter and the time periods they are covering in the online application.
- If several positions have been held at the same employer, each position should be listed separately in the online application, and with the duties of each position listed separately.

## Documentation Required Outside of Online Application

All documentation outlined below must be received by **May 31** in the year of application.

### Verification of Academic Education

Applicants must arrange for an official transcript of the degree used as the basis for qualification to be forwarded directly from the granting institution to the ABT office. Please note that couriers such as FedEx, UPS, and DHL will not deliver to the ABT post office box. If you wish to utilize one of these courier services, please contact the ABT office for further instruction. There is no need to have transcripts for lower degrees sent. (e.g., a Bachelors degree when a PhD is being used for eligibility) Please note that a scanned copy is NOT a certified true copy.

### Outside of the United States

If it is not possible to obtain official transcripts from non-U.S. colleges or universities, applicants must provide certified true copies of their diplomas and a listing of courses passed. For candidates claiming earned doctoral degree status, the course listing must permit a determination of educational equivalence to a doctoral degree.

### Verification of Work Experience

Applicants must arrange for letters from present and former supervisors to be sent to the ABT office. Employers are welcome to send scanned, signed letters via email to [info@abtox.org](mailto:info@abtox.org). For self-employed applicants, letters from clients or employers may substitute if acceptable to the ABT Eligibility Committee. It is preferred that if a supervisor is providing documentation of multiple positions that a **separate letter be submitted for each position**. If separate letters are not submitted, then each position

must be outlined individually with dates and duties for each described. These letters must explicitly specify the time period of the position, and must accurately and fully document the applicant's duties, responsibilities and full-time professional

experience in toxicology. The supervisor should review the above section on experience in toxicology before preparing the support letter. The supporting letters must cover the entire period of experience required with the actual degree conferral date used as the basis for qualification. A letter verifying experience in the current year must be among those submitted. The letters may contain other information as deemed appropriate by the supervisor or employer. This information will be disclosed to the applicant upon request so that accuracy can be assured.

**Please note that supervisor letters must be sent to the ABT office by the supervisor. Letters forwarded by the candidate will not be accepted. There is a form letter for supervisors available on the website, it is strongly encouraged that supervisors use this form when completing work verifications. To access the letter, please click [here](#).**

Applicants submitting part-time equivalent as job experience will be considered on a case-by-case basis by the Eligibility Committee.

### Statement of Understanding

All candidates will be required to agree to the following prior to submitting an application via the ABT website. Agreement will be made via the website.

I hereby apply for certification as a Diplomat of the American Board of Toxicology, Inc.® I understand the information obtained from me and others on my behalf as part of the certification process may be used for statistical purposes, and for the evaluation of the program. I understand the information in my records will be treated confidentially except as otherwise provided by law. If I am certified, I consent to my name being released to publicly identify me as a Diplomat of the American Board of Toxicology®. I understand that ABT releases of a list of Diplomates will not include addresses or other contact information. I understand that ABT does list Diplomat names, addresses and other contact information on the non-public password-protected Diplomat area of the ABT website for the purpose of enabling Diplomates to more easily contact each other.

If I desire that my name not be included in public releases, or my contact information not be on the password-protected Diplomat portion of the website, I will inform the ABT office of that choice in writing and in a timely manner.

Note: Attainment of Diplomat status entitles the bearer to represent him/herself as a "Diplomat of the American Board of Toxicology"® (DABT). Initial certification as a DABT shall be granted by the Board of Directors based upon acceptability of the applicant's qualifications





and successful completion of a written examination. To maintain certification, a Diplomate must successfully complete a recertification process every five years. Diplomate status and all entitlements therein, including the use of the designators ABT and DABT, shall cease upon

failure to complete the recertification process within established deadlines. I understand that as a Diplomate, I am subject to the “Grounds for Revocation of Diplomate Status” as outlined in the Recertification Manual on the ABT website. If I am accepted to take the examination, I understand that I will be informed only of whether I have passed or failed the examination. I understand the examination questions and any answer sheets or electronic records are not available afterward to me and at all times are the property of the American Board of Toxicology, Inc. If I do not pass the examination, I understand that I may ask for a review of my examination answers (without identifying me), and that there is no other appeal from the result of my examination answers.

I understand that the American Board of Toxicology reserves the right to withhold or cancel my scores or revoke certification if there is any cheating, improper conduct, or other irregularities associated with the submission of my examination or candidacy. I certify that I have read and will abide by the above statements and that all of the information I have provided on this application is true, complete and correct to the best of my knowledge. I understand that the use of false or misleading information may result in a finding of ineligibility or a rescinding of certification by the Board of Directors.

### Applicants with a Disability

Reasonable testing accommodations will be provided for candidates with documented disabilities as recognized under the Americans with Disabilities Act [ADA].

Candidates must request consideration for reasonable testing accommodations **at the time of exam eligibility application**. Requests must be made in writing or via email to [info@abtox.org](mailto:info@abtox.org) by the application deadline date of that year. Exceptions may be permitted for unexpected health-related needs, which arose after the candidate initially applied for the exam. If the exam is not passed in full in the first year and the candidate must request reasonable testing accommodations upon future testing, this request must again be made in writing or via email to [info@abtox.org](mailto:info@abtox.org) by the next year’s eligibility deadline. Score reports will not reflect whether a test was taken with accommodations.





