NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 7. BOARD OF CHIROPRACTIC EXAMINERS

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R4-7-701	Repeal
R4-7-702	Repeal
R4-7-702	New Section
R4-7-901	Amend

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 32-904(B)(2)

Implementing statutes: A.R.S. §§ 32-921 and 32-924

3. The effective date of the rules:

January 7, 2003

4. A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening: 7 A.A.R. 473, January 12, 2001

Notice of Proposed Rulemaking: 7 A.A.R. 1704, April 27, 2001

Notice of Supplemental Proposed Rulemaking: 7 A.A.R. 2506, June 15, 2001

Notice of Public Information: 8 A.A.R. 857, March 1, 2002

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Patrice A. Pritzl, Executive Director

Address: 5060 N. 19th Avenue, Suite 416
Phoenix, AZ 85015

Telephone: (602) 864-5088

Fax: (602) 864-5099

6. An explanation of the rule, including the agency's reasons for initiating the rule:

There are three rule amendments in this package. The first repeals the rule addressing application for approval of unaccredited colleges because the rule no longer reflects Board policy. The second maintains the standards of education applied to colleges. The third states that the use of the terms "specialist," "specializing," or "expert," in advertising is deceptive or misleading in nature.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, any analysis of each study and other supporting material:

None

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

The economic impact of the rule amendments will be minimal. The standards of education in R4-7-702 reflect statutory standards and reference those standards applied by the Council on Chiropractic Education, by which all chiropractic colleges are currently accredited. Therefore, this rule does not hold applicants to a higher level of education and does not cause the applicant to incur an additional cost. R4-7-901 may require some chiropractors to change advertising. However, because that change cannot be made until a new printing of the advertising medium, there should be no additional costs incurred. A licensee may incur minimal cost of $25 to $50 if the prohibited language appears on business cards that must be replaced.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

Minor technical changes have been made based on suggestions from G.R.R.C. staff.

11. A summary of the comments made regarding the rule and the agency response to them:

The agency did not receive written or oral comment.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rules:

None

14. Was this rule previously adopted as an emergency rule?

No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 7. BOARD OF CHIROPRACTIC EXAMINERS

ARTICLE 7. STANDARDS OF EDUCATION

Section
R4-7-701. ~~Application for Accreditation by Board from College not Otherwise Accredited~~ Repealed
R4-7-702. ~~Standards of Education as Determined by the Board~~ Educational Requirements for Licensure

ARTICLE 9. UNPROFESSIONAL CONDUCT

Section
R4-7-901. Advertising of a Deceptive and ~~Fraudulent~~ Misleading Nature

ARTICLE 7. STANDARDS OF EDUCATION

R4-7-701. ~~Application for Accreditation by Board from College not Otherwise Accredited~~ Repealed

~~A school or college of chiropractic which is not accredited by or does not have status with Council on Chiropractic Education or which is not accredited by an accrediting agency recognized the U.S. Department of Education or the Council on Postsecondary Accreditation may qualify its graduates for purposes of the examination for licensure by submitting an application to the Board that demonstrates that the college meets the educational standards established below.~~

R4-7-702. ~~Standards of Education as Determined by the Board~~ Educational Requirements for Licensure

~~**A.** Pre-professional education:~~
- ~~1. The college of chiropractic shall require by January 1, 1977, all its students, for admittance purposes, proof of having acquired at least two years (or 60 acceptable semester hours) leading to a baccalaureate degree in the arts and sciences. This should include one year each of chemistry and biology with laboratories.~~
- ~~2. Those that have matriculated with the fall enrollment of 1980 shall furnish proof of having credit of a minimum of three courses totaling not less than nine semester hours in chemistry with laboratory, one course of which shall be in organic chemistry or foreign equivalency.~~

~~**B.** The objective of the chiropractic college shall be to prepare the chiropractic doctor for the practice of chiropractic. The college shall be familiar with the distinctive characteristics of the chiropractic profession.~~

~~**C.** The organization of the college:~~
- ~~1. The college shall be incorporated under the laws of the state of its residence.~~
- ~~2. The college shall be exempt from taxes due to its educational program and purposes.~~
- ~~3. Control shall be vested in a board composed of chiropractic doctors and lay persons receiving no financial benefits from the college.~~

~~**D.** The administration:~~

1. ~~There shall be a chief administrative officer. The chief administrative officer shall appoint to assist him a staff of administrative officers conforming to the accepted standards for professional education. These shall include a dean of academic affairs, dean of student affairs, and a dean of business affairs.~~

2. ~~There shall be a self-study/evaluation committee. This committee shall be composed of faculty, students, administration, and other appropriate persons who shall be responsible for a report reflecting the autonomy and integrity of the institution. The report shall provide a factual picture of the various aspects of the educational program to each standard. It should relate the activities of the college with its stated purpose. It should reflect the planning for the future.~~

3. ~~The records of the college shall be up to date and open for inspection. These shall include the financial report, clinic records, and scholastic records, not to include individual student records without consent.~~

4. ~~The college shall issue a catalog or bulletin that is available upon request. The catalog shall include a listing of the members of the faculty, trustees, all officers of the college with their respective credentials; e.g. degree, etc. The catalog shall list the courses that are given, information regarding entrance requirements, discipline, attendance, examinations, grades, procedures, and graduation. The fees for tuition, matriculation, laboratory, or any other special fees shall be listed. The catalog or bulletin, which should be published annually, shall include the college calendar. The college shall have an adequate student/teacher ratio, adequate library, adequate laboratories, and a public clinic, providing sufficient clinical expertise to adequately prepare the student for the practice of chiropractic.~~

~~**E.** Professional education:~~

1. ~~The courses of education shall include the following subjects: human anatomy, dissection, physiology, pathology, orthopedics, principles of chiropractic and adjusting, neurology, chemistry including biochemistry, nutrition, hygiene and public health, chiropractic spinal analysis, x-ray, laboratory subjects, bacteriology, and diagnosis including physical, clinical and differential.~~

2. ~~The length of the course: There shall be a resident course of four years of not less than nine months each year, or the equivalent of 36 months of continuous study, comprising not less than 4,000 60-minute class hours of resident study.~~

~~**F.** Guidelines for the colleges with graduates making application to sit for the examination:~~

~~A detailed self-study report shall be submitted 120 days before the date of examination to allow for questions and, if necessary, an onsite visitation by the Board and/or a consultant appointed by the Board.~~

~~**G.** Guidelines for the Board:~~

1. ~~A college meeting the equivalency standards of education as determined by the Board shall be granted an "Equivalency Status" only for that period of time, not to exceed two years, during which it continues to meet the standards set forth by the Board. "Equivalency Status" may be withdrawn at any time that the Board determines that its standards are no longer being met.~~

2. ~~The Board shall accept those graduate applicants from schools or colleges of chiropractic which have been determined by the Board to have achieved an "Equivalency Status". Graduate applicants from colleges not having met the Board's equivalency standards or from colleges whose "Equivalency Status" has been withdrawn by the Board at the time of the applicant's graduation shall not be considered qualified graduates of chiropractic schools or colleges having the equivalency of such standards required by the Board.~~

To qualify for licensure, an individual shall have graduated from a college of chiropractic that is accredited as specified in A.R.S. § 32-921(B)(2)(a) or that meets the standards of education for accreditation contained in The Council on Chiropractic Education Standards for Doctor of Chiropractic Programs and Institutions.

ARTICLE 9. UNPROFESSIONAL CONDUCT

R4-7-901. Advertising of a Deceptive and ~~Fraudulent~~ Misleading Nature

The Board shall ~~cause a license to be investigated, suspended, or revoked for advertising that is likely to deceive or defraud the public, including but not limited to the following examples:~~ investigate an allegation of advertising in a false, deceptive, or misleading manner by a licensee and may sanction a licensee for a violation under A.R.S. § 32-924. Advertising of a false, deceptive, or misleading manner includes, but is not limited to, the following:

1. Advertising painless procedures;
2. Advertising complete health services; or
3. Advertising that uses the words "specialist," "specializing," or "expert."

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1. Sections Affected **Rulemaking Action**

R4-23-110	Amend
R4-23-501	Amend
R4-23-502	Amend

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 32-1904(A)(1)

Implementing statute: A.R.S. § 32-1904(A)(1)

3. The effective date of the rules:

January 5, 2003

4. A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening: 8 A.A.R. 797, February 22, 2002

Notice of Proposed Rulemaking: 8 A.A.R. 2292, May 31, 2002

5. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy
4425 W. Olive, Suite 140
Glendale, AZ 85302

Telephone: (623) 463-2727, ext. 131

Fax: (623) 934-0583

E-mail: rxcop@msn.com

6. An explanation of the rule, including the agency's reasons for initiating the rule:

In the five-year rule review approved by G.R.R.C. on September 9, 1997, the Board identified R4-23-502 for amending because it lacks clarity in relation to current statutory language, specifically the use of the term "Rx Only" instead of "Caution: Federal law prohibits dispensing without a prescription." The Board staff decided to amend R4-23-501 by updating the style, format, and language to current standards. The Board staff intends to add the word "label" after the last word "medication" in the definition for "dispensing pharmacist" in R4-23-110 to improve clarity and understandability. A new definition for "dietary supplement" is added to R4-23-110. The heading of R4-23-501 is changed from "Vitamins and Other Substances" to "Dietary Supplements." The rule is amended to reflect the use of the term "dietary supplements" for the words "vitamins and other substances." The amended rules will include format, style, and grammar changes necessary to comply with the Secretary of State's and Governor's Regulatory Review Council's current administrative rules.

The Board believes that approval of these rules will benefit the public health and safety by improving the language that defines the non-drug products that may be marketed to supplement the diet and those persons or firms who may distribute nonprescription veterinary drugs in Arizona.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

Not applicable

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

The rules have minimal to no economic impact. There may be a nonquantifiable impact on personnel time due to a more clear, concise, and understandable rule generating fewer questions or interpretations. The changes involve style,

format, punctuation, and grammar necessary to provide a clear, concise, and understandable rule. The changes are nonsubstantive in nature. The term "dietary supplement" more clearly describes the classification of products that R4-23-501 is intended to characterize.

The Board, pharmacists, pharmacies, nonprescription drug retailers, full-service and nonprescription drug wholesalers, drug manufacturers, and the public benefit from a rule that is clear, concise, and understandable. The rule establishes the non-drug products that may be marketed to supplement the diet and those persons or firms who may distribute nonprescription veterinary drugs in Arizona.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

There are no substantive changes in the final rules from the proposed rules. There are minor changes to style, format, grammar, and punctuation requested by G.R.R.C. staff.

11. A summary of the comments made regarding the rules and the agency response to them:

No one attended the public hearing, and no written comments were received by the Board.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rules:

None

14. Was this rule previously approved as an emergency rule?

No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 5. DRUG CLASSIFICATION

Section
R4-23-501. ~~Vitamins and Other Substances~~ Dietary Supplements
R4-23-502. Veterinary

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 4 A.A.C. 23:

"Active ingredient" No change

"Alternate physician" No change

"Approved course in pharmacy law" No change

"Approved Provider" No change

"Authentication of product history" No change

"AZPLEX" No change

"Batch" No change

"Beyond-use date" No change

"Biological safety cabinet" No change

"Certified pharmacy technician" No change

"Class 100 environment" No change

"Community pharmacy" No change

"Component" No change

"Computer system" No change

"Computer system audit" No change

"Container" No change

"Continuing education" No change

"Continuing education activity" No change

"Continuing education unit" or "CEU" No change

"Contact hour" No change

"Correctional facility" No change

"CRT" No change

"Current good compounding practices" No change

"Current good manufacturing practice" No change

"Cytotoxic" No change

"Day" No change

"DEA" No change

"Delinquent license" No change

"Dietary supplement" means a product (other than tobacco) that:

Is intended to supplement the diet that contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients;

Is intended for ingestion in pill, capsule, tablet, or liquid form;

Is not represented for use as a conventional food or as the sole item of a meal or diet; and

Is labeled as a "dietary supplement."

"Dispensing pharmacist" means a pharmacist who, in the process of dispensing a prescription medication after the complete preparation of the prescription medication and before delivery of the prescription medication to a patient or patient's agent, verifies, checks, and initials the prescription medication label, as required in R4-23-402(A).

"Drug sample" No change

"Drug therapy management" No change

"Drug therapy management agreement" No change

"Extreme emergency" No change

"FDA" No change

"Immediate notice" No change

"Inactive ingredient" No change

"Internal test assessment" No change

"Limited-service correctional pharmacy" No change

"Limited-service mail-order pharmacy" No change

"Limited-service nuclear pharmacy" No change

"Long-term care consultant pharmacist" No change

"Lot" No change

"Lot number" or "control number" No change

"Materials approval unit" No change

"Mediated instruction" No change

"MPJE" No change

"NABP" No change

"NABPLEX" No change

"NAPLEX" No change

"Other designated personnel" No change

"Outpatient" No change

"Outpatient setting" No change

"Patient profile" No change

"Pharmaceutical care" No change

"Pharmacy law continuing education" No change
"Pharmacy technician" No change
"Prepackaged drug" No change
"Provider pharmacist" No change
"Radiopharmaceutical" No change
"Radiopharmaceutical quality assurance" No change
"Radiopharmaceutical services" No change
"Red C stamp" No change
"Remote drug storage area" No change
"Resident" No change
"Responsible person" No change
"Score transfer" No change
"Sight-readable" No change
"Single-drug audit" No change
"Single-drug usage report" No change
"Sterile pharmaceutical product" No change
"Strength" No change
"Supervision" No change
"Supervisory physician" No change
"Supplying" No change
"Support personnel" No change
"Transfill" No change
"Wholesale distribution" No change
"Wholesale distributor" No change

ARTICLE 5. DRUG CLASSIFICATION

R4-23-501. ~~Vitamins and Other Substances~~ Dietary Supplements

~~Classification of vitamin products.~~

~~1.~~ ~~Any vitamin product which is marketed only for the purpose of supplementing the diet is a non-drug product if the following requirements are met:~~
   ~~a.~~ ~~The label supplies adequate information as to the normal intake of each vitamin contained in the product;~~
   ~~b.~~ ~~The label supplies adequate information as to the amount of each vitamin contained in the product;~~ and
   ~~c.~~ ~~The product is not held out for the treatment or prevention of any disease but merely as a food accessory.~~

~~2.~~ ~~Any vitamin preparation which~~ A person who sells, distributes, or provides a product that is labeled as a dietary supplement and is ~~held out~~ labeled or marketed ~~to be~~ as a treatment for any deficiency disease, ~~or~~ for the correction of any symptom of disease, or for the prevention, mitigation, or cure of any disease, either by direct statement or by inference, is selling, distributing, or providing a drug and is subject to the requirements of A.R.S. Title 32, Chapter 18 and 4 A.A.C. 23.

R4-23-502. Veterinary

Veterinary preparation~~.~~. ~~Veterinary preparations distributed by manufacturers of veterinary supplies which do not contain the caution label shall be classified as patent or proprietary medicines and thus may be distributed by any person or firm licensed in this category in addition to being distributed by licensed pharmacies~~ A veterinary drug manufacturer or supplier may distribute:

1. A prescription-only veterinary drug to:
   a. A veterinary medical practitioner licensed under A.R.S. Title 32, Chapter 21,
   b. A full-service drug wholesaler permitted under A.R.S. Title 32, Chapter 18, or
   c. A pharmacy permitted under A.R.S. Title 32, Chapter 18, and
2. A nonprescription veterinary drug to:
   a. A veterinary medical practitioner licensed under A.R.S. Title 32, Chapter 21,
   b. A nonprescription drug retailer permitted under A.R.S. Title 32, Chapter 18,
   c. A full-service or nonprescription drug wholesaler permitted under A.R.S. Title 32, Chapter 18, or
   d. A pharmacy permitted under A.R.S. Title 32, Chapter 18.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R4-23-110	Amend
R4-23-651	Amend
R4-23-652	Amend
R4-23-653	Amend
R4-23-654	Amend
R4-23-655	Amend
R4-23-656	Amend
R4-23-657	Amend
R4-23-658	Amend
R4-23-659	Repeal
R4-23-659	New Section
R4-23-660	Repeal
R4-23-660	New Section
R4-23-661	Repeal
R4-23-662	Repeal
R4-23-663	Repeal
R4-23-664	Repeal

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 32-1904(A)(1) and (2) and 32-1904(B)(3) and (5)

Implementing statutes: A.R.S. §§ 32-1929, 32-1930, 32-1931, and 32-1934

3. The effective date of the rules:

January 5, 2003

4. A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening: 8 A.A.R. 2640, June 21, 2002

Notice of Proposed Rulemaking: 8 A.A.R. 2604, June 21, 2002

5. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy
4425 W. Olive, Suite 140
Glendale, AZ 85302

Telephone: (623) 463-2727, ext. 131

Fax: (623) 934-0583

E-mail: rxcop@msn.com

6. An explanation of the rule, including the agency's reasons for initiating the rule:

During the five-year rule review on September 9, 1997, the Board determined that the hospital pharmacy rules in R4-23-651 through R4-23-664 should be amended, including format, style, and grammar changes necessary to comply with the current Administrative Procedure Act and to provide a clear, concise, and understandable document. At the March 7, 2001 Board meeting, Board president Jerry Ritt appointed a subcommittee, chaired by Board member Bill Jones, to review the hospital pharmacy rules. The committee included five actively-practicing hospital pharmacists, Bill Jones, Linda McCoy, Larry Anderson, Larry Borggren, Michael Noel, the Board's Executive Director Llyn Lloyd, and Board Compliance Officer Dean Wright. The hospital rules were last updated in February 1990. The subcommittee was tasked to bring Arizona's hospital pharmacy rule language and concepts into the 21st Century. The subcommittee completed its task and presented the first draft proposed hospital pharmacy rules to the Board on November 15, 2001.

The proposed rules amend the definition of "certified pharmacy technician" in R4-23-110 by adding language specific to hospital pharmacy. The proposed rules amend R4-23-651 through R4-23-660 and repeal R4-23-661 through

R4-23-664. Language deemed necessary from the repealed Sections is incorporated into the amended Sections, where appropriate. The headings of R4-23-652, R4-23-653, R4-23-656, R4-23-659, and R4-23-660 are amended to reflect the amended content. R4-23-653 is amended to mandate the use of certified pharmacy technicians in all hospitals, including a one-year grace period for non-certified pharmacy technicians to become certified. The minimum number of hours of pharmacy services provided by a hospital is changed to 40 hours per week for all hospitals, except by specific permission of the Board. Previous rule allowed hospitals with one to 25 beds to provide a minimum of five hours per week of pharmacy services and 26 to 49 beds to provide a minimum of 20 hours per week of pharmacy services with the specific permission of the Board. The hospital pharmacy policy and procedure requirements are updated, and the technician policy and procedure requirements are expanded. In R4-23-654, the term "remote drug storage area" is used instead of "night cabinet." In R4-23-655, the minimum area of a hospital pharmacy is amended from 220 square feet to 500 square feet for any hospital pharmacy permit issued or hospital pharmacy remodeled after January 31, 2003. R4-23-656 through R4-23-660 are amended to reflect current practice standards regarding sanitation, equipment, security, drug distribution and control, drug administration, and investigational drug procedures.

The Board believes that approval of these rules will benefit the public health and safety by establishing clear and current standards governing hospital pharmacy practice.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

Not applicable

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

The proposed rules will impact the Board, pharmacists, technicians, and pharmacies. Most of the changes to the rule have no economic impact, but rather provide more clear, concise, and understandable language. The proposed rules include three changes that have possible economic impact on pharmacy technicians and hospital pharmacies, the requirement that all hospital pharmacy technicians have a certification recognized by the Board, the increase in the minimum number of pharmacy service hours, and the increase of the minimum hospital pharmacy area to 500 square feet which is not retroactive but applies only to newly established or remodeled pharmacies.

The public, Board, pharmacists, technicians, and pharmacies benefit from rules that are clear, concise, understandable, and reflect current practice standards. A rule that reflects current practice standards is easier to enforce because there are fewer gray areas that require subjective interpretation by compliance staff. The proposed rules will not have an economic impact on the Board office.

The proposed rules will have no economic impact on pharmacists.

The proposed rules will economically impact hospital pharmacy technicians who are not already certified. The rule provides a one-year grace period in which a non-certified pharmacy technician may become certified. The minimum cost of certification is the $120 fee to take the Board-recognized Pharmacy Technician Certification Board examination. Three books to help a pharmacy technician prepare for the examination through self-study are available for $85. The Arizona Pharmacy Association provides a class to help pharmacy technicians prepare for the examination. The cost of the class is $250 which includes a quick-study guide or $300 which includes the quick-study guide and two other study books. The maximum cost of certification would be $420. Many of the pharmacies that employ pharmacy technicians are reimbursing the pharmacy technician for the cost of certification after the pharmacy technician passes the certification examination. The majority of Arizona hospital pharmacies already use a large number of certified pharmacy technicians and have been encouraging technician certification through various methods. Certified pharmacy technicians benefit from a national certification that is portable throughout the country and an increase in salary. We estimate that this may affect from 125 to 250 pharmacy technicians who are not now certified.

The rules change the required number of hours per week that a hospital pharmacy shall provide pharmacy services from a graduated scale based on the number of hospital beds to a flat minimum of 40 hours per week. The Board estimates that only ten to eighteen hospital pharmacies will be affected by the change in the required minimum number of pharmacy service hours. The rules allow a hospital pharmacy to request a waiver from the minimum hours requirement. Any hospital that does not choose to increase pharmacy service hours should send a written letter to the Board requesting that the matter be placed on the next Board meeting agenda for approval by the Board. The Board does not see this as an issue, and those hospitals that have been operating on reduced hours without complaints or adverse effects to patients will receive quick approval to continue using reduced pharmacy service hours.

The proposed increase in the minimum hospital pharmacy area may affect small and medium size hospitals. The proposed rules allow the Board to grant a variation to the minimum area requirement for out-of-the-ordinary conditions. The proposed minimum area requirement only affects new or remodeled hospital pharmacy permits issued after January 31, 2003. An existing hospital pharmacy with less than the proposed minimum pharmacy area is only affected by the increased minimum area requirement if the pharmacy is remodeled or changes ownership. When a remodel of

the hospital pharmacy is desired, the hospital may request a variation from the minimum area requirements by showing out-of-the-ordinary conditions. The cost to increase a hospital pharmacy area from 220 square feet to 500 square feet could be several thousand dollars. The Board does not believe an Arizona hospital pharmacy will be forced to increase the minimum pharmacy area solely because of this rule. The pharmacy area of the majority of Arizona hospital pharmacies already exceed 500 square feet.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

At the request of G.R.R.C. staff, the Board made necessary punctuation, grammar, style, and format changes to produce a clear, concise, and understandable document. R4-23-660 is changed with the addition of language that requires specific clinical information on an investigational drug and the proper storage, labeling, and dispensing of an investigational drug in the pharmacy. The definition for "dietary supplement" is added to R4-23-110 as an existing definition because a rule package containing "dietary supplement" as a new definition was on the G.R.R.C. agenda for approval immediately before this rule package.

11. A summary of the comments made regarding the rules and the agency response to them:

The Board received a written comment from a hospital pharmacist who expressed concern with the repeal of requirements for investigational drugs in R4-23-660 and R4-23-663. The commentor feels that the suggested change reduces pharmacy involvement and patient safety by limiting the pharmacy role to ensuring only that the medication is not dispensed until it is approved by a physician committee. The commentor states that the change takes out the specific requirement that an investigational drug is stored in the pharmacy. The commentor states that physicians have tried to bypass pharmacy and take an investigational drug directly to the patient. The commentor believes a reduction in pharmacy involvement will lead to patient harm from an investigational drug. The commentor is also concerned that the rule change removes the requirement that the pharmacy receives specific clinical information on an investigational drug. A pharmacist needs as much clinical information as possible to fully review a patient's drug profile for safety, including drug interactions and adverse reactions. The commentor also asked about the pharmacist's role in disaster preparedness.

The Board staff responded and explained to the commentor that investigational drugs are addressed in R4-23-658(B), which states that, "the Director of Pharmacy is responsible for the safe and efficient procurement, dispensing, distribution, administration, and control of drugs, including the following: 2. Proper handling, distribution, and recordkeeping of investigational drugs." The commentor was informed that the Board is looking at the role of pharmacists in disaster preparedness, but that issue will be addressed in another rule. The Board made changes to R4-23-660 based on the written comment by adding additional language that requires specific clinical information on an investigational drug and the proper storage, labeling, and dispensing of an investigational drug in the pharmacy.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None

13. Incorporations by reference and their location in the rules:

None

14. Was this rule previously approved as an emergency rule?

No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section
R4-23-651. Definitions
R4-23-652. ~~Application/Registration~~ Hospital Pharmacy Permit
R4-23-653. Personnel: Professional~~, Supportive~~ or Technician
R4-23-654. Absence of Pharmacist
R4-23-655. Physical ~~Requirements~~ Facility
R4-23-656. ~~Other Standards~~ Sanitation and Equipment
R4-23-657. Security
R4-23-658. Drug Distribution and Control

R4-23-659. ~~Non-distributive Roles of the Pharmacist~~ Administration of Drugs
R4-23-660. ~~Administration of Drugs~~ Investigational Drugs
R4-23-661. ~~Drugs from Outside Sources~~ Repealed
R4-23-662. ~~Quality Assurance~~ Repealed
R4-23-663. ~~Investigational Drugs~~ Repealed
R4-23-664. ~~Inspections~~ Repealed

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 4 A.A.C. 23:

"Active ingredient" No change

"Alternate physician" No change

"Approved course in pharmacy law" No change

"Approved Provider" No change

"Authentication of product history" No change

"AZPLEX" No change

"Batch" No change

"Beyond-use date" No change

"Biological safety cabinet" No change

"Certified pharmacy technician" means:

~~an~~ An individual who receives a passing grade on a certification examination for pharmacy technicians recognized by the Arizona State Board of Pharmacy and meets the requirements of a pharmacy technician as defined in A.A.C. R4-23-110; or

An individual employed in a hospital pharmacy who meets the requirements in R4-23-653(F)(1) and performs, under the supervision of a pharmacist, activities related to the preparation, dispensing, or distribution of prescription medication consistent with the policies and procedures required in R4-23-653(G).

"Class 100 environment" No change

"Community pharmacy" No change

"Component" No change

"Computer system" No change

"Computer system audit" No change

"Container" No change

"Continuing education" No change

"Continuing education activity" No change

"Continuing education unit" or "CEU" No change

"Contact hour" No change

"Correctional facility" No change

"CRT" No change

"Current good compounding practices" No change

"Current good manufacturing practice" No change

"Cytotoxic" No change

"Day" No change

"DEA" No change

"Delinquent license" No change

"Dietary supplement" No change

"Dispensing pharmacist" No change

"Drug sample" No change

"Drug therapy management" No change

"Drug therapy management agreement" No change

"Extreme emergency" No change

"FDA" No change
"Immediate notice" No change
"Inactive ingredient" No change
"Internal test assessment" No change
"Limited-service correctional pharmacy" No change
"Limited-service mail-order pharmacy" No change
"Limited-service nuclear pharmacy" No change
"Long-term care consultant pharmacist" No change
"Lot" No change
"Lot number" or "control number" No change
"Materials approval unit" No change
"Mediated instruction" No change
"MPJE" No change
"NABP" No change
"NABPLEX" No change
"NAPLEX" No change
"Other designated personnel" No change
"Outpatient" No change
"Outpatient setting" No change
"Patient profile" No change
"Pharmaceutical care" No change
"Pharmacy law continuing education" No change
"Pharmacy technician" No change
"Prepackaged drug" No change
"Provider pharmacist" No change
"Radiopharmaceutical" No change
"Radiopharmaceutical quality assurance" No change
"Radiopharmaceutical services" No change
"Red C stamp" No change
"Remote drug storage area" No change
"Resident" No change
"Responsible person" No change
"Score transfer" No change
"Sight-readable" No change
"Single-drug audit" No change
"Single-drug usage report" No change
"Sterile pharmaceutical product" No change
"Strength" No change
"Supervision" No change
"Supervisory physician" No change
"Supplying" No change
"Support personnel" No change
"Transfill" No change
"Wholesale distribution" No change
"Wholesale distributor" No change

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-651. Definitions

The following definitions apply to R4-23-651 through R4-23-659:

"Administration" means the giving of a ~~unit~~ dose of medication to a patient as a result of an order of a medical practitioner.

"Direct copy" means an electronic, facsimile or carbonized copy.

"Dispensing for hospital inpatients" means the ~~issuing to authorized hospital personnel of one or more doses of medication in a suitable container with appropriate label for subsequent administration to, or use by, an inpatient~~ interpreting, evaluating, and implementing a medication order including preparing for delivery a drug or device to an inpatient or inpatient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, an inpatient (~~hereinafter~~ hereafter referred to as "dispensing").

"Drug distribution" means the delivery of drugs other than "administering" or "dispensing.".~~.~~

"Emergency medical situation" means a condition of emergency in which immediate drug therapy is required for the preservation of health, life, or limb of a person or persons.

"Floor stock" means a ~~minimum~~ supply of essential drugs not labeled for a specific patient ~~which is~~ and maintained and controlled by the pharmacy at a patient care area for the purpose of timely administration to a patient of the hospital.

"Formulary" means a continually revised compilation of pharmaceuticals (~~plus important~~ including ancillary information) that reflects the current clinical judgment of the medical staff.

"Hospital pharmacy" means a pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board pursuant to A.R.S. § 32-1931, and is located in a hospital as defined in A.R.S. § 32-1901.

"Inpatient" means ~~a~~ any patient who ~~is registered as such~~ receives non-self-administered drugs from a hospital pharmacy for use while within a facility owned by the hospital.

"Intravenous admixture" means a sterile parenteral solution to which one or more additional drug products have been added ~~in the hospital~~.

"Medication order" means a written, electronic, or verbal order from a medical practitioner or ~~his~~ a medical practitioner's authorized agent for administration of a drug or device.

"On-call" means ~~to be~~ a pharmacist is available ~~for anything about, or for dispensing of, medications~~ to:

Consult or provide drug information regarding drug therapy or related issues; or

Dispense a medication order and review a patient's medication order for pharmaceutical and therapeutic feasibility under R4-23-653(E)(2) before any drug is administered to a patient, except as specified in R4-23-653(E)(1).

"Patient care area" means any area ~~whose~~ for the primary purpose ~~is to provide~~ of providing a physical environment~~,~~ that is owned by or operated in conjunction with a hospital, for ~~patients~~ a patient to obtain health care services, except those ~~places~~ areas where ~~physicians, dentists, veterinarians, osteopaths~~ a physician, dentist, veterinarian, osteopath, or other medical ~~practitioners engage~~ practitioner engages primarily in private practice.

"Repackaged drug" means a drug product ~~which~~ that is transferred by pharmacy personnel from an original manufacturer's container to another container properly labeled for subsequent dispensing.

"Satellite pharmacy" means a work area in a hospital setting under the direction of a pharmacist that is a remote extension of ~~the~~ a centrally licensed hospital pharmacy ~~but within the same facility~~ and owned by and dependent upon the centrally licensed hospital pharmacy for administrative control, staffing, and drug procurement.

"Single unit" means a package of medication ~~which~~ that contains one discrete pharmaceutical dosage form.

"Supervision" means the process by which a pharmacist ~~observes and~~ directs the activities of ~~a~~ hospital pharmacy ~~intern, technician or clerk~~ personnel to a sufficient degree to ensure that all ~~such~~ activities are performed accurately, safely, and without risk of harm to patients.

~~"Unit dose" means a package of medication which contains the particular dose of a drug ordered for the patient. A single unit package is a unit dose package if it contains that particular dose of drug ordered for the patient.~~

R4-23-652. ~~Application/Registration~~ Hospital Pharmacy Permit

A. The following rules are applicable to all ~~Hospitals~~ hospitals as defined by A.R.S. § 32-1901 and ~~Hospital Pharmacies~~ hospital pharmacies as defined by R4-23-651 ~~hereinabove~~.

B. ~~All hospital pharmacies shall obtain a pharmacy permit for which a biennial fee set by the Board shall be required and shall be collected in accordance with the provisions of A.R.S. § 32-1931. Renewals shall not be granted for a period of less than 24 months. Fees are not refunded under any circumstances.~~ Before opening a hospital pharmacy, a person shall obtain a pharmacy permit as specified in R4-23-602 and R4-23-606.

C. Discontinued hospitals.~~:Whenever~~ If a hospital license is discontinued by the state Department of Health Services, the pharmacy ~~permit shall be returned to the Board of Pharmacy for cancellation and all drug signs removed from the premises. The drugs shall be adequately secured until legally disposed of. In addition, records and reports shall be furnished concerning drugs and prescription orders if required by the Board~~ permittee or pharmacist-in-charge shall follow the procedures described in R4-23-613 for discontinuing a pharmacy.

R4-23-653. Personnel: Professional~~, Supportive~~ or Technician

A. Each hospital pharmacy shall be directed by a pharmacist~~, hereinafter~~ who is licensed to engage in the practice of pharmacy in Arizona and is referred to as the Director of Pharmacy~~, who is licensed to engage in the practice of pharmacy in Arizona, and who is knowledgeable in and thoroughly familiar with the specialized functions of hospital pharmacies, as a result of satisfactory completion of a hospital pharmacy residency program or as a result of no less than two years experience in a hospital pharmacy~~. ~~The Director of a hospital pharmacy shall be a full-time employee of the hospital facility in which the pharmacy is located, except that the Director may be a part-time employee and may be exempt from the education and experience requirements above upon written request by the hospital and with express permission of the Board~~.

~~1.~~ The Director of Pharmacy shall be the pharmacist-in-charge, as defined in A.R.S. § 32-1901 or shall appoint a pharmacist-in-charge.

~~2.~~ The Director of Pharmacy and the pharmacist-in-charge, if a different individual, shall be responsible for all the activities of the hospital pharmacy and for meeting the requirements of the Arizona Pharmacy Act and these rules.

~~3. Contractual providers of pharmacy services shall meet the same requirements as for the Director of Pharmacy.~~

B. ~~Hospitals with 50 or more beds.~~ In all hospitals ~~with 50 beds or more~~, a pharmacist shall be in the hospital during the time the pharmacy is open for pharmacy services, except ~~in case of emergencies~~ for an extreme emergency as defined in R4-23-110. Pharmacy services shall be provided for a minimum ~~or~~ of 40 hours per week, unless an exception for less than the minimum hours is made upon written request by the hospital and with express permission of the Board or its designee.

C. ~~Hospital with less than 50 beds. In hospitals with less than 50 beds, a pharmacist shall be in the hospital during the time the pharmacy is open for pharmacy services. Upon written request by the hospital and with the express permission of the Board, the services of a pharmacist shall be required on a part-time basis, according to the needs of the hospital. The services of a pharmacist shall be required as follows: 1-25 beds - minimum of 5 hours per week 26-49 beds - minimum of 20 hours per week~~ In a hospital where the pharmacy is not open 24 hours per day for pharmacy services, a pharmacist shall be "on-call" as defined in R4-23-651 when the pharmacy is closed.

D. ~~Other personnel.~~ The Director of Pharmacy may be assisted by other personnel approved by the Director of Pharmacy in order to operate the pharmacy competently, safely, and adequately to meet the needs of the hospital's patients ~~of the hospital~~.

~~1.~~**E.** Pharmacists. ~~Pharmacists shall assist the Director of Pharmacy in meeting the responsibilities for all the activities of the hospital pharmacy and for meeting the requirements of the Arizona Pharmacy Act and these rules. The following professional practices shall be performed only by a~~ A pharmacist or a pharmacy intern or graduate intern under the supervision of a pharmacist shall perform the following professional practices:

~~a.~~1. ~~Receipt and transaction of all verbal medication orders other than refill approval by the prescriber.~~ Verify a patient's medication order before administration of a drug to the patient, except:

a. In an emergency medical situation; or

b. In a hospital where the pharmacy is open less than 24 hours a day for pharmacy services, a pharmacist shall verify a patient's medication order within four hours of the time the pharmacy opens for pharmacy services;

~~b.~~2. ~~Verification of the legal,~~ Verify a medication order's pharmaceutical and therapeutic feasibility ~~of dispensing, including an assessment of patient~~ based upon:

a. The patient's medical condition,

b. The patient's allergies,

c. The pharmaceutical and therapeutic incompatibilities, ~~unusual quantities of dangerous drugs and controlled substances and frequency of refills.~~ and

d. The recommended dosage limits;

~~c. Verification that the dosage is in proper limits.~~

~~d. Interpretation and evaluation of the medication order.~~

~~c.~~3. ~~Compounding, admixing, combining, measuring, counting~~ Compound, admix, combine, measure, count, or otherwise ~~preparing~~ prepare and ~~packaging~~ package the ~~medication~~ drug needed for dispensing, except ~~in accordance with~~ a certified pharmacy technician may compound, admix, combine, measure, count, or otherwise prepare and package the drug needed for dispensing under the supervision of a pharmacist according to written policies and procedures approved by the Board or its designee;

4. ~~, for pharmacy technicians, whereby~~ Verify the accuracy, correct procedure, ~~and preparation~~ compounding, admixing, combining, measuring, counting, preparing, packaging, and safety of ~~pharmaceutical constituents can be verified by the pharmacist.~~ a drug prepared and packaged by a certified pharmacy technician according to subsections (E)(3) and (G);

~~f.~~5. ~~Supervising the~~ Supervise drug repackaging ~~of drugs~~ and ~~checking~~ check the completed ~~repackaging procedure and~~ repackaged product as specified in R4-23-402(A)~~.~~;

~~g.~~6. ~~Training~~ Supervise training and ~~educating~~ education in aseptic technique and drug incompatibilities for all personnel involved in the admixture of parenteral products within the hospital pharmacy~~. When any part of these processes is not under direct pharmacist supervision, the pharmacist shall have the responsibility for providing and approving written guidelines and procedures to assure that all pharmaceutical requirements are met.~~;

~~h.~~7. ~~Consultation~~ Consult with the ~~prescriber~~ medical practitioner regarding the patient's drug therapy or medical condition~~.~~;

~~i.~~8. ~~Consultation~~ When requested by a medical practitioner, patient, patient's agent, or when the pharmacist deems it necessary, provide consultation with ~~the~~ a patient regarding the medication order, patient's profile, ~~and/~~or overall drug therapy~~, both prior to and after the medication is delivered to the patient or patient's agent.~~;

~~j. Interpretation of data in the patient's medication profile and/or medical record.~~

~~k.~~9. ~~Determination of the factors necessary for the pharmacist monitoring and evaluating the patient's therapeutic response.~~ Monitor a patient's drug therapy for safety and effectiveness;

~~l.~~10.~~Provision of~~ Provide drug information to patients and health care professionals~~.~~;

~~m.~~11.~~Overseeing all of~~ Manage the activities of certified pharmacy technicians~~, clerks, and~~ other personnel, and systems to ~~insure~~ ensure that all ~~such~~ activities are performed accurately, safely, and without risk of harm to patients~~.~~;

~~n.~~12.~~Final checking and responsibility for~~ Verify the accuracy of all aspects of the original, completed medication order ~~including but not limited to the accuracy of drug, strength, labeling and appropriate container.~~; and

~~o.~~13.~~Compliance~~ Ensure compliance by pharmacy personnel with a quality assurance program developed by the ~~pharmacist in charge~~ hospital.

~~2.~~**F.** ~~Pharmacy~~ Certified pharmacy technicians.

~~a.~~1. ~~Pharmacy technicians shall not perform duties which may be performed only by a pharmacist.~~ Before working as a certified pharmacy technician, an individual shall:

a. Be at least 18 years of age;

b. Have a high school diploma or equivalent;

c. Have a current pharmacy technician certificate recognized by the Arizona State Board of Pharmacy;

d. Complete a training program, as specified in subsection (H), at the pharmacy of employment;

e. Read and discuss with the pharmacist-in-charge of the pharmacy where employed, the Board rules concerning certified pharmacy technicians, the certified pharmacy technician job description, and the policy and procedure manual of that pharmacy; and

f. Date and sign a statement affirming understanding of the Board rules for certified pharmacy technicians, the job description, and the policy and procedure manual.

~~b.~~2. ~~Pharmacy technicians,~~ Acting in compliance with all applicable statutes and rules and under the supervision of a pharmacist, a certified pharmacy technician may assist a pharmacist in ~~all~~ activities not defined as professional practices as outlined in ~~Section~~ R4-23-653(~~D~~E)~~(1) above~~.

~~c.~~3. ~~Pharmacy technicians must be 18 years or older and have a high school diploma or equivalent.~~ Subsection (F)(1) does not prevent additional off-site training of a certified pharmacy technician. Any currently employed hospital pharmacy technician who does not meet the requirement in subsection (F)(1)(c) before the effective date of this rule shall complete the requirement in subsection (F)(1)(c) within one year from the effective date of this rule.

~~d.~~**G.** ~~Pharmacy technicians shall complete a training program at the pharmacy of employment. The training program shall be developed by the pharmacist-in-charge and shall be based on the needs of the individual pharmacy. The training program shall include written guidelines that define the specific tasks the technician shall be expected to perform and how the technician's competency is to be assessed. A copy of the training guidelines shall be kept in the pharmacy at all times. The pharmacist-in-charge shall certify that the technician has successfully completed the training program. Pharmacy technicians may perform only those tasks for which they have been trained and in which competency has been demonstrated.~~ Technician policies and procedures. Before employing a certified pharmacy technician, a Director of Pharmacy or pharmacist-in-charge shall:

1. Develop policies and procedures that specify:
   a. The activities a certified pharmacy technician may perform, and
   b. The quality assurance methods used to ensure the accuracy and safety of a certified pharmacy technician's activities,
2. Implement the policies and procedures,
3. Review and revise the policies and procedures biennially,
4. Document the review and revision process,
5. Assemble the policies and procedures as a written manual or by another method approved by the Board or its designee, and
6. Make the policies and procedures available within the hospital pharmacy for reference by a certified pharmacy technician and inspection by the Board or its designee.

c.**H.** ~~Pharmacy technicians may prepare parenteral products in accordance with written policies and procedures, whereby the preparation, accuracy and safety of the final product is verified by the pharmacist prior to dispensing or administration to the patient.~~ Certified pharmacy technician training program.

1. A Director of Pharmacy or pharmacist-in-charge shall:
   a. Develop a training program for certified pharmacy technicians based on the needs of the hospital pharmacy;
   b. Implement the certified pharmacy technician training program;
   c. Include written training guidelines that:
      i. Define the specific tasks the certified pharmacy technician may perform;
      ii. Specify how the certified pharmacy technician's competency will be assessed; and
      iii. Provide a copy of the training program and guidelines in the hospital pharmacy for reference by a certified pharmacy technician and inspection by the Board or its designee; and
   d. Attest that a certified pharmacy technician successfully completes the training program.
2. A certified pharmacy technician shall:
   a. Perform only those tasks for which training and competency has been demonstrated; and
   b. Not perform professional practices reserved for a pharmacist, graduate intern, or pharmacy intern in subsection (E), except as specified in subsection (E)(3).
   ~~f. The pharmacist in charge shall implement written policies and procedures to specify the duties to be performed by pharmacy technicians in that pharmacy, and the quality assurance procedures to be used to assure the accuracy and safety of the technician's activities.~~
   ~~g. Pharmacy technicians may perform the duties of a pharmacy clerk.~~
~~3. Pharmacy clerk~~
   ~~a. Pharmacy clerks may not perform the tasks of a pharmacist, pharmacy intern or pharmacy technician.~~
   ~~b. Pharmacy clerks, under the supervision of a pharmacist, may perform clerical duties associated with the practice of pharmacy including but not limited to typing, filing, refiling, bookkeeping, pricing, stocking, delivery, non-professional telephone inquires and documentation of third party reimbursement.~~
~~4. Secretarial personnel. Secretarial support may be provided as required to assist with record keeping, report submission and other administrative duties.~~

~~5.~~**I.** Supervision. ~~All~~ A hospital pharmacy's Director of Pharmacy and the pharmacist-in-charge, if a different individual, shall supervise all of the activities and operations of ~~the~~ a hospital pharmacy ~~shall be supervised by its Director or designee~~. ~~All~~ A pharmacist shall supervise all functions and activities of certified pharmacy technicians and other hospital pharmacy personnel ~~shall be supervised by pharmacists~~ to ~~insure~~ ensure that all ~~such~~ functions and activities are performed competently, safely, and without risk of harm to patients.

R4-23-654. Absence of Pharmacist

A. ~~Procedure in the absence of a pharmacist. During times that a pharmacist is not on duty in the hospital, arrangements shall be made in advance by the Director for provision of drugs to the medical staff and other authorized personnel of the hospital by use of night cabinets and in emergency circumstances, by access to the pharmacy.~~ If a pharmacist will not be on duty in the hospital, the Director of Pharmacy or pharmacist-in-charge shall arrange, before the pharmacist's absence, for the medical staff and other authorized personnel of the hospital to have access to drugs in the remote drug storage area defined in R4-23-110 or in the hospital pharmacy if a drug is not available in a remote drug storage area and is required to treat the immediate needs of a patient. A pharmacist shall be ~~"on call"~~ on-call during all absences.

B. If a pharmacist will not be on duty in the hospital pharmacy, the Director of Pharmacy or pharmacist-in-charge shall arrange, before the pharmacist's absence, for the medical staff and other authorized personnel of the hospital to have telephone access to an on-call pharmacist.

C. The hospital pharmacy permittee shall ensure that the hospital pharmacy is not without a pharmacist on duty in the hospital for more than 72 consecutive hours.

D. ~~1. Night cabinets. If night cabinets are used when the pharmacist is not on duty in the hospital, the locked cabinets or other enclosures shall be constructed and located outside the Pharmacy area, accessed only by specifically authorized personnel and securely locked to deny access to unauthorized persons by force or otherwise.~~ Remote drug storage area. The Director of Pharmacy or pharmacist-in-charge shall, in ~~conjunction~~ consultation with the appropriate committee of the hospital~~,~~:

1. ~~develop~~ Develop and maintain an inventory listing of ~~those~~ the drugs to be included in ~~such cabinets~~ a.remote drug storage area; and ~~shall insure~~
2. Develop and implement policies and procedures in the same manner described in R4-23-653(G) that~~:~~ ensure proper storage, access, and accountability for drugs in a remote drug storage area.
   ~~a. Such drugs are available therein, properly labeled;~~
   ~~b. Only drugs packaged in amounts sufficient for immediate therapeutic requirements are available therein;~~
   ~~c. Whenever access to such cabinet shall have been gained, written physician's orders and a record of withdrawal are provided;~~
   ~~d. All drugs therein are inventoried no less than once per week;~~
   ~~e. A complete audit of all activity concerning such cabinets is conducted no less than once per month; and~~

~~f. Written policies and procedures shall be established to implement the requirements of this subsection.~~

~~B.~~**E.** Access to ~~Pharmacy~~ hospital pharmacy. ~~Whenever any~~ If a drug is not available from ~~night cabinets~~ a remote drug storage area and ~~such~~ the drug is required to treat the immediate needs of a patient whose health may ~~otherwise~~ be compromised, ~~such~~ the drug may be obtained from the hospital pharmacy ~~in accordance with~~ according to the requirements of this subsection. ~~One supervisory nurse in any given shift is responsible for removing drugs therefrom. The responsible nurse may, in times of emergency, delegate this duty to another nurse. The responsible nurse shall be designated by position in writing by the appropriate committee of the hospital and shall, prior to being permitted to obtain access to the Pharmacy, receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required. Such education and training shall be given by the Director of Pharmacy.~~

1. The Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate committee of the hospital, develop and implement policies and procedures in the same manner described in R4-23-653(G) to ensure that access to the hospital pharmacy during the pharmacist's absence conforms to the following requirements:
   a. Access is delegated to only one supervisory nurse in each shift;
   b. The policy and name of supervisory nurse is communicated in writing to the medical staff of the hospital;
   c. Access is delegated only to a nurse who has received training from the Director of Pharmacy, pharmacist-in-charge, or Director's designee in the procedures required for proper access, drug removal, and recordkeeping; and
   d. Access is delegated by the supervisory nurse to another nurse only in an emergency.
2. If a nurse to whom authority is delegated to access the hospital pharmacy removes a drug from the hospital pharmacy, the nurse shall:
   a. Record the following information on a form or by another method approved by the Board or its designee:
      i. Patient's name,
      ii. Drug name, strength, and dosage form,
      iii. Quantity of drug removed, and
      iv. Date and time of removal;
   b. Sign or initial, if a corresponding signature is on file in the hospital pharmacy, the form recording the drug removal;
   c. Attach the original or a direct copy of the medication order for the drug to the form recording the drug removal; and
   d. Place the form recording the drug removal conspicuously in the hospital pharmacy.
3. Within four hours after a pharmacist's absence, a pharmacist shall verify all records of drug removal that occurred during the pharmacist's absence according to R4-23-653(E).

~~C. Record of drug removal. Removal of any drug from the night cabinet or the Pharmacy by an authorized nurse shall be recorded on a suitable form showing:~~

~~1. Patient's name;~~

~~2. Name of the drug, strength and dosage form;~~

~~3. Dose prescribed;~~

~~4. Amount removed;~~

~~5. Time and date of removal;~~

~~6. Signature of the authorized nurse removing the drug; and~~

~~7. The original or a direct copy of the medication order. The record of drug removal shall be placed conspicuously in the night cabinet or pharmacy and must be verified within four hours of the pharmacist returning to duty in the hospital or a maximum of 72 hours.~~

R4-23-655. Physical ~~Requirements~~ Facility

A. General. ~~Each~~ A hospital pharmacy permittee shall ensure that the hospital pharmacy has ~~have~~ sufficient equipment and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations.

B. Minimum area of hospital pharmacy. The minimum area of a hospital pharmacy ~~shall depend~~ depends on the type of hospital, the number of beds, and the pharmaceutical services ~~to be performed~~ provided. ~~The minimum floor space for any hospital pharmacy shall not be less than that required in Table 1. Plans for new construction shall be submitted to the Board for approval.~~

~~**Table 1**~~.

~~Bed Size of Hospital~~
~~Square Feet Per Bed for Pharmacy~~

	~~1 to 50 beds~~	~~51 to 100 beds~~	~~101 to 200 beds~~	~~201 to 500 beds~~	~~Over 500 beds~~
~~Dispensing~~	~~4.4~~	~~3.2~~	~~3.25~~	~~2.1~~	~~1.77~~
~~Storage~~	~~1.4~~	~~1.7~~	~~1.3~~	~~1.44~~	~~1.2~~
~~Preparations~~	~~0.6~~	~~1.85~~	~~1.0~~	~~0.6~~	~~0.6~~
~~Administrative~~		~~0.8~~	~~0.8~~	~~1.12~~	~~0.93~~
~~TOTAL SQUARE FEET PER BED~~	~~6.4*~~	~~7.55~~	~~6.35~~	~~5.26~~	~~4.5~~

~~*~~ Any hospital pharmacy permit issued or hospital pharmacy remodeled after January 31, 2003 shall provide a ~~The~~ minimum hospital pharmacy area ~~of any hospital pharmacy~~, the actual area primarily devoted to drug dispensing and preparation functions, exclusive of bulk drug storage, satellite pharmacy, and office areas ~~shall not be~~ that is not less than ~~220~~ 500 square feet. ~~Satellite pharmacy areas may be included in this minimum area upon the approval of the Board of Pharmacy. These are~~ The minimum area ~~requirements~~ requirement, not including ~~unutilizable~~ unusable area, ~~unless variations are approved~~ may be varied upon approval by the Board for out-of-the-ordinary conditions or for systems that require less space.

C. The Board may also require that a hospital pharmacy permittee or applicant provide:

1. More than the minimum area ~~in instances where~~ if equipment, inventory, personnel, or other factors cause crowding to ~~such~~ a degree ~~as to interfere~~ that interferes with safe pharmacy practice~~.~~;
2. ~~Storage and dispensing areas may be required to be enlarged~~ Additional dispensing, preparation, or storage areas because of the increased number of specific drugs prescribed per day, the increased use of intravenous and irrigating solutions, and the increased use of disposable and prepackaged products~~.~~;
3. Additional ~~service areas may be required~~ dispensing, preparation, or storage areas to handle investigational drugs, emergency drug kits, chemotherapeutics, alcohol and other flammables, poisons, external preparations, and radioisotopes, and to accommodate quality control procedures~~.~~; and
4. ~~More~~ Additional office space ~~may be required~~ to provide for an increased number of personnel, a drug information library, a poison information library, ~~for~~ research support, teaching and conferences, and a waiting area.

~~Conversely, the Board may approve a reduction in the size of the pharmacy for innovative systems that require less space.~~

~~**C.**~~**D.** ~~Description of hospital~~ Hospital pharmacy area. ~~All of the required space for a hospital pharmacy, including adequate shelving and cabinets, shall lend itself to efficient pharmaceutical practice. The~~ A hospital pharmacy permittee shall ~~be~~ ensure that the hospital pharmacy area is enclosed by a permanent barrier or partition from floor to ceiling with entry doors that can be securely locked, constructed ~~similarly~~ according to R4-23-609~~(G)~~(F)(1)~~, for community pharmacies~~.

~~**D.**~~**E.** Hospital pharmacy storage areas. ~~All drugs, shall be~~ The hospital pharmacy permittee, Director of Pharmacy, or pharmacist-in-charge shall ensure that all undispensed or undistributed drugs are stored in designated areas within the hospital pharmacy or other locked areas under the control of ~~the~~ a pharmacist ~~which~~ that ~~are sufficient to insure~~ ensure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security.

~~**E.** Storage of alcohol and flammables. Alcohol and flammables shall be stored in areas that shall, at a minimum, meet basic local fire and building code requirements for volatiles and such other laws, ordinances or regulations that may apply.~~

R4-23-656. ~~Other Standards~~ Sanitation and Equipment

~~**A.**~~ ~~The~~ A hospital pharmacy permittee or Director of Pharmacy shall ensure that a hospital pharmacy:

1. ~~shall have~~ Has a professional reference library consisting of ~~at least one reference/text from each of the following subject areas; pharmacology/toxicology, theoretical and practical pharmacy, therapeutics, sterilization and disinfection in intravenous admixtures practice, drug compatibility/interaction and other references~~ hard-copy or electronic media appropriate for the scope of pharmacy services provided by the ~~institution.~~ hospital;

~~**B.** The hospital pharmacy shall be arranged in an orderly fashion and shall be kept clean. All equipment shall be clean and in good condition.~~

~~**C.**~~2. ~~A~~ Has a sink, other than a sink in a toilet facility, that:

a. ~~With~~ Has hot and cold running water;

b. ~~shall be available to all pharmacy personnel and shall be~~ Is within the hospital pharmacy area for use in preparing drug products; and

c. Is maintained in a sanitary condition ~~at all times.~~ and in good repair;

~~**D.** The hospital pharmacy shall be properly lighted and ventilated.~~

~~**E.**~~3. ~~The temperature of the hospital pharmacy shall be maintained~~ Maintains a room temperature within a range compatible with the proper storage of drugs~~.~~;

4. ~~The temperature of the~~ Has a refrigerator and freezer ~~shall be~~ with a temperature maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing~~.~~; and

~~**F.** The hospital pharmacy shall have locked storage for Schedule II controlled substances and other controlled drugs requiring additional security.~~

~~**G.** The hospital pharmacy shall have~~ Has a designated area for ~~the~~ a laminar air flow hood and other supplies required for the preparation of sterile products as specified in R4-23-670. ~~This area shall include facilities for handwashing, be designed to minimize personnel traffic, have non-porous and cleanable surfaces, be ventilated to not interfere with air-flow of the laminar hood, and be cleaned and disinfected routinely.~~

~~**H.** The hospital pharmacy shall have a designated area for the storage of poisons and external preparations.~~

R4-23-657. Security

A. Personnel security standards. ~~No one~~ A Director of Pharmacy shall ~~be~~ ensure that:

1. No one is permitted in the pharmacy unless ~~the~~ a pharmacist is present except as provided in this ~~section~~ Section and R4-23-654. If ~~the~~ only one pharmacist is on duty in the pharmacy and that pharmacist must leave the pharmacy for an emergency or patient care duties, ~~pharmacy technicians~~ nonpharmacist personnel may remain in the pharmacy to perform duties as outlined in R4-23-653~~(D)(2)~~, provided that all C-II controlled ~~drugs~~ substances are secured ~~in such a manner as~~ to prohibit access by other than a pharmacist, and that the pharmacist remain available in the hospital~~.~~;

~~**B.**~~2. All hospital pharmacy areas ~~shall be capable of being~~ are kept locked by key or programmable lock~~, so as~~ to prevent access by unauthorized personnel~~.~~; and ~~The Director shall designate in writing, by title and specific area, those persons who shall have access to particular pharmacy areas.~~

~~**C.** Each pharmacist on duty shall be responsible for the security of the hospital pharmacy, including provisions for adequate safeguards against theft or diversion of drugs including controlled substances and the records thereof.~~

~~**D.**~~3. ~~Personnel identification.~~ Pharmacists, pharmacy or graduate interns, certified pharmacy technicians, and other personnel working in the pharmacy ~~shall~~ wear identification badges, including name and position, whenever on duty.

~~**E.**~~**B.** Prescription blank security. The Director of Pharmacy shall ~~be responsible for~~ develop and implement policies and procedures in the same manner described in R4-23-653(G) for the safe distribution and control of prescription blanks bearing identification of the hospital.

R4-23-658. Drug Distribution and Control

A. General. The Director of Pharmacy or pharmacist-in-charge shall:

1. ~~Establish~~ In consultation with the medical staff, develop and implement written policies and procedures for the effective operation of a drug distribution system ~~which~~ that ~~optimize~~ optimizes patient safety~~.~~;
2. ~~These~~ Make the policies and procedures ~~shall be~~ available in the pharmacy for reference by pharmacy employees and inspection by the Board or its designee~~.~~;
3. ~~These~~ Review and revise the policies and procedures ~~will be developed with the advice of the medical staff and shall be reviewed and revised at least~~ biennially~~.~~;
4. Document the review and revision process; and
5. ~~The written policies and procedures shall include, but not be limited to, the following:~~ Assemble the policies and procedures as a written manual or by another method approved by the Board or its designee.

~~1. Physicians orders~~
~~2. Authorized abbreviations~~
~~3. Formulary system~~
~~4. Procurement and distribution of inpatient medications~~
~~5. Controlled substances~~
~~6. Stop orders~~
~~7. Pass/Discharge medications~~
~~8. Adverse drug reaction reports~~
~~9. Drug recall~~
~~10. Outdated drugs~~
~~11. Medication error and dispensing error monitoring These policies and procedures shall be available in the pharmacy for inspection.~~

B. Responsibility. The Director of Pharmacy ~~shall be~~ is responsible for the safe and efficient procurement, dispensing, distribution, administration, and control of drugs~~. Other professional, technical and clerical staff may assist the Director in meeting this responsibility. The Director shall be responsible for, at a minimum~~, including the following:

~~1. Establishment of specifications for procurement of all materials, including drugs, chemicals and biologicals;~~

~~2.~~1. ~~Participation in the development of~~ In consultation with the appropriate department personnel and medical staff committee, develop a medication formulary for the hospital;

~~3. Compounding and repackaging of drugs;~~

~~4. Preparation and sterilization of parenteral medications within the hospital;~~

~~5. Admixture of parenteral products;~~

~~6. Filling and labeling all containers from which drugs are to be distributed, dispensed or administered;~~

~~7.~~2. Proper handling, distribution, and recordkeeping of investigational drugs; and

~~8. Dispensing and distribution of drugs to be administered to inpatients and outpatients;~~

~~9. Ensuring the availability of an effective and efficient means for transportation of medications and orders within the hospital;~~

~~10. Records of all transactions of the hospital pharmacy as may be necessary to maintain accurate control over and accountability for all pharmaceutical services;~~

~~11.~~3. ~~Inspection~~ Regular inspections of drug storage and preparation areas within the hospital~~;~~

~~12. Maintaining and making available a sufficient inventory of floor stock drugs, antidotes and other emergency drugs both in the pharmacy and in patient care areas;~~

~~13. Participation in those aspects of the hospital quality assurance program relevant to pharmaceutical services; and~~

~~14. Participation of pharmacy personnel in relevant training and education programs including orientation of new employees~~.

C. ~~Physicians~~ Physician orders. ~~Drugs shall be~~ A Director of Pharmacy or pharmacist-in-charge shall ensure that:

1. Drugs are dispensed from the hospital pharmacy only upon a written ~~orders~~ order, direct ~~copies~~ copy or ~~facsimiles thereof~~ facsimile of a written order, or verbal ~~orders~~ order of an authorized medical practitioner~~.~~; and
2. ~~The~~ A pharmacist ~~shall review~~ reviews the original, ~~order or~~ direct or facsimile copy, or verbal order before ~~the~~ an initial dose of medication is ~~dispensed~~ administered, except ~~in an emergency~~ as specified in R4-23-653(E)(1).

~~1. Authorization. The medical staff shall designate those medical practitioners who are authorized to prescribe medications for hospital patients.~~

~~2. Abbreviations. Orders employing abbreviations and chemical symbols shall be processed only if such abbreviations and symbols appear on a published approved list of accepted abbreviations for the hospital~~

~~3. Requirements - Orders for drugs for use by inpatients. Orders for drugs for use by inpatients at a minimum shall contain: patient name and location, drug name, dose, frequency, directions for use, date and medical practitioner's signature (or that of his authorized representative).~~

~~4. Requirements - Orders for drugs for self-administration by outpatients. Orders for drugs to be self-administrated by outpatients become prescriptions and shall meet all applicable requirements of the Arizona Pharmacy Act and these rules.~~

~~**D.** Formulary. Under the direction of the proper hospital committee, the pharmacist in charge shall be available for inspection by the Board or its designee a medication formulary that addresses such subjects as:~~

~~1. Information of hospital policies and procedures concerning drugs;~~

~~a. Categories of drugs,~~

~~b. Description of the hospital pharmacy and therapeutics committee,~~

~~c. Hospital regulations governing the prescribing, dispensing and administration of drugs,~~

~~d. Pharmacy operating procedures,~~

~~e. Information on using the formulary;~~

~~2. Drug products listing;~~

~~3. Formulary item entries;~~

~~4. Indexes to the drug products listing;~~

~~5. Special information;~~

~~**E.**~~**D.** Labeling. ~~All~~ A Director of Pharmacy or pharmacist-in-charge shall ensure that all drugs distributed or dispensed by a hospital pharmacy ~~shall be~~ are packaged in appropriate containers and labeled as follows:

1. For use inside the hospital;
   a. Labels for all single unit packages ~~shall~~ contain at a minimum, the following information:
      i. Drug name, strength, and dosage form;
      ii. Lot number and beyond-use-date ~~where applicable~~; and
      iii. Appropriate auxiliary labels~~.~~;
   b. Labels for repackaged ~~or compounded~~ preparations ~~shall~~ contain at a minimum the following information:
      ~~i. Identification of the hospital pharmacy;~~
      ~~ii.~~i. Drug name, ~~identification, or list of active ingredients~~ strength, and dosage form;

~~iii. Strength of drug or amount of active ingredients;~~
~~iv.~~ii. Lot number and beyond-use-date ~~where applicable~~;
~~v.~~iii. Appropriate auxiliary labels; and
~~vi.~~iv. Mechanism to identify pharmacist accountability for ~~preparation or packaging.~~ repackaging;

c. Labels for all intravenous admixture preparations ~~shall~~ contain at a minimum the following information:
   i. Patient's name and location;
   ii. Name and quantity of the basic parenteral ~~solutions~~ solution;
   iii. Name and amount of ~~drugs~~ drug added;
   iv. Date ~~and, if appropriate, time~~ of preparation;
   v. Beyond-use-date and time;
   vi. ~~Date, time and guidelines~~ Guidelines for administration;
   vii. ~~Ancillary labels~~ Appropriate auxiliary label or precautionary ~~statements as appropriate~~ statement; and
   viii. Initials of pharmacist responsible for admixture preparation~~.~~; and

2. For use outside the hospital~~.~~: ~~All drugs~~ Any drug dispensed to a patient by a hospital pharmacy ~~which are~~ that is intended for self-administration outside of the hospital ~~shall be~~ is labeled ~~with, at a minimum, the following information:~~ as specified in A.R.S. §§ 32-1963.01(C) and 32-1968(D) and R4-23-402.
   ~~a. Name, address and telephone number of hospital pharmacy;~~
   ~~b. Date and identifying serial number;~~
   ~~c. Full name of the patient;~~
   ~~d. Name of drug, strength and number of units;~~
   ~~e. Directions for use to the patient;~~
   ~~f. Name of prescribing physician;~~
   ~~g. Initials of pharmacist dispensing;~~
   ~~h. Required precautionary information regarding controlled substances;~~
   ~~i. Name of manufacturer or distributor of the dispensed generic equivalent drug or abbreviations of such information approved by the Board; and~~
   ~~j. Such other and further accessory cautionary information as may be required or desirable for proper use and safety to the patient.~~

~~F.~~ ~~Records. The Director shall maintain appropriate records which document the selection, repackaging, manufacturing, distribution, dispensing and quality assurance processes for drug products and physician medication orders. Such documentation shall be maintained as required by law or for a minimum of one year. All records and labeling shall be devised in such a manner that professional responsibility can be traced to a pharmacist.~~

~~G.~~**E.** Controlled substance accountability. ~~The hospital shall establish~~ A Director of Pharmacy or pharmacist-in-charge shall ensure that effective policies and procedures ~~and maintain adequate records~~ are developed and implemented in the same manner described in R4-23-653(G) regarding the use, ~~and~~ accountability, and recordkeeping of controlled substances~~. If controlled drugs are stored in patient care areas, there shall be~~ in the hospital, including the use of locked storage areas when controlled substances are stored in patient care areas.

~~H.~~ ~~Discontinued drugs. Discontinued or outdated drugs and containers or packages of drugs with worn, illegible or missing labels shall be returned to the pharmacy for proper and safe destruction in accordance with written policies and procedures.~~

~~I.~~**F.** Emergency ~~care center~~ services dispensing. If ~~the~~ a hospital permits dispensing of drugs from the ~~Emergency Care Center~~ emergency services department when the pharmacy is unable to provide ~~these services~~ this service, the Director of Pharmacy, in ~~conjunction~~ consultation with the appropriate department personnel and medical staff committee shall develop and ~~supervise~~ implement written policies and procedures ~~which shall be used~~ in the same manner described in R4-23-653(G) for dispensing drugs for outpatient use from ~~a hospital for outpatient use~~ the hospital's emergency services department. ~~Such~~ The policies and procedures shall include ~~but not be limited to~~ the following requirements:

1. ~~Drugs may~~ Drugs are only ~~be~~ dispensed to patients who have been admitted to the emergency ~~care center~~ services department;
2. ~~Drugs may~~ Drugs are only ~~be~~ dispensed by an authorized medical ~~practitioners~~ practitioner, not ~~their~~ a designee or agent;
3. The nature and type of drugs available for dispensing ~~shall be~~ are designed to meet the immediate needs of the patients treated within the hospital;
4. ~~Drugs shall~~ Drugs are only ~~be~~ dispensed in quantities sufficient to meet patient needs until ~~such time as~~ outpatient pharmacy services are available;
5. ~~Such drugs shall be~~ Drugs are prepackaged by a pharmacist in suitable containers and appropriately prelabeled with the drug name, strength, dosage form, quantity, manufacturer, lot number, beyond-use-date, and any ~~necessary~~ appropriate auxiliary labels~~.~~;
6. Upon dispensing, the authorized medical practitioner ~~shall complete~~ completes the label on the prescription container ~~which shall comply~~ that complies with the requirements of R4-23-658~~(E)~~(D)~~.~~; and

7. The hospital pharmacy maintains a dispensing log, hard-copy prescription, or electronic record, approved by the Board or its designee and includes the patient name and address, drug name, strength, dosage form, quantity, directions for use, medical practitioner's signature or identification code, and DEA registration number, if applicable.

R4-23-659. ~~Non-distributive Roles of the Pharmacist~~ Administration of Drugs

~~The non-distributive roles of the pharmacist may include, but are not limited to, chart review, audits, drug therapy monitoring, committee participation, drug information, in-service training of pharmacy and other health professionals, poison control and patient care area inspections.~~

A. Self-administration. A hospital shall not allow self-administration of medications by a patient unless the Director of Pharmacy or pharmacist-in-charge, in consultation with the appropriate department personnel and medical staff committee, develops and implements policies and procedures for self-administration of medications by a patient in the same manner described in R4-23-653(G). The policies and procedures shall specify that self-administration of medications, if allowed, occurs only when:

1. Specifically ordered by a medical practitioner; and
2. A patient is educated and trained in the proper manner of self-administration.

B. Drugs brought in by a patient. If a hospital allows a patient to bring a drug into the hospital and before a patient brings a drug into the hospital, the Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate department personnel and medical staff committee, develop and implement policies and procedures for a patient-owned drug brought into the hospital in the same manner described in R4-23-653(G). The policies and procedures shall specify the following criteria for a patient-owned drug brought into the hospital:

1. When policy allows the administration of a patient-owned drug, the drug is not administered to the patient unless:
   a. A pharmacist or medical practitioner identifies the drug; and
   b. A medical practitioner writes a medication order specifying administration of the identified patient-owned drug; and
2. If a patient-owned drug will not be used during the patient's hospitalization, the hospital pharmacy's personnel shall:
   a. Package, seal, and give the drug to the patient's agent for removal from the hospital; or
   b. Package, seal, and store the drug for return to the patient at the time of discharge from the hospital.

C. Drug samples. The Director of Pharmacy or pharmacist-in-charge is responsible for the receipt, storage, distribution, and accountability of drug samples within the hospital, including developing and implementing specific policies and procedures in the same manner described in R4-23-653(G) regarding drug samples.

R4-23-660. ~~Administration of Drugs~~ Investigational Drugs

~~**A.** General. Drugs shall be administered at a hospital only upon the order of authorized medical practitioners. Drugs shall be administered only by authorized hospital personnel in accordance with policies and procedures developed in accordance with R4-23-660(B).~~

~~**B.** Policies. The Director of Pharmacy shall develop in conjunction with the medical staff and other disciplines in the hospital written policies and procedures that govern the safe administration of drugs.~~

~~**C.** Record of Administration. Each dose of medication administered shall be recorded in the patient's medication record and shall show the date, time, dosage and method of administration and a method of identifying the person who administered drug. When initials are used, the name identification shall be noted on each medication record.~~

~~**D.** Self-administration. If permitted in the hospital, self-administration of medications by patients shall be allowed only when specifically ordered by the physician and provided that patients are educated and trained in the proper manner of self-administration. If self-administration is allowed, policies and procedures shall be developed.~~ The Director of Pharmacy or pharmacist-in-charge shall ensure that:

1. The following information concerning an investigational drug is available for use by hospital personnel:
   a. Composition,
   b. Pharmacology,
   c. Adverse reactions,
   d. Administration guidelines, and
   e. All other available information concerning the drug, and
2. An investigational drug is:
   a. Properly stored in, labeled, and dispensed from the pharmacy, and
   b. Not dispensed before the drug is approved by the appropriate medical staff committee of the hospital.

R4-23-661. ~~Drugs from Outside Sources~~ Repealed

~~**A.** Drugs brought in by patients. If patients are permitted to bring their own drugs into the hospital, these drugs shall not be administered unless they can be identified by the pharmacist or medical practitioner and until the medical practitioner's order is written to administer these specific drugs. If the drug brought in by the patient is not to be used during the patient's hospitalization, it shall be packaged and sealed and given to the patient's agent or stored and returned to the patient at the time of discharge.~~

~~**B.** Drug samples. Receipt, distribution and accountability of drug samples shall be under the direct control of the pharmacy department.~~

R4-23-662. ~~Quality Assurance~~ Repealed

~~**A.** General. The Director of Pharmacy shall be responsible for developing procedures for an ongoing Quality Assurance Program of pharmaceutical services that includes a mechanism for reviewing and evaluating dispensing, distribution, control and use of drugs in relation to patient care.~~

~~**B.** Sterile product preparation. The Director of Pharmacy shall be responsible for developing procedures for quality assurance in all areas where sterile product preparation takes place. Such procedures shall include the selection, education, training and evaluation of personnel, duties of personnel involved, handwashing technique, safe handling of antineoplastics, housekeeping of the intravenous admixture area, in-process controls and end-product verification. An annually certified laminar air flow hood is required for the preparation of sterile products by pharmacy personnel. Documentation of hood maintenance, including HEPA filter inspection, prefilter maintenance, disinfecting, and cleaning shall be kept in the pharmacy for a one-year period.~~

R4-23-663. ~~Investigational Drugs~~ Repealed

~~**A.** The pharmacist in charge shall obtain and make available to hospital personnel the following information concerning investigational drugs in use at the hospital:~~

~~1. Composition,~~
~~2. Pharmacology,~~
~~3. Adverse reactions,~~
~~4. Administration guidelines,~~
~~5. All other available information concerning the drug.~~

~~**B.** Investigational drugs shall be stored in the pharmacy and shall be properly labeled.~~

~~**C.** The pharmacist in charge shall not permit the dispensing of investigational drugs unless such drugs have been approved by the appropriate medical staff committee of the hospital.~~

R4-23-664. ~~Inspections~~ Repealed

~~Patient care area inspections. The pharmacist in charge or designee shall perform periodic inspections of all drug storage areas. These areas shall be well lighted and shall be located in a place where the nursing personnel are not interrupted when preparing drugs for administration to the patient. Records shall be maintained that verify compliance with current requirements as defined by the Board.~~

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 28. STATE REAL ESTATE DEPARTMENT

PREAMBLE

1. Sections Affected **Rulemaking Action**

R4-28-104 Amend

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 32-2107(E)

Implementing statutes: A.R.S. §§ 32-2124(E), (F), and (G), 32-2132, 32-2181.01, 32-2182, 32-2183, 32-2194.02, 32-2195.01, 32-2195.02, 32-2197.07, 32-2197.23, and 32-2198.10

3. The effective date of the rules:

January 5, 2003

4. A list of all previous notices appearing in the Register addressing this final rule:

Notice of Rulemaking Docket Opening: 8 A.A.R. 1976, April 26, 2002

Notice of Proposed Rulemaking: 8 A.A.R. 2887, July 12, 2002

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Cindy Wilkinson, Policy Officer

Address: Arizona Real Estate Department
2910 N. 44th Street, Suite 100
Phoenix, AZ 85018

Telephone: (602) 468-1414, ext. 120

Fax: (602) 468-0562

E-mail: cwilkinson@re.state.az.us

6. An explanation of the rule, including the agency's reasons for initiating the rule:

The Arizona Department of Real Estate (Department) is charged with protecting the public by licensure and regulation of real estate salespersons, brokers, and regulation of land development and sales, including timeshares, cemetery property, and membership campgrounds.

Candidates for licensure as a real estate, cemetery, or membership camping salesperson or broker must pass a state license exam required by A.R.S. § 32-2124(E), (F), and (G). Pursuant to R4-28-403(A), the Department contracts with a third party for administration of these license examinations. The candidates pay the third party vendor the fee established in R4-28-104(A)(1) and (5), which is within the range for the fees set in A.R.S. § 32-2132(A)(1), (2), (5), and (6). The maximum permissible amount under statute to apply for and take the license examination is $225 for broker candidates and $125 for salesperson candidates. Broker license candidates currently pay $110; salesperson license candidates pay $85.

The current contract, awarded to Experior Assessments, L.L.C. in November 1999 as a one-year contract with the option of four one-year renewals, allows for an annual adjustment to the fees with a limit of 6% over the base amount, beginning the fourth year. The Department anticipates that Experior will increase the fees. Because of the current budget situation and the required balance of appropriation and revenue, the Department is amending the rule to pass a nominal increase of $5 per exam to the consumer of the service—the candidate—to cover the expected increase by Experior.

Minor formatting changes were made to clarify descriptions of other fees.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

None

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

Applicants for licensure as a real estate, cemetery, or membership camping salesperson or broker must pass a state license exam pursuant to A.R.S. § 32-2124(E), (F), and (G). Pursuant to R4-28-403(A), the Department contracts with a third party for administration of these license examinations. The amount charged applicants is set by contract with the third party vendor (currently Experior Assessments LLC) and is within the range for the fees set in A.R.S. § 32-2132(A)(1), (2), (5), and (6). The minimum and maximum of the range, along with the current fees and amended fees, are as follows:

	Minimum	Current	Amended	Maximum
Salesperson	$30	$85	$90	$125
Broker	$70	$110	$115	$225

The current contract provides for adjustments to the fees, and based on inflation and rising costs of personnel, facilities and other resources, the Department anticipates that Experior will increase the fees for taking the state license examination. Given the current budget situation and the balance between appropriations and revenues the Department is required to maintain, the Department is amending the rule to pass the nominal fee increase on to the consumer of the service—the candidate.

This statement analyzes the costs, savings and benefits that accrue to the Department of Real Estate, license candidates, small businesses, and the public.

The rule's impact on the Department of Real Estate is minimal, and offsets an adverse economic impact that will accrue if the fee increase is not passed on to the candidate. The candidate pays the fee for exam application and examination directly to the testing provider contracted to provide the services under R4-28-403. These fees amounts are within the range for these fees authorized by A.R.S. § 32-2132(A)(1), (2), (5), and (6).

Candidates for licensure will be impacted minimally. A license candidate will pay $5 more to apply for and take the salesperson's examination or broker's examination. Under statute, the salesperson's exam and exam application fees, collectively, can range from $30 to $125; for a broker's license, the fee for exam application and examination, collectively, can fall between $70 and $225. These fees have been at their current levels since approximately 1987.

The amended fee will have no or minimal impact on businesses and small businesses in Arizona, since a candidate, rather than a brokerage company, traditionally pays the costs associated with a candidate obtaining the required license.

No members of the public, other than license candidates, will be affected.

Persons who are affected, bear costs, or directly benefit include a candidate, who is minimally affected. The amount a candidate will pay to take the state license exam under the amended rule is only slightly higher than the current fee. Statutory fee limits prevent excessive fees. The Department and candidates will benefit from a competitive fee that still provides the benefits available through a third party provider, including testing six days a week in multiple locations, and the instantaneous availability of exam results.

The scale used in measuring costs and revenues designates the change as minimal when less than $1,000 in additional costs or revenues, moderate when between $1,000 and $10,000 in additional costs or revenues, and substantial when greater than $10,000 in additional costs or revenues.

Increased costs to the Department are minimal, and include staff time to write this rule and prepare the economic and small business and consumer impact statement. Increased costs would be moderate without adjusting the exam fee to cover the vendor's increased fees. Under the current contract, Experior retains $55 for each examination and passes the additional amount ($30/salesperson's exam and $55/broker's exam) through to the Department. Once Experior exercises its option and increases its fee to schedule and administer the examinations, it will retain $58.30 per examination. The difference between Experior's increase and the $5.00 increase provided for by these rules, $1.70 per examination, is increased revenue to the Department. If the fees charged candidates are not increased, Department revenues will decrease by $3.30 per examination.

Probable costs and benefits to businesses include an increased benefit to the contracted testing provider. The increased revenues to Experior are minimal per candidate but substantial overall. During 2001, approximately 6,900 candidates took the real estate sales exam, 575 the real estate broker exam. These figures have been adjusted to estimate the number of candidates rather than "exams." Experior administers the exam as two parts, state and general, but counts each portion of the exam. Therefore, statistics routinely recorded exaggerate exam activity by approximately double. The number of candidates testing each month has shown an increase as the state grows. Fewer than 200 cemetery and membership camping salesperson and broker exam candidates tested during 2001.

Other than the contracted test provider, businesses and small businesses are not expected to be affected by this change.

Probable costs and benefits to consumers (candidates) include a minimal increased cost, and no increase in revenues. Candidates benefit from having a third party contractor, rather than the Department, administer the examination. Services have improved significantly since this responsibility was outsourced.

A candidate to take the state license exam for licensure as a real estate, cemetery, or membership camping salesperson or broker will bear the additional minimal cost of the increased fee. The benefit to the testing administrator is potentially substantial.

The effect on state revenues is expected to be minimal, if any, and beneficial unless the rule is not adopted. The effect will be adverse if the Department, rather than the candidate, has to absorb the increased cost.

10. A description of changes between the proposed rule, including supplemental notices, and final rules:

There are no substantive changes between the proposed rule and these final rules.

11. A summary of the comments made regarding the rule and the agency's response to them:

The sole comment received to the proposed rulemaking was favorable, that the fees for examination had not changed in years and an increase was understandable.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None

13. Incorporations by reference and their location in the rules:

None

14. Was the rule previously made as an emergency rule?

No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 28. STATE REAL ESTATE DEPARTMENT

ARTICLE 1. GENERAL PROVISIONS

Section
R4-28-104. Fees

ARTICLE 1. GENERAL PROVISIONS

R4-28-104. Fees

A. Licensing Fees.
1. Broker's exam and examination application, ~~$110.00~~ $115.00;
2. Broker's license, $125.00;
3. Broker's renewal ~~(Timely)~~, $125.00;
4. ~~Broker Renewal~~ Broker's late renewal pursuant to A.R.S. § 32-2130(C), additional $20.00~~; (Additional~~ per month fee~~. Maximum~~ up to a maximum of $120~~);~~
5. Salesperson's exam and examination application fee, ~~$85.00~~ $90.00;
6. Salesperson's license, $60.00;
7. Salesperson's renewal ~~(Timely)~~, $60.00;
8. Salesperson's late renewal pursuant to A.R.S. § 32-2130(C), additional $10.00~~; (Additional~~ per month fee~~. Maximum~~ up to a maximum of $60~~);~~
9. Branch office license,
   a. 12 months or less, $35.00;
   b. 13 to 24 months, $50.00;
   c. Renewal, $50.00;
10. Change of name ~~and~~ or address, $10.00;
11. Temporary broker's license, $50.00;
12. Temporary cemetery salesperson's license, $50.00;
13. Membership camping ~~Certificate of Convenience~~ salesperson's certificate of convenience, $50.00.

B. No change
C. No change

NOTICE OF FINAL RULEMAKING

TITLE 17. TRANSPORTATION

CHAPTER 1. DEPARTMENT OF TRANSPORTATION ADMINISTRATION

PREAMBLE

1. Sections Affected **Rulemaking Action**
R17-1-104 New Section

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):
Authorizing statute: A.R.S. § 28-366

Implementing statute: A.R.S. § 41-1023

3. The effective date of the rules:
January 5, 2003

4. A list of all previous notices appearing in the Register addressing the final rule:
Notice of Rulemaking Docket Opening: 8 A.A.R. 3485, August 9, 2002

Notice of Proposed Rulemaking: 8 A.A.R. 3286, August 9, 2002

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: George R. Pavia, Department Rules Supervisor

Address: Administrative Rules Unit
Department of Transportation, Mail Drop 507M
3737 N. 7th Street, Suite 160
Phoenix, AZ 85014-5079

Telephone: (602) 712-8446

Fax: (602) 241-1624

E-mail: gpavia@dot.state.az.us

Please visit the ADOT web site to track progress of this rule and any other agency rulemaking matters at www.dot.state.az.us/about/rules/index.htm.

6. An explanation of the rule, including the agency's reasons for initiating the rulemaking:

The Department makes this Section to provide guidelines for public participation in agency rulemaking oral proceedings. This is a new rulemaking that does not arise from a five-year rule review previously submitted to the Governor's Regulatory Review Council.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not rely on any study for this rulemaking.

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

This rulemaking will have negligible economic impact. The only cost is the minimal cost of rulemaking. Benefits are to the agency itself and to potential public participants in any agency rulemaking oral proceeding. The benefits are:

1. Clarity and specificity of oral proceeding protocol,
2. Reduction in confusion or misunderstanding by participants, and
3. Assurance to the public that the agency fully complies with A.R.S. § 41-1023 in conducting an oral proceeding.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

The agency made changes recommended by Governor's Regulatory Review Council staff that accomplish the following:

1. Decrease regulation originally published in the Notice of Proposed Rulemaking,
2. Eliminate regulatory provisions already imposed by statute,
3. Offer necessary clarification to agency application of Arizona's Open Meeting Law, and
4. Bring this Section's structure and grammar into conformity with current G.R.R.C. rulemaking style.

11. A summary of the comments made regarding the rule and the agency response to them:

The agency received no comments on this rulemaking.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

No

13. Incorporations by reference and their location in the rules:

None

14. Was this rule previously adopted as an emergency rule?

No

15. The full text of the rules follows:

TITLE 17. TRANSPORTATION

CHAPTER 1. DEPARTMENT OF TRANSPORTATION ADMINISTRATION

ARTICLE 1. GENERAL PROVISIONS

Section

ARTICLE 1. GENERAL PROVISIONS

R17-1-104. Rulemaking Oral Proceeding

A. Public request for an oral proceeding. A person may request an oral proceeding as prescribed under A.R.S. § 41-1023(C) by submitting the following information in writing to the agency official identified in a proposed rule's preamble:

1. Identify the specific proposed rule for oral proceeding by Section number and title heading; and
2. Provide the following requestor information:
   a. Name;
   b. Address;
   c. Telephone number during regular state business hours as prescribed under A.R.S. § 38-401; and
   d. Optional information, if applicable:
      i. The requestor's occupational title; and
      ii. The name of the entity the requestor represents.

B. Oral proceeding protocol.

1. The Department shall record an oral proceeding electronically or stenographically, and shall make any audio or video cassette, transcript, register, and written comment received part of the Department's rulemaking record as required under A.R.S. § 41-1029(B)(4) and (5).
2. The Department's presiding official shall use the following guidelines to conduct an oral proceeding:
   a. Registration of attendees. Attendee registration is voluntary;
   b. Registration of persons intending to speak. A person wishing to speak shall provide the person's name, representative capacity, if applicable, a brief statement of the person's position regarding the proposed rule, and the approximate length of time the person wishes to speak;
   c. Opening of the record. The Department's presiding official shall identify:
      i. The rule to be considered;
      ii. The location;
      iii. The date;
      iv. The time of day;
      v. The purpose of the proceeding including applicable background information or Department representative's opening statement on the proposed rule; and
      vi. Any applicable time limitation of the meeting location's use or electronic communication linkage.
   d. A public oral comment period. Any person may speak at an oral proceeding. A person who speaks shall ensure that all comments address the rule being considered. The Department's presiding official may limit the time allotted to each speaker and preclude undue repetition;
   e. A recess provision. If an oral proceeding must recess because of a time limitation indicated in subsection (B)(2)(c)(vi), the Department's presiding official shall ensure that the oral proceeding's continuation complies with the meeting notice provision prescribed under A.R.S. § 38-431.02(E).
   f. Closing remarks. Before closing an oral proceeding record, the Department's presiding official shall announce:
      i. The location and last day for submitting written comments about the rule; and
      ii. Any known future rulemaking steps the Department intends to take regarding the rule after the rulemaking public record closes.

NOTICE OF FINAL RULEMAKING

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 9. DEPARTMENