

American Board of Toxicology, Inc.

Certification Handbook

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ABT Certification Handbook

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Introduction

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.¹ 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.² 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

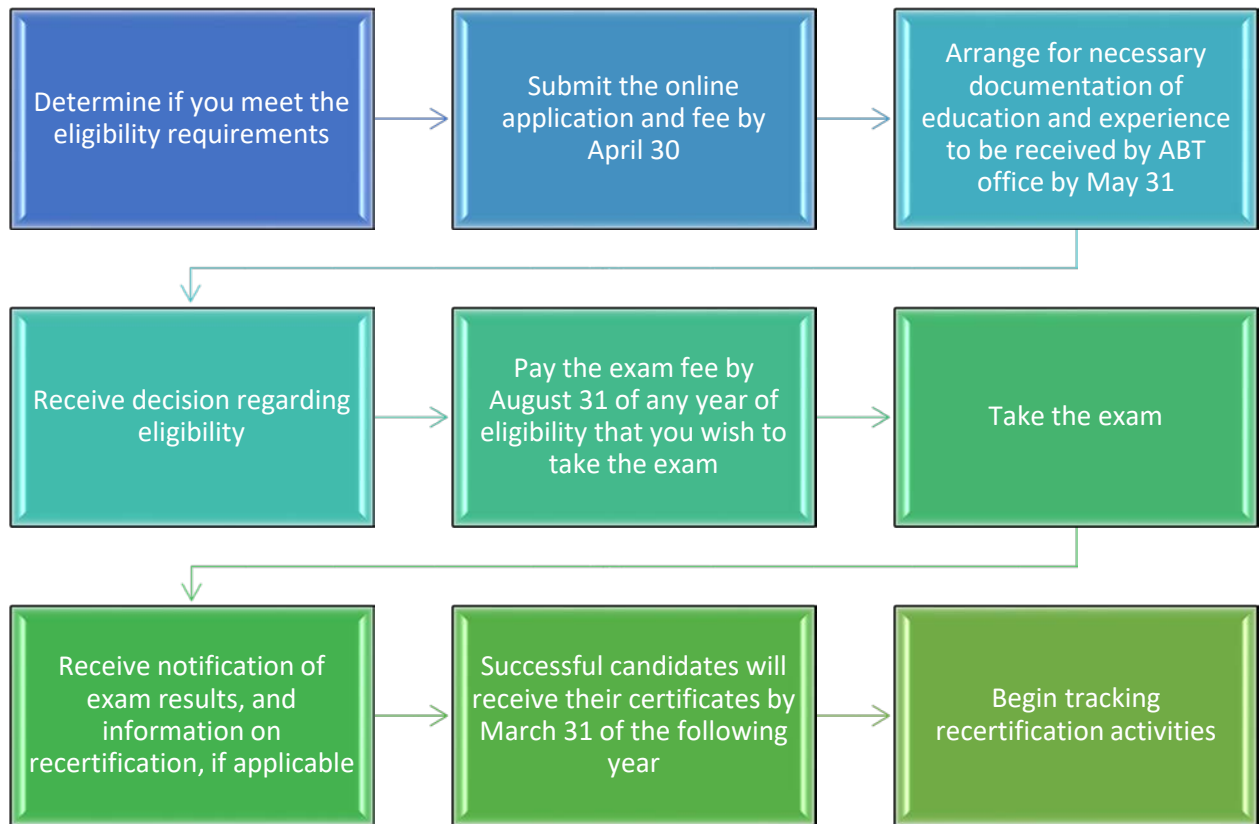
- ABT certification provides an objective demonstration of a toxicologist's breadth and currency of knowledge and supports scientific credibility.
- Certification by the ABT facilitates access to other certified colleagues who can provide expertise in diverse areas.
- ABT certification is recognized 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

Website: www.abtox.org

Quick Reference for Requirements and Deadlines

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 th |
| Application fee due (\$300) | April 30 th |
| Confirmation of degree (transcripts) received by ABT office (sent from institution) | May 31 st |
| Confirmation of professional work experience (supervisor letters) received by ABT (sent directly from supervisor via email or post) | May 31 st |
| Application withdrawal for \$275 refund | June 1 st |
| Exam fee due from eligible candidates (\$275) | August 31 st |

ELIGIBILITY REQUIREMENTS

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.
3. 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 |
|-----------------------------|--|--|
| Bachelors | 10 years full-time or part-time equivalent* | Transcript of Bachelor's degree sent directly from institution |
| Masters | 7 years of full-time or part-time equivalent post-baccalaureate 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. |
| Doctorate | 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

Application Deadlines and Fees

| Fee Due | Deadline |
|-----------------------|------------------|
| \$300 Application fee | April 30 |
| \$275 Exam fee | August 31 |

Applications are only accepted online via the ABT website at www.abtox.org. Complete the information required and pay the Application fee of three-hundred (\$300) 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.

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. If certified copies of diplomas or course listings are not provided, the applicant must satisfactorily explain their omission and provide an alternate method for determining educational status.

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. 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 Diplomate 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 Diplomate of the American Board of Toxicology®. I understand that ABT releases of its list of Diplomates will not include addresses or other contact information. I understand that ABT does list Diplomate names, addresses and other contact information on the non-public password-protected Diplomate 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 Diplomate portion of the website, I will inform the ABT office of that choice in writing and in a timely manner.

Note: Attainment of Diplomate status entitles the bearer to represent him/herself as a “Diplomate 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 the answer sheets 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 committee of the Board of Directors to review 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 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 be writing or via email to 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

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 information, the application will be reviewed again. All decisions regarding eligibility appeals are final.

PREPARING FOR THE EXAM

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, Inc. 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. This can be in person or virtually.
- **Allow time to prepare.** Many candidates begin preparing up to a year in advance.
- **Purchase the ABT Practice app.** The Board has released hundreds of previous exam questions in the form of a practice app available for Android and iOS devices. The app has been updated for 2018 to be more reflective of the types of questions on the new format of the exam. The app is available on iTunes and Google Play.



- **Study List.** The Board has prepared a study list, on the next page, 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

- Klaassen, C.D., Ed.: Casarett and Doull's Toxicology: The Basic Science of Poisons. 9th and 8th 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, 12th Edition (2011)
- ICH Guidelines for Pharmaceuticals: Safety (S) and Multidisciplinary (M3, M4, M7) (<https://www.ich.org/page/ich-guidelines>).
- OECD Guidelines for the Testing of Chemicals:
 - Human Health Effects (Section 4) (https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788) Test Numbers 404, 405, 408, 413, 414, 425, 432, 442B, 443, 471, 474, and 476/490
 - Effects on Biotic Systems (Section 2) (https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-2-effects-on-biotic-systems_20745761) Test Numbers 202, 203, and 207.
- 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). 2009. Science and Decisions: Advancing Risk Assessment (Silver Book). National Academy Press, Washington, D.C.
(<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>
- US FDA Guidance for Industry:
 - [The Least Burdensome Provisions: Concept and Principles; Draft Guidance for Industry and Food and Drug Administration Staff \(PDF - 513KB\)](#) (CDRH/CBER, December 2017)
 - [Guidance for Industry: Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients \(PDF - 230KB\)](#) (CDER/CBER, May 2005)
 - [CVM GFI #232 \(VICH GL54\) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose \(ARfD\) \(PDF - 100KB\)](#)
 - [Guidance for Industry: Safety of Nanomaterials in Cosmetic Products](#)
 - [Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products Guidance for Industry \(PDF - 115KB\)](#)
 - Food Additives: [Frequently Asked Questions about GRAS](#) (October 2016)
 - Food Additives: [Toxicological Principles for the Safety Assessment of Food Ingredients: Redbook 2000](#) (July 2007)
 - Food Additives: [Estimating Dietary Intake of Substances in Food](#) (August 2006)
 - Pharmacology / Toxicology: [Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers \(PDF - 702KB\)](#) Final Guidance 07/28/05
 - Pharmacology / Toxicology: [Carcinogenicity Study Protocol Submissions \(PDF - 29KB\)](#) Final Guidance 05/22/02
 - Pharmacology / Toxicology: [Safety Testing of Drug Metabolites: Guidance for Industry \(Revision 1; Nov 2016\)](#)



EXAM SCHEDULING AND ADMINISTRATION

The ABT exam is held once per year at several locations. Beginning with the 2017 administration, the exam will be 6 hours in length and consist of 200 questions delivered in two, 3-hour segments with an interim break. The exam will be scored as a single part. 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 Location and Date Notification

In July, eligible applicants will be notified via email of the exact time and locations of the examination to be held in October. Applicants will be assigned to a location based on proximity to their address. If an applicant wishes to take the exam at one of the other locations, they must inform the ABT office at the time they make the exam payment. It is the responsibility of the applicant to ensure that their email and mailing address remains current in the online system.

Exam Locations

Each year, the geographical exam locations will be posted on the ABT website by January 1.

The exam is currently administered in the following locations. Please note these are subject to change each year.

- Research Triangle Park, NC
- Santa Clara, California
- Edinburgh, Scotland
- Chennai, India
- Seoul, South Korea

Exam Fee and Payment Deadline

In order to take the examination in any year of eligibility, the candidate must submit a non-refundable examination fee by August 31st of that year. 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. A link to pay the fee online will be made available in July of the examination year.

Test Day

Be at the assigned room 15 minutes before the actual starting time but do not enter until permitted by the proctors. If a candidate is late, they may be allowed to take the examination,



but will be required to finish at the scheduled time. Examinations will start and end promptly at the scheduled times.

The examination will be conducted under the supervision of the Board's proctors. The proctors will be introduced at each session. Any question or problem should be directed to the proctors only. The proctors may not define technical terms or answer any inquiry about any question on the examination other than printing errors.

Bathroom visitation or any request to leave the room must be approved by the proctor. Generally, one candidate per escort (a proctor) is allowed.

Do not start work until the proctor has given instructions and permission. Time remaining will be announced at regular intervals. Work must end at the announced end of the session.

What to Bring to the Test

- Photo ID: Entrance to each session of the examination will require that the examinee present a government-issued photo ID. If you do not resemble the photograph you will not be admitted.
- Food/Beverages: In general, food is not allowed in the exam room. A power bar, small candies, gum, or cough drops are acceptable but must be placed on the table in front of the examinee prior to the start of the exam. Water will be provided in the examination room. A small juice bottle or energy drink is acceptable but must be placed on the table in front of the examinee prior to the start of the exam.
- A small number of tissues may be placed on the table in front of examinees
- Bring several #2 or HB pencils with an eraser and a pencil sharpener.

What NOT to Bring to the Test

- Electronic Devices: All electronic devices (e.g., cell phones, iPads, Blackberry, iPhone, etc.) must be turned OFF and placed in the front of the room in plain view with your other personal items. Electronic devices are not allowed in restrooms.
- Noise making devices, paging devices or alarm watches that will produce an audible signal will not be permitted.
- Paper or notepads: Candidates may write in the exam booklet if needed
- Calculators
- Bookbags or luggage. If brought, these will need to be put at the front of the room
- Ear phones of any type.



AFTER THE EXAMINATION

Examination Scoring

The exam is scored by machine after all answer cards are received from all locations after the examination.

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 committee of the Board of Directors to 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 exam location 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.

Receipt of Certificate

New Diplomates will be sent a certificate acknowledging their accomplishment. Certificates are prepared by a professional calligrapher, and then signed by the Board Secretary and President. Due to the length of this process, certificates may not be received until the month of March following the examination. It is the responsibility of the candidate to ensure their mailing address is correct.

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

1. Where and when is the examination given?

By January 1 each year, the geographical locations and date of the examination will be posted on the ABT website. The locations of the exam are subject to change each year. In 2016, it was given on the east and west coast of the US, Europe, and two locations in Asia.

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.

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 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. 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. By the time the fee is paid, we have already contracted for the exam site based on the number of expected applicants.

11. 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.

12. 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.

13. How do I find out my scores?

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

14. What if I pass the first session of the exam, but not the second?

While there will be two sessions to the exam of 3 hours each, all questions will be graded as a whole, for one grade.



OVERVIEW OF ABT EXAMINATION CONTENT OUTLINE

| Domain/Sub-domain | % of Exam |
|--|-----------|
| I. Design, Execute, and Interpret Toxicology Studies | 31 |
| II. Descriptive Toxicology: Environmental, Clinical, Non-clinical, and Forensic Investigations | 13 |
| III. Mechanistic Toxicology | 9 |
| IV. Risk Assessment (Total, A through D) | <u>38</u> |
| A. Hazard Identification | 13 |
| B. Exposure Assessment | 8 |
| C. Dose Response Assessment | 9 |
| D. Risk Characterization and Management | 8 |
| V. Applied Toxicology: Public, Environmental, and Occupational Health | 9 |
| TOTAL | 100 |

For each Task in the five 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. Design, Execute, and Interpret Toxicology Studies

Tasks

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

Know what a scientific hypothesis is and the elements of a scientifically valid, hypothesis-driven or regulatory guideline study.

2. Comply with applicable regulations and guidelines specific to the agent under study.

Have knowledge of the standard US and global testing guidelines for pharmaceuticals and chemicals (GLP, OECD, OPPTS, ICH [S, M3, M7], USFDA).



3. Select and characterize the chemical and physical identity of the test agent.

Know the common analytical methods used in toxicology for test agent characterization.

4. Characterize toxicological effects *in vivo*.

Know the relevant endpoints measured in standard animal toxicology studies.

5. Characterize toxicological effects *in vitro*.

Know the relevant endpoints measured in standard *in vitro* toxicology studies and principles of the 3Rs (Reduce/Refine/Replace).

6. Characterize toxicological effects *in silico*.

Understand the concept of *in silico* toxicology and standard *in silico* methods and their application in toxicology.

7. Characterize toxicological effects in a field or clinical setting.

Be familiar with the endpoints obtained from standard controlled field (ecotoxicological) studies and human clinical trials.

8. Develop, qualify, and validate new testing methods and techniques.

- A. Be familiar with validated alternative test methods in toxicology.
- B. Know the accepted standards of validity applied to such methods.

9. Analyze test results and integrate existing data using informatics, statistics, and modeling.

Understand how data are analyzed and integrated in toxicology, including the role of bioinformatics, statistics, and computer modeling.

10. Interpret and integrate study results into a scientifically cogent narrative to develop conclusions and/or inform next steps.

Understand the elements of a toxicology study report (and all subparts that support the study), and principles used in interpreting the results or relevance for human or animal safety assessment.

11. Prepare research report or summary that is fit for purpose.

Understand the role of one's target audience (e.g., other scientists, managers, sponsor) when writing study reports in toxicology.



Domain II. Descriptive Toxicology: Environmental, Clinical, Non-clinical, and Forensic Investigations

Tasks

- 1. Analyze and integrate toxicology data obtained from diverse sources to identify toxicological patterns of concern (molecules, cells, tissues, target organs, individuals, populations, communities, ecosystems).**
 - A. Be familiar with the appropriate knowledge, methods and means used to bridge experimental findings across levels of biological organization.
 - B. Understand how findings/results from simple and/or lower-level experimental systems may be applied to more complex, higher-level systems.
- 2. Identify hazards, risks, and putative mechanisms.**
 - A. Know the differences between adverse (“harmful”) and non-adverse test article-related effects, and between false negative and false positive information.
 - B. Know the common biological pathways used to develop hypotheses for modes and mechanisms of action.
 - C. Distinguish routes of exposure and toxic agent effects on cells, tissues, organisms and the environment.
 - D. Be familiar with relevant international guidelines used to determine risks from toxic agents.
- 3. Develop strategies to test hypotheses.**
 - A. Know the essential elements of a testable scientific hypothesis.
 - B. Know the necessary experimental (e.g. test article, treatment) and control (e.g. positive and negative control agents, non-treatment) groups used to evaluate a specific scientific hypothesis and/or for regulatory decision-making.
 - C. Understand the most appropriate statistical models used in specific experimental designs in toxicology.
- 4. Perform weight of evidence analyses.**

Know WoE criteria for integrating potentially disparate lines of evidence to reach a conclusion appropriate for decision-making.
- 5. Develop strategies to mitigate toxicity.**

Understand the various strategies or technologies/practices/procedures used to reduce exposure and/or mitigate toxicity (e.g. antidotes, remediation, engineering controls, personal protective equipment).



6. Translate results of descriptive toxicological investigations between species.

- A. Understand the salient anatomical, physiological, biochemical, pharmacological, and toxicological differences across species that determine relevance and magnitude of specific effects.
- B. Know appropriate international guidelines for interspecies comparisons.

Domain III. Mechanistic Toxicology

Tasks

1. Develop mechanistic hypotheses.

- A. Understand that *in vitro* and animal data can be used to test mechanistic hypotheses.
- B. Know the molecular/signaling pathways associated with chemical-specific toxicities in animal tissues/*in vitro* systems.
- C. Understand basic physiology and organ function as related to toxicology.
- D. Know the steps involved in developing a mechanistic hypothesis.
- E. Be aware of the role of genetic variant phenotypes (KOs, SNPs, etc) in mechanisms of toxicity.
- F. Be aware of various “omic” technologies used to test hypotheses.

2. Assess role of toxicokinetics in mechanism of toxicity.

- A. Understand how ADME parameters can be used to predict/describe systemic exposure and describe site-specific toxicity.
- B. Understand how changes in PK/TK parameters (e.g. clearance, absorption, half-life) contribute to changes in systemic and/or site-specific exposure and ultimately toxicity.
- C. Understand that individual and species differences in metabolism (e.g. parent vs. metabolite) may impact toxicity.
- D. Know how species differences in anatomy and physiology may affect uptake and absorption (e.g., respiratory tract, dermal, oral).
- E. Understand the differences between the local and systemic toxicokinetics of parent, metabolite, and ultimate toxicant (e.g., systemic vs portal of entry effects).

3. Assess role of toxicodynamics in mechanism of toxicity.

- A. Know the fundamental molecular toxicological mechanisms and their relationship to adverse responses.
- B. Understand various molecular level (e.g. receptor/protein level) toxicant interactions.
- C. Understand various chemical-specific biomarkers of effect.



4. Identify susceptibility factors.

Identify those attributes (e.g., genetic polymorphisms, life-stage, gender, etc.) that might affect susceptibility to toxins/toxicants.

5. Distinguish direct and indirect action.

Understand toxicity that results directly from a targeted interaction/direct insult (e.g., at a cellular/receptor/pathway level) versus toxicity from a secondary/indirect effect (e.g., delayed ossification due to maternal toxicity, reduced fetal body weight, food consumption, stress, off-target interaction, etc.).

6. Use differential mechanistic information to develop products.

- A. Understand domestic and international guidelines that address the use of toxicity data in the development of safer or “greener” products.
- B. Understand how screens and counter-screens are used in drug discovery to develop lower-risk drug products.

7. Translate results between mechanistic studies and toxicological outcomes, prevention, and clarification of risk (human, environmental, animal).

- A. Understand the relationship between mechanism or mode of action data for a chemical and remediation of environmental exposures/sites.
- B. Understand the relationships between mechanism or mode of action of chemical(s), human/environmental exposure and the legislation/regulation of certain products (e.g., endocrine disruptors, microbeads, DDT).
- C. Understand how mechanistic or mode of action data for a chemical from *in vitro/in vivo* animal studies can inform adverse outcome pathways (AOPs).
- D. Understand how toxic effects of a chemical mixture can differ from the toxic effects its individual chemicals.
- E. Understand how cellular, biochemical, and molecular mechanisms of chemical toxicity can be used in interpretation/evaluation of risk to humans/environment/animals.
- F. Know how to calculate human equivalent dose/human equivalent concentration (HED/HEC).

8. Develop and apply mechanistic information to disease models.

- A. Understand and evaluate relevance of mechanistic toxicity data generated from *in vitro* studies to human safety/risk.
- B. Be aware of how mechanistic data are applied in the development of alternative animal disease models.
- C. Understand how animal disease models differ from human conditions, including strengths and limitations of disease models.



9. Apply principles of systems toxicology.

- A. Understand utility and limitations of analytical/computational tools to study mechanisms of toxicity and interpret disruption of biological networks.
- B. Understand the relationship of “omics” data to organism-level effects.

Domain IV. Risk Assessment

A. Hazard Identification

Tasks

1. Characterize, describe and interpret effects and test system endpoints of toxicological concern - including but not limited to acute and repeat dose toxicity, reproductive effects, genotoxicity, carcinogenicity, local effects/tolerance, and ecotoxicology.

- A. Know the various possible toxic effects to an organism or ecosystem
- B. Understand the difference between adverse health effects and adaptive health effects.
- C. Know the major effects and endpoints measured in acute lethality/toxicity, repeat dose toxicity, reproductive toxicity, developmental toxicity, *in vivo* and *in vitro* genotoxicity, carcinogenicity, sensitization, immunotoxicity, phototoxicity, *in vivo* and *in vitro* (e.g., dermal, ocular), and ecological studies as well as toxicity by different routes of exposure (e.g., oral, inhalation, dermal).
- D. Be familiar with translatability of data collected with *in vivo* and *in vitro* endpoints to humans.

2. Apply appropriate test systems and study types for safety evaluation.

- A. Understand how to apply data from various methods (e.g., structure-activity, *in vitro* or short-term studies, animal bioassays, and human epidemiologic studies) to identify hazards.
- B. Be aware of relevant target organism(s) for selection of appropriate test species used in safety evaluation.

3. Identify systemic effects and/or target organs, dose response, and thresholds of effect.

- A. Be familiar with the criteria from methodologies / guidelines for analyzing, interpreting, and identifying target organs and adverse effects from the following types of studies: acute lethality/toxicity, repeat dose toxicity, reproductive toxicity, developmental toxicity, *in vivo* and *in vitro* genotoxicity, carcinogenicity, sensitization, immunotoxicity, phototoxicity, route-specific studies (e.g., oral, inhalation, dermal), alternative *in vitro* studies (e.g., for dermal or ocular irritation); and ecotoxicology studies.
- B. Understand the concept of point of departure (POD) and its use in risk assessment.
- C. Be familiar with various criteria for application of thresholds of toxicity (e.g. TTC).



4. Assess mechanisms of action and relevance to humans or other target species, including sensitive sub-populations and individuals.

- A. Recognize study designs that allow for identification of mechanisms that are species-dependent and/or specific to life stage of experimental animals and/or humans.
- B. Identify those mechanisms or modes of action that are species-dependent and/or specific to life stage of experimental animals and/or humans.

5. Identify toxicological endpoints using the actual route, or appropriate surrogate of primary exposure.

- A. Know what environmental and/or occupational exposure patterns may be relevant to human and other environmental receptors (e.g. know how to develop a conceptual site model).
- B. Be familiar with the environmental fate and transport processes that may influence exposure.
- C. Know the basic principles of SAR, QSAR, and other in silico approaches and how those outputs can be used in a risk assessment context.
- D. Know the differences between types of oral toxicity studies as they apply to hazard identification, e.g., gavage vs. dietary or drinking water.
- E. Know the differences between types of inhalation toxicity studies as they apply to hazard identification, e.g., aerosol vs. vapor vs. intratracheal instillation.
- F. Know the metabolic differences between various routes of administration (e.g., sublingual vs oral).
- G. Be familiar with the anatomical differences across species for various routes of exposure (e.g., inhalation, oral and dermal exposures).

B. Exposure Assessment

Tasks

6. Select appropriate endpoints with which to document exposure to toxicants in test systems and populations.

Understand the various measures and units of exposure (dose, airborne concentration, plasma level, etc.) reported in toxicological investigations and assessments.



7. Assess toxicant exposure in the general public, occupationally exposed individuals, populations, and the environment using appropriate technologies (including but not limited to analytical, bioassay, biomonitoring).

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

8. Assess relevance of biomarkers of exposure in individuals, populations and the environment.

Understand the various biomarkers of exposure and their appropriate use in toxicology.

9. Characterize absorption (A), disposition (D), metabolism (M), excretion (E), and kinetics (PK or TK) of toxicants."

- A. Understand the impact of ADME processes on dose (external, internal, absorbed), including the role of route-specific factors (e.g. for inhalation: particle size, aerosol/vapor/gas, surface chemistry; dermal: flux characteristics, atomic/molecular characteristics; oral: acute vs. chronic).
- B. Understand the influence of chemical species/physical form on absorption processes.
- C. Know the components of a PBPK model.

10. Assess and document behavior, fate, and transport of chemicals entering the environment (for example, biotransformation, bioavailability, bioaccumulation, biomagnification).

Understand the concepts and processes utilized in environmental fate and transport (e-fate) assessments including: vapor pressure (VP), Henry's law, log Kow, log Koc, biotransformation, bioavailability, bioaccumulation, biomagnification, and bioaccessibility.

11. Consider issues of disproportional, unique, and reactive metabolites arising in specific species.

Understand the relevance or non-relevance and impact of species-specific metabolites in exposure assessment.



12. Identify primary and secondary interactions between agents and biological systems.

Understand the difference between primary and secondary interactions of agents with biological systems and how exposure to toxicants can lead to downstream effects in individuals and populations.

13. Assess impact of target and off-target interactions on cellular, tissue, organ, organism, population, and environmental functions.

Understand the differences between target and off-target interactions at the cellular, tissue, organ, organism, population and environmental levels, and associated regulatory guidance.

C. Dose Response Assessment

Tasks

14. Quantitatively and/or qualitatively characterize relationships between dose (or concentration) and incidence and severity of health effects or toxicological endpoint.

- A. Recognize and interpret different types of dose-response curves including those for: (a) lethality, (b) threshold responses, and (c) non-monotonic responses.
- B. Interpret cumulative and frequency dose-response curves.
- C. Define the parameters of a dose-response curve (slope, plateau, midpoint, etc).
- D. Identify and define an ED50, EC50, LD50, and LC50 from a dose response curve.
- E. Know the general principles of benchmark dose (BMD) methodologies.
- F. Understand the outputs of physiologically-based pharmacokinetic (PBPK) modeling and their utility in characterizing dose-response relationships.
- G. Be familiar with methods for dosimetric adjustments across species and exposure duration.

15. Analyze toxicity data to determine a safe dose (or concentration) or protective threshold (for example, benchmark dose).

- A. Be familiar with methods to derive a cancer slope factor (CSF; $q1^*$).
- B. Know the methodology and inputs necessary to derive guidance values such as REACH DNELs and DMELs, RfD, RfC, ADI, and health-based OELs.
- C. Know the types, values and sources of safety/uncertainty factors and sources of information needed for their application.
- D. Be familiar with the different approaches for allometric scaling including default values and when they should be applied.

- E. Understand possible reasons for species differences in sensitivity and impact on derivation of toxicity reference values.
- F. Understand the impact of study design (e.g. number of treatment groups, sample size) on choice of dose-response assessment approach e.g. BMD vs. NOAEL.
- G. Be familiar with the appropriate statistical methods and dose-response modeling approaches for different types of toxicological endpoints.
- H. Be able to identify some benefits and limitations of extrapolating laboratory data in the development of safety benchmarks (e.g. LOAELs/NOAELs, NOECs/LOECs).

16. Analyze toxicity data to determine an effective or toxic dose (or concentration).

- A. Be able to generate and analyze threshold and non-threshold (linear) dose-response curves
- B. Know the difference between adaptive and adverse health effects.
- C. Understand how diverse endpoints, e.g. organ weights, clinical chemistry, histopathology, can be integrated to perform a comprehensive dose-response assessment.
- D. Know the dose-response dynamics of essential nutrients and hormetic responses.
- E. Know the basis for calculating a Therapeutic Index (TI) and a Hazard Index (HI).

D. Risk Characterization and Management

Tasks

17. Integrate toxicity and exposure information to characterize potential health risks and margins of safety.

- A. Know metrics that may be used in risk characterization, e.g., margin of exposure (MOE), hazard quotient (HQ) and probability estimates, including their appropriate application and limitations.
- B. Understand the concepts of aggregate exposure and risk and cumulative risk in the context of risk characterization. Understand principals of mixtures toxicity and their potential application in risk characterization, e.g., dose and response additivity, toxicity equivalency factors.
- C. Understand various types of dose-response extrapolations and how to characterize the uncertainties associated with them.



18. Assess health risks and management options to protect environmental or public health (including but not limited to cleanup goals, emission limits, safe concentrations, efficacious concentrations).

a. Evaluate and implement alternatives to reduce risks.

Understand engineering, economic, social and political factors that contribute to and modify risk characterization. Know principals of risk perception and communication. Understand the precautionary principle and its implications.

b. Derive safety limits that are protective of environmental or public health.

Know how to derive health protective exposure limits for various populations, exposure durations, and exposure scenarios.

c. Identify and implement emergency risk management options to reduce chemical exposures or risks.

- A. Understand concepts of emergency management and remedial responses
- B. Know steps needed to perform an impact/feasibility assessment and initiate a cleanup strategy.

Domain V. Applied Toxicology: Public, Environmental, and Occupational Health

Tasks

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

- A. Understand the differences in responses between individuals and populations.
- B. Be familiar with the concept of “indirect effects” from exposure in an ecological community (e.g. why biomagnification may affect top predators resulting in a net increase in prey populations).
- C. Be familiar with the concept of a Species Sensitivity Distribution.

2. Identify critical effects and thresholds from dose-response assessment.

Know what biologically relevant effects are and of the importance of biological variation in evaluating dose-response data for a community or occupational setting.

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

Given an issue of community or public health toxicologic concern, understand the elements of a response and risk communication plan; know about risk perception concepts and mitigation strategies.

4. Assess public health impacts from ecosystem effects of environmental toxicants.

- A. Explain how threats to ecosystem services (e.g., clean/safe water, clean air) affect human health.
- B. Considering animal-human interactions, understand the ways that toxicants may affect disease prevalence (e.g. zoonoses).

5. Investigate health outcomes in specific groups with respect to measured or modeled chemical exposures.

Understand exposure reconstructions for dose-response evaluation in the context of epidemiological findings.

6. Use population-based biomonitoring studies to ascertain temporal trends in chemical exposures.

- A. Be familiar with, and understand, the utility of national studies and databases, e.g., NHANES.
- B. Know the difference between cross-sectional vs. longitudinal epidemiology studies.
- C. Understand toxicological implications of biomonitoring data reported as part of a community public health investigation.

7. Identify sensitive or susceptible subpopulations.

Given an incident or situation of toxicological concern in a community or occupational setting, identify those factors or circumstances that would increase the risks of adverse health effects in a particular group or sub-group of individuals.

8. Design or implement programs to reduce the exposure to hazardous substances.

Identify sources of exposure, describe environmental distribution, and apply mitigation technologies, practices, and procedures.

9. Evaluate products and communicate potential environmental, health, or safety issues (including product stewardship).

- A. Be familiar with the principles of green chemistry and tiered approaches to gathering toxicology information.
- B. Understand the probabilistic nature of side effects from product use, potential environmental impacts resulting from use and ways to mitigate such effects through labeling and manufacturing controls.

10. Evaluate the safety or risk of toxic agents for the treatment of diseases (including but not limited to drug development).

- A. Know the potential side effects from use of common therapeutics/drugs and the mitigation strategies for each.



B. Know the elements of drug risk-benefit analysis and margins of safety (MOS) calculations.

11. Evaluate the signs and symptoms of toxicity.

Describe responses (signs, symptoms) of organism, population, or ecosystem responses to a toxic insult.

12. Develop or provide treatment recommendations for poisoning incidents (including antidotes).

Be familiar with the concept of mechanism of toxic action and how it relates to treatment of poisoning, including physical measures (e.g., decontamination procedures) and clinical treatment options (e.g., antidotes).

13. Have an understanding of U.S. and global regulations that pertain to toxic chemicals.

Be familiar with global regulations, in particular those administered by OSHA, FDA, CPSC, EPA, and ECHA, relevant to occupational and community health.

¹Wood, Carol S., Christopher P. Weis, Carla M. Caro, and Amy Roe. "A Practice Analysis of Toxicology." *Regulatory Toxicology and Pharmacology* (2016): n. pag. Web.

² Gad & Sullivan, 2016. Ninth Triennial Toxicology Salary Survey. *Int. J. Toxicol*, 35(2): 243-251