## Application Withdrawal/Refunds

If a candidate withdraws his/her application by June 1 in the year of applying for eligibility, \$275 of the application fee will be refunded. The fee is non-refundable in any other circumstance. Withdrawals must be made in writing; email is acceptable. All forms, fees, supporting documentation and other materials submitted to the American Board of Toxicology become the property of the Board and will be maintained in confidentiality solely for evaluation of the candidate's eligibility to take the certification examination.

## APPLICATION PROCESSING

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### Status of Submitted Documentation

It is the responsibility of the applicant to assure timely receipt of the required documentation. Incomplete or late documentation will result in an ineligible status. An applicant should not assume that transcripts or letters of verification requested from a third party have been sent to the ABT office. If unsure, an applicant may check the status by logging into their online account. If still unsure, they may call or e-mail the ABT office to confirm receipt of requested documentation.

### Confidentiality

All applicant information is kept confidential. Any inquiries regarding an application and/or eligibility must be made by the applicant. Information will not be released to other parties.

### Determination of Eligibility and Notification

Applicants will be notified of their eligibility by August 15th. All eligibility decisions are at the discretion of the Board of Directors. All applicants are urged to initiate their preparation for the examination well before the notification date. The Examination usually is given in October. Exact dates are available on the ABT website.

### Ineligibility and Appeals Process

If an applicant is found ineligible to take the certification examination, the applicant will be informed of that fact and of the reasons for the determination in sufficient detail to allow the preparation of a petition for reconsideration. Any petition and evidence or documentation in support of the petition must be submitted in writing to the ABT office prior to the date specified in the notification letter. Any petition or supporting materials received after the specified date will not be considered. After the deadline for providing supplemental formation, the application will be reviewed again. All decisions regarding eligibility appeals are final.

## PREPARING FOR THE EXAM

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The ABT exam is challenging! It is important to develop a study plan. Different methods work better for different applicants, but here are some options to consider. **Note:** The American Board of Toxicology does not sponsor or endorse any review courses. This includes courses that are advertised as ABT examination preparation.

- **Review the content outline in this manual.** Determine your strengths and weaknesses from the outline. This allows you to determine which areas you need to focus on the most.
- **Get advice from previous candidates.** Ask current Diplomates and former candidates how they prepared. What worked for them? What didn't?
- **Form a study group.** Many candidates form groups that meet weekly either. This can be in person or virtually.
- **Allow time to prepare.** Many candidates begin preparing up to a year in advance.
- **Study List.** The Board has prepared a study list of references that can be used to study for the examination. Please note that the references cited provide a general survey of the science of toxicology and its sub-disciplines. Utilization of these references should in no way be construed to guarantee that all topics contained in the examination are covered or that successful completion of the examination will result. Familiarity with the current literature in toxicology is recommended also. This list is to be used as a guideline only and does not mean that other texts or journals cannot be used.

## Toxicology References

### Books

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- Klaassen, C.D., Ed.: Casarett and Doull's Toxicology: The Basic Science of Poisons. 9<sup>th</sup> and 8<sup>th</sup> Editions, McGraw-Hill (2018, 2013).
- Hayes, A.W., Ed.: Principles and Methods of Toxicology. 6th Edition, CRC Press (2014).
- Torres, J. and Bobst, S. (eds.). Toxicological Risk Assessment for Beginners, Springer (2015).
- Gilman, A.G., Rall, T.W., Nies, A.S. and Taylor, P., Eds: Goodman and Gilman's The Pharmacological Basis of Therapeutics, 13<sup>th</sup> Edition (2017).

### ICH and VICH Guidelines for Pharmaceuticals

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- Safety (S) and Multidisciplinary (M3, M4, M7) (<https://www.ich.org/page/ich-guidelines>).

## OECD Guidelines for the Testing of Chemicals

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- Human Health Effects (Section 4) Test Numbers 408, 413, 414, 420, 432, 437, 438, 442, 443, 471, and 492 ([https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects\\_20745788](https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788)).
- Effects on Biotic Systems (Section 2): Test Numbers 202, 203, and 207 ([https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-2-effects-on-biotic-systems\\_20745761](https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-2-effects-on-biotic-systems_20745761)).

## US FDA Guidance for Industry

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- The Least Burdensome Provisions: Concept and Principles. Guidance for Industry and Food and Drug Administration Staff. CDRH/CBER, February 2019 (<https://www.fda.gov/media/73188/download>).
- Guidance for Industry: Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipient, Guidance for Industry. CDER/CBER, May 2005 (<https://www.fda.gov/media/72260/download>).
- Safety of Nanomaterials in Cosmetic Products. Guidance for Industry. June 2014 (<https://www.fda.gov/media/83957/download>).
- Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD). Guidance for Industry #232 (VICH GL54). August 2017 (<https://www.fda.gov/media/92063/download>).
- Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products. Guidance for Industry. October 2020 (<https://www.fda.gov/media/115150/download>).
- Frequently Asked Questions about GRAS for Substances Intended for Use in Human or Animal Food, Guidance for Industry. October 2016 (<https://www.fda.gov/media/101042/download>).
- Toxicological Principles for the Safety Assessment of Food Ingredients: Redbook 2000, July 2007 (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-and-other-stakeholders-redbook-2000>).
- Estimating Dietary Intake of Substances in Food. Guidance for Industry. August 2006 (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-estimating-dietary-intake-substances-food>).
- Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers. Guidance for Industry. Pharmacology and Toxicology, July 2005 (<https://www.fda.gov/media/72309/download>).
- Safety Testing of Drug Metabolites. Guidance for Industry. Pharmacology and Toxicology, March 2020 (<https://www.fda.gov/media/72279/download>).

- Carcinogenicity Study Protocol Submissions. Guidance for Industry. Pharmacology and Toxicology, May 2022 (<https://www.fda.gov/media/72270/download>).

#### US EPA Human Health and Ecological Risk Assessment Guidelines

- Risk Assessment Guidance for Superfund (RAGS): Part A (<https://www.epa.gov/risk/risk-assessment-guidance-superfund-rags-part>).
- Guidelines for Carcinogen Risk Assessment (<https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment>).
- Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation (<https://www.epa.gov/sites/production/files/2015-01/documents/ddef-final.pdf>).
- 1998 Guidelines for Ecological Risk Assessment (<https://www.epa.gov/risk/guidelines-ecological-risk-assessment>).

#### National Research Council (NRC) publications

- National Research Council (NRC). Science and Decisions: Advancing Risk Assessment (Silver Book). National Academy Press, Washington, D.C., 2009 (<https://www.nap.edu/catalog/12209/science-and-decisions-advancing-riskassessment>).
- National Research Council of the National Academies of Science. 2007 *Toxicity Testing in the 21st Century: A Vision and a Strategy (2007)*. Washington, DC: The National Academies Press. (<https://www.nap.edu/catalog/11970/toxicity-testing-in-the-21st-century-a-vision-and-a>).

## EXAM SCHEDULING AND ADMINISTRATION

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The ABT exam is held once per year at testing centers throughout the world and administered via computer. Details can be found on the Pearson VUE website [here](#). The examination is 4 hours in length and consists of 160 questions delivered in a four-hour time block. Of the 160 questions, 140 are scored and 20 are pre-test, unscored items. The candidate will not be told which items are not scored. The exam is graded as a whole for one single score. An applicant may take the exam in any of the three years of eligibility. In order to become certified, applicants must pass the entire exam in one of those years.

### Exam Fee Payments Deadline

In order to take the examination in any year of eligibility, a **non-refundable** examination fee must be paid by August 31<sup>st</sup> of that year. In July, eligible applicants will be notified via email to pay the examination fee. Information regarding location options will also be provided. All fees and costs related to conversion of foreign currency to U.S. dollars are the responsibility of the applicant. If the applicant does not appear for the examination, this fee is forfeited and must be paid again to take the examination in subsequent years of eligibility.

### Exam Registration

After August 31, candidates who have paid the examination fee will be sent instructions via email regarding how to register for their specific examination location on the test administrator vendor's website. The registration period and deadline will be announced at this time as well. It is the responsibility of the applicant to ensure that their email and mailing address remains current in the online system.

### Test Day

Be at the testing center no later than 30 minutes before the actual starting time. Late arrivals will be considered no-shows and the fee forfeited. All personal items (other than the identification document) must be locked in a locker at the Exam Center and outside of the testing area.

### What to Bring to the Test

- Copy of examination registration notice (available after registering at location online)
- Valid, non-expired government-issued identification with current photograph and signature. The identification must be in Latin characters and match the name and ID number on the registration notice. Acceptable types of identification will be listed on the registration form.
- Soft ear plugs if desired

## What NOT to Bring to the Test

- Food or beverages
- Reference materials, papers, notes, dictionaries, cameras, cellular telephones, PDAs, computers or tablets, calculators, digital watches, scanners or other electronic or communications devices.

## AFTER THE EXAMINATION

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### About the Passing Score

Standard setting is a technique used to determine the passing test score that corresponds to a minimally qualified candidate for the ABT exam. When the initial form of an examination is developed following a job analysis, a criterion referenced Standard Setting exercise is conducted. Such a study ensures that passing the examination depends on the amount of knowledge displayed, not on the population of candidates taking the exam. The standard setting process uses a committee of subject matter experts (SMEs) who are representative of the toxicology profession and come from diverse backgrounds. Under the guidance of a psychometrician, the SMEs identify the point on the theoretical continuum that separates the test taker who is minimally competent from one who is not. The participants then examine each individual item on the exam, taking into account the difficulty of each. When the process is complete, the knowledge standard is able to be translated into a passing score.

### Notification of Exam Results

Examination results are typically available about six weeks after the testing date. This allows time for scoring, Board review of exam and preparation of results letters. Letters will be sent via mail to the mailing address provided by the candidate in the online system. Results will also be available via the ABT website by logging into your account. Once results are released, those who passed will see themselves listed as "Diplomate" upon logging into the ABT site. Scores and results will not be released via email or telephone. Candidates are requested not to contact the ABT office to ask about when results will be released.

### Verification of Exam Score Request

Unsuccessful candidates may ask for a review their examination answers within 1 month of exam results being released. There is no other appeal from the result of any such review.

### DABT Recognition

A list of new Diplomates is published to the ABT website. The list may also be released to other professional organizations. Any request to have your name withheld from this list must be made in writing (email is acceptable) to the ABT office within 2 weeks of results being released to individuals. New Diplomates will also be listed in the searchable, online Diplomate directory. This Directory is accessible only by Diplomates.

## Use of the DABT Designation

Those who have successfully passed the ABT examination are permitted to use the acronym "DABT" after their name as long as they continue to successfully recertify. If a Diplomate's certification lapses, one is only allowed to use "DABT" if followed by the years they were certified, e.g., John Doe, DABT 2012-2017.

## Retaking the Exam

If a candidate is unsuccessful, they are automatically eligible to take the exam if they have remaining years of eligibility. Candidates will be notified via email of the registration/payment details in July of the following year, and given instructions. The exam fee is due again by August 31 of any year that the exam is taken. If there are no years of eligibility remaining, the candidate will need to reapply for eligibility.

## Digital Badge

New Diplomates will be sent an email with a link to a digital badge acknowledging their accomplishment. Badges will be available approximately three months following notification of the examination results.

## Length of Certification

Certification is good for five years. The first year the exam is passed does not count as one of the five years. For example, if a candidate passes the exam in 2017, their certification is good until December 31, 2022. In order to maintain certification, Diplomates must complete the recertification process every five years. Recertification begins in fourth year of the cycle. So, Diplomates passing the exam in 2017 would have to apply for recertification by March 31, 2021.



## FREQUENTLY ASKED QUESTIONS REGARDING THE APPLICATION AND EXAM PROCESS

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### 1. Where and when is the examination given?

In January of each year, the date of the examination will be posted on the ABT website. The examination is given at testing locations all over the world.

### 2. Do you accept credit cards?

We accept MasterCard, Visa, and American Express.

### 3. What is a "certified true copy" of a transcript?

A certified true copy is a photocopy of your original document signed and certified to be the same as the original by someone authorized to do so. Notary publics are often authorized to do this. However, if a notary simply notarizes *the candidate's* attestation and signature that the copy is official, this is not a certified true copy. In addition, a scanned copy is NOT an official copy.

### 4. Is a CV required? How do I submit it?

Yes, a current CV is required. This can be uploaded under the current work history where it says "upload job description." If you are unable to locate this, an electronic copy can be emailed to the ABT office at [info@abtox.org](mailto:info@abtox.org).

### 5. Should I send follow up materials via postal mail, such as journal articles and training certificates?

No, this is not necessary or recommended. All applications are reviewed electronically, so no papers other than transcripts need to be sent to the ABT office. All publications and training details can be listed on your CV.

### 6. I need to make a change to my application, how do I do this?

You can only make changes to your application before you hit the final "submit" button. Once the application is formally completed and submitted online, changes cannot be made. If you need something changed or added, please contact the ABT office at [info@abtox.org](mailto:info@abtox.org) for assistance.

### 7. Do you accept electronic transcripts?

Many institutions now offer secure links to download transcripts online. These are official transcripts and are acceptable. **Emailed photocopies, however, are not.**

8. My supervisor sent the recommendation letter directly to me. Can I forward it to you?

Unfortunately, no. All supervisor letters need to be sent to the ABT office directly from the supervisor. The supervisor can submit via email, and are strongly encouraged to use the available online form, available [here](#).

9. The Committee said I am ineligible. How can I appeal?

A petition for reconsideration may be submitted in writing by the date specified in the letter of ineligibility. The petition must be submitted in writing. The Board will make the final decision at their summer meeting. Please refer to the section in this manual.

10. How do I know if there will be testing locations close to me?

Candidates will schedule examination appointments directly through Pearson VUE. Details and locations can be found on their website by clicking [here](#). Note that availability at any particular site cannot be guaranteed.

11. I paid the exam fee, but I can't sit the exam this year. Can I have a refund, or transfer the fee to next year's exam?

The exam fee is non-refundable and non-transferable to future years.

12. Can I have a refund?

If a candidate requests withdrawal of their application in writing (email is sufficient) by June 1, a refund less a \$25 administrative fee will be given. **After that date, no refunds are given.**

13. When will I be notified that I passed the examination?

Notifications are typically sent out before the end of November. Results will be posted on a candidate's online account, as well as sent out via postal mail. Results will not be released via email or telephone.

14. How do I find out my scores?

It is Board policy not to release scores under any circumstances.

## OVERVIEW OF ABT EXAMINATION CONTENT OUTLINE

Domain/Sub-domain	% of Exam
<b>I. Conduct of Toxicological Studies (Total, A through C)</b>	<b><u>36</u></b>
A. Design	11
B. Execute	9
C. Interpret	16
<b>II. Mechanistic Toxicology</b>	<b><u>13</u></b>
<b>III. Risk Assessment (Total, A through D)</b>	<b><u>38</u></b>
A. Hazard Identification	12
B. Exposure Assessment	8
C. Dose Response Assessment	9
D. Risk Characterization and Management	9
<b>IV. Applied Toxicology</b>	<b><u>13</u></b>
<b>TOTAL</b>	<b>100</b>

For each Task in the four Domains, the exam questions are designed to test the knowledge needed to perform the tasks. Below, the Knowledge Statements are listed beneath each Task. Candidates should be aware that overlap exists among all Domains, Tasks and Knowledge statements.

### Domain I. Conduct of Toxicological Studies

#### A. Design

##### 1. Design scientifically valid studies to answer questions or address defined hypotheses.

- A. Elements of a scientific hypothesis
- B. Elements of a scientifically valid hypothesis-driven research or regulatory guideline study, including selection of statistical analyses
- C. Experimental (e.g., test article or agent) and control (e.g., positive and negative control agents, untreated controls) groups used to evaluate scientific hypotheses and/or for regulatory decision-making

- D. Considerations for identifying toxic responses including dose/concentration, duration of treatment, life-stage, endpoints, route of administration, alternative *in vitro* and ecotoxicological studies
- E. Principles of the 3Rs (Reduce/Refine/Replace) for animal use
- F. Selection of appropriate species for study

**2. Comply with applicable regulations and guidelines specific to the agent when designing a study.**

Standard US and global non-clinical testing guidelines for pharmaceuticals and chemicals (e.g., GLP, OECD, USEPA, ICH, USFDA, EMA)

**3. Identify the characteristics of the test agent necessary for the study (e.g., chemical identity and physical properties).**

- A. Analytical methods commonly used in toxicology for test agent characterization (e.g., HPLC, MS, ELISA)
- B. Characterization of formulated test agent for administration (e.g., stability, homogeneity)
- C. Solubility, stability, formulation, vehicles, and excipients
- D. Content and qualification of impurities in new drug substances per regulatory guidance (e.g. ICH Q3A[R2]) including organic (process or drug-related) impurities, inorganic impurities, and residual solvents

**4. Identify and apply new testing methods and techniques that are fit for purpose.**

- A. Accepted standards of validation applied to testing methods
- B. Validated alternative testing methods in toxicology
- C. Study design for new assays (e.g., dermal sensitization, irritation, cell-based assays, “omics” technologies)
- D. Limitations and advantages of assays, including specificity and sensitivity

**B. Execute**

**1. Ensure compliance with regulatory guidances, Good Laboratory Practice (GLPs), and standard operating procedures (SOPs) when performing studies.**

Standard US and global non-clinical testing guidelines for pharmaceuticals and chemicals (e.g., GLP, OECD, USEPA, ICH, USFDA, EMA)

**2. Characterize toxicological effects *in vivo*.**

- A. Typical *in vivo* models used in toxicology
- B. Relevant endpoints measured in standard animal toxicological studies

### 3. Characterize toxicological effects *in vitro*.

- A. Typical *in vitro* models used in toxicology
- B. Relevant endpoints measured in standard *in vitro* toxicological studies

### 4. Characterize toxicological effects *in silico*, incorporating computational models and methods.

- A. Standard *in silico* methods and their application in toxicology (e.g., quantitative structure activity relationships[QSARs], read-across, PBPK modeling)
- B. Artificial intelligence, deep and machine learning used in toxicology

### 5. Characterize toxicological effects in a field or clinical setting.

Endpoints obtained from standard controlled field (ecotoxicological) studies, human clinical trials, and studies with human subjects, and epidemiological studies

## C. Interpret

### 1. Analyze test results using tools such as informatics, statistics, and modeling.

- A. Standard data analysis methods, approaches, and techniques used in toxicology, including the role of bioinformatics, statistics, and computer modeling
- B. Distinctions between toxicological and biological significance

### 2. Identify systemic and local effects, target organs, dose response, thresholds of effect, and reversibility.

Criteria, methodologies, and guidelines for analyzing, interpreting, and identifying target organs and adverse effects

### 3. Prepare research reports or summaries that are fit for purpose.

- A. Elements of a toxicology study report, including all supporting subparts
- B. Written communication styles, protocols, and approaches used to tailor reports to specific target audiences (e.g., other scientists, managers, sponsor, regulatory bodies, the general public)
- C. Narrative, tabular, and graphical presentation of findings and interpretations

### 4. Interpret and integrate study results with other available data (e.g., literature, existing data) into a scientifically cogent narrative to develop conclusions and/or inform next steps.

- A. Basic principles of and approaches to systematic literature review (e.g. risk of bias, search strategies)
- B. Principles, strategies, heuristics, methods and approaches for interpreting the results or relevance for human or animal safety

## Domain II. Mechanistic Toxicology

- 1. Develop hypotheses to investigate and/or identify mechanisms and understand toxicological outcomes.**
  - A. Steps involved in developing a mechanistic hypothesis
  - B. Methods to test mechanistic hypotheses using *in vitro* and *in vivo* studies
  - C. Established molecular/signaling pathways associated with chemical-specific toxicities in animal tissues/*in vitro* systems
  - D. Physiology and organ function as related to toxicology
  - E. Role of genetic variant phenotypes e.g., (KOs, SNPs) in mechanisms of toxicity
  - F. Application of “omics” technologies appropriate to test hypotheses under investigation
- 2. Assess role of species differences in mechanism of toxicity.**
  - A. Standard parameters used to predict or describe differences in localized and systemic toxicity (e.g., ADME, PK/TK, PK/PD, parent versus metabolite)
  - B. Role of species-specific toxicokinetics and toxicodynamics in mechanism of toxicity
  - C. Effects of species differences in anatomy and physiology on uptake and absorption (e.g., respiratory tract, dermal, oral)
- 3. Identify susceptibility factors that may impact toxicological outcomes.**

Attributes (e.g., genetic polymorphisms, life-stage, gender, background disease-states) affecting individual susceptibility to test agents, toxins, or toxicants
- 4. Assess mode of action (MOA)/adverse outcome pathway (AOP) for relevance to humans or other target species, including sensitive subpopulations and individuals.**
  - A. Adverse outcome pathway concept
  - B. Fundamental molecular toxicological mechanisms and their relationship to adverse responses
  - C. Molecular level (e.g., receptor/protein level) toxicant interactions
- 5. Distinguish direct and indirect action, primary/secondary, and on-target versus off-target effect.**
  - A. Toxicity resulting directly from a targeted interaction/direct insult (e.g., at a cellular/receptor/pathway level)
  - B. Toxicity resulting from a secondary/indirect effect (e.g., delayed ossification due to maternal toxicity, reduced fetal body weight, food consumption, stress, off-target interaction)
  - C. How exposure to toxicants leads to downstream effects in individuals and populations
- 6. Translate toxicological results across biological levels (sub-cellular, cellular, tissue, individual, species, populations) using principles of systems toxicology.**
  - A. Methods to translate experimental findings across levels of biological organization

- B. Methods to apply findings/results from simple and/or lower-level experimental systems to more complex, higher-level systems
- C. Anatomical, physiological, biochemical, pharmacological, and toxicological differences across species, and magnitude of specific effects
- D. Utility and limitations of analytical/computational tools to study mechanisms of toxicity and interpret disruption of biological networks
- E. Relationship of “omics” data to organism-level effects

**7. Apply results from mechanistic studies to toxicological outcomes, prevention, and clarification of risk (human, environmental, animal).**

- A. The relationships between mechanism or MOA of chemical(s), human/environmental exposure, and the regulation of certain products (e.g., endocrine disruptors, microbeads, tobacco/nicotine, persistent bioaccumulative toxins (PBTs), nanoparticles)
- B. Mechanistic or MOA data for a chemical from *in vitro/in vivo* animal studies that inform AOPs
- C. Toxic effects of a chemical mixture, including concepts of synergism, potentiation, additive, and antagonistic
- D. Cellular, biochemical, and molecular mechanisms of chemical toxicity used for the interpretation and evaluation of risk to humans, animals, and the environment

**8. Apply disease and genetically-engineered models to mechanistic investigations.**

- A. Application of mechanistic data to the development of alternative animal disease models
- B. Difference between animal disease models and human conditions, including strengths and limitations of disease models

## Domain III. Risk Assessment

### A. Hazard Identification

**1. Characterize, describe, and interpret effects, target organs, and test system endpoints of toxicological concern.**

- A. Major effects and endpoints measured in acute lethality/toxicity, repeat dose toxicity, reproductive toxicity, developmental toxicity, genotoxicity, carcinogenicity, sensitization, local effects/tolerance, immunotoxicity, and phototoxicity
- B. Ecotoxicological studies
- C. Toxicity by different routes of exposure
- D. Relevant toxic agents such as pesticides, metals, solvents and vapors, radiation, nanomaterials, air pollution, and naturally-occurring toxins (e.g., plant- and animal-based, mycotoxins)



- E. Toxic responses of organ systems (e.g., blood, bone, immune system, gastrointestinal tract, liver, kidney, respiratory tract, nervous system, eye, heart, skin, reproductive organs, endocrine system)
  - F. Adverse versus non-adverse or adaptive effects
  - G. Concepts of false negative and false positive results
  - H. Chemical-specific biomarkers of effect
- 2. Apply appropriate *in silico*, *in vitro*, *in vivo* systems, models, and study types for safety evaluation.**
- A. Application of data from various methods (e.g., structure-activity, *in vitro* or short-term studies, animal bioassays, human epidemiologic studies) for hazard identification
  - B. Relevant target organism(s) for selection of appropriate test species used in safety evaluation
- 3. Identify toxicological approaches using exposure routes that are appropriate surrogates or alternatives to the primary exposure route of concern.**
- A. Basic principles of SAR, QSAR, and other *in silico* approaches and how those outputs can be used in a risk assessment context
  - B. Types of oral toxicity studies applied to hazard identification (e.g., gavage versus dietary or drinking water)
  - C. Types of inhalation toxicity studies as they apply to hazard identification (e.g., aerosol versus vapor versus intratracheal instillation)
  - D. Metabolic differences between various routes of administration (e.g., sublingual versus oral)
  - E. Anatomical differences across species for various routes of exposure (e.g., inhalation, oral and dermal exposures)
- 4. Assess impact of anticipated versus unanticipated effects on organism, species, population, and environmental functions.**

Target and off-target effects at organism, species, population, and environmental levels

## B. Exposure Assessment

- 1. Select appropriate exposure endpoints to document exposure to toxicants in test systems and populations.**
- A. Measures and units of exposure (e.g., dose, airborne concentration, plasma level) reported in toxicological investigations and assessments
  - B. Relevance of biomarkers of exposure in individuals, populations, and the environment
  - C. Disproportional, unique, reactive metabolites, and toxicophores arising in specific species

**2. Assess internal exposure in tissues, organs, systems, or whole organism resulting from an administered or exposure dose.**

- A. Routes of exposure and toxic agent effects on cells, tissues, organisms, and the environment
- B. Absorption (A), distribution (D), metabolism (M), excretion (E), kinetics (PK or TK), and storage following toxicant exposure
- C. Considerations for measuring the appropriate constituent (e.g., parent versus metabolite, unbound/free or total)

**3. Assess toxicant exposure in the general public, occupationally exposed individuals, populations, and the environment using appropriate technologies (e.g., analytical, bioassay, biomonitoring).**

- A. Emerging and existing technologies used to assess exposure in target populations (e.g., biomonitoring endpoints/dosimeters, sentinel species, spatially-explicit models)
- B. Generally-accepted default values used in human exposure and dose calculations (e.g., body weight, surface area, inhalation rates)

**4. Assess and document behavior, environmental fate, and transport of chemicals entering the environment.**

- A. Major concepts and processes in environmental fate and transport (efate) assessments (e.g., persistence, biotransformation, bioavailability, bioaccumulation, biomagnification)
- B. Environmental and/or occupational exposure patterns relevant to human and other environmental receptors (e.g., conceptual site model)
- C. Environmental fate and transport processes that influence exposure

**C. Dose Response Assessment**

**1. Quantitatively and/or qualitatively characterize relationships between dose (or concentration) and incidence and severity of health effects or toxicological endpoints.**

- A. Interpretation of different types of dose-response curves including those for: (a) lethality, (b) threshold responses, (c) linear, nonlinear, non-monotonic, responses, and (d) hormesis
- B. Interpretation of frequency and cumulative dose-response curves
- C. Parameters of dose-response curve (e.g., slope, plateau, midpoint)
- D. ED50, EC50, LD50, and LC50 from dose response curve
- E. General principles and approaches of benchmark dose (BMD) methodologies, including statistical methods and dose-response modeling
- F. Outputs of physiologically-based pharmacokinetic (PBPK) modeling and their utility in characterizing dose-response relationships

- G. Methods for dosimetric adjustments across species and exposure duration (e.g., HED/HEC calculations)
- H. Dose-response extrapolations and how to characterize their associated uncertainties in susceptible populations, including traditional uncertainty factors (UFs), chemical-specific adjustment factors (CSAFs), data-derived extrapolation factors (DDEFs)

**2. Analyze toxicity data to determine safety margin and first in human dose.**

First-in-Human dose (FIH) criteria/standards per regulatory guidance(s)

**3. Analyze toxicity data to determine safe dose or concentration, toxicologically relevant dose, reference dose, protective threshold, or benchmark dose.**

- A. Threshold and non-threshold (linear) dose-response curves
- B. Integration of endpoints (e.g., organ weights, clinical chemistry, histopathology) in comprehensive dose-response assessment
- C. Dose-response dynamics of essential nutrients and hormetic responses
- D. Calculation of Therapeutic Index (TI)
- E. Point of departure (POD) (e.g., LOAEL, BMD, NOAEL, HNSTD, MABEL, STD10) and uncertainty factors and their use in risk assessment
- F. Concepts and uses of safety thresholds (e.g., TTC, Cramer Class, REACH DNELs and DMELs, reference values, ADI, health-based OELs)
- G. Approaches for allometric scaling including default values and when they should be applied

## **D. Risk Characterization and Management**

**1. Integrate various lines of toxicity evidence (e.g., animal, *in vitro*, epidemiological, read-across) with exposure information to characterize potential health risks.**

- A. Metrics used in risk characterization (e.g., margin of exposure (MOE), margin of safety (MOS), hazard quotient (HQ), Hazard Index (HI), probability estimates) and their application and limitations
- B. Aggregate exposure and risk and cumulative risk in the context of risk characterization
- C. Principles of mixtures toxicity and potential application in risk characterization (e.g., dose-response additivity, toxicity equivalency factors)

**2. Perform weight of evidence analyses to reach conclusions and inform decision making.**

- A. Weight of evidence criteria (WoE) criteria for integrating potentially disparate lines of evidence (e.g., Bradford Hill criteria)
- B. Systematic review concepts, processes, and procedures (e.g., Cochrane review)

**3. Assess health risks and management options to protect occupational, environmental, or public health by deriving protective safety limits and mitigation strategies.**

- A. Factors that contribute to and modify risk characterization (e.g., engineering, economic, social, political)
- B. Principles of risk perception and communication
- C. Precautionary principle and its implications
- D. Health protective exposure limits for various populations (e.g. immunocompromised, child-bearing potential, pregnant, lactating, elderly, asthmatic), exposure durations, and exposure scenarios

**4. Evaluate and implement alternatives to reduce risk through actions such as emergency risk management and reduction of chemical exposure or risks.**

- A. Strategies, technologies, practices, and procedures to reduce exposure and/or mitigate toxicity (e.g., antidotes, remediation, engineering controls, personal protective equipment)
- B. Cleanup goals, emission limits, safe concentrations
- C. Health-based guidance values (e.g., Provisional Advisory Levels (PALs), Acute Exposure Guideline Levels (AEGs))

## Domain IV. Applied Toxicology

**1. Characterize, describe, and interpret effects of ecotoxicological concern in individuals, populations, communities, and ecosystems.**

- A. Differences in responses between individuals and populations
- B. Indirect effects from exposure in an ecological community on susceptible populations

**2. Respond to public health issues, including new or emerging public health concerns.**

- A. Elements of response and risk communication plan, risk perception, and mitigation strategies
- B. Lessons learned from events of major toxicological significance (e.g., Bhopal, radium dial painters, cytokine storm release syndrome, Minamata Bay, thalidomide, DDT)
- C. Toxicological impact of emerging risks (e.g., climate change, infrastructure issues, food scarcity, infectious diseases)

**3. Assess impact on public health from environmental toxicants resulting from ecological disruptions.**

- A. Impact of threats to ecosystem services (e.g., clean/safe water, clean air) on human health
- B. Effects of toxicants on disease prevalence (e.g., zoonoses) in animal-human interactions

**4. Investigate health outcomes in exposed groups using measured or modeled exposures.**

Exposure reconstructions for dose-response evaluation in the context of epidemiological findings

**5. Use population-based biomonitoring studies to ascertain temporal trends in environmental exposures.**

- A. Population-level national studies and databases (e.g., NHANES)
- B. Cross-sectional versus longitudinal epidemiology studies
- C. Toxicological implications of biomonitoring data reported as part of a community public health investigation

**6. Identify sensitive or susceptible subpopulations and identify factors or circumstances that would increase the risks of adverse health effects in incidents or situations of toxicological concern in a community or occupational setting.**

- A. Factors related to susceptibility and increased risk in groups or sub-groups of individuals (e.g., comorbidities, age, ethnicity)
- B. Biomarkers of susceptibility (e.g., polymorphisms, genetic variants)

**7. Collaborate in the development and manufacture of safe, sustainable, and environmentally responsible pharmaceutical and consumer products.**

- A. Principles of green chemistry, sustainable substitution, regrettable substitution, benign by design
- B. Extractables and leachables (e.g., packaging and food contact, medical devices, primary container closure systems)
- C. Toxicological or hazard criteria for designations (e.g., EPA SaferChoice, USDA Biobased, NSF International)

**8. Evaluate the safety/toxicity or risk/benefit of agents for the treatment of diseases.**

- A. Potential side effects from use of common therapeutics/drugs and the mitigation strategies for each
- B. Elements of drug risk-benefit analysis and margins of safety (MOS) calculations

**9. Contribute to product stewardship, including evaluating products and communicating potential environmental, health, or safety risks and mitigation strategies.**

- A. Tiered approaches to gathering toxicological information
- B. Potential unintended effects from product use or misuse, potential environmental impacts resulting from use, and mitigation strategies through labeling and manufacturing controls

**10. Evaluate the clinical signs and symptoms of toxicity in the context of relevant standards, metrics, and reference values.**

- A. Translatability of pre-clinical data to clinical results or findings
- B. Standard sources of information for toxicity-related metrics and reference values

**11. Develop or provide clinical treatment recommendations for poisoning incidents, including antidotes.**

Mechanism of toxic action and how it relates to treatment of poisoning, including physical measures (e.g., decontamination procedures, decorporation) and clinical treatment options (e.g., antidotes)

**12. Adhere to regulation pertaining to toxic chemicals.**

- A. Regulations and standards relevant to occupational and consumer health (e.g., OSHA, CPSC, ASTM Standards)
- B. Regulations relevant to public exposure to chemicals (e.g., TSCA, REACH, FIFRA)

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<sup>1</sup>[Wood, Carol S., Christopher P. Weis, Carla M. Caro, and Amy Roe. "A Practice Analysis of Toxicology." \*Regulatory Toxicology and Pharmacology\* \(2016\): n. pag. Web.](#)

<sup>2</sup>[Soucy NV, Masten S, Caro C, et al. Updating the Standards of Professional Competence in the Field of Toxicology: The Second Generation of Best Practice. \*International Journal of Toxicology\*. 2023;42\(5\):430-444. doi:10.1177/10915818231184411](#)

<sup>3</sup>Sullivan DW Jr, Gad SC. Eleventh Triennial Toxicology Salary Survey. *Int J Toxicol*. 2023 Jul-Aug;42(4):309-325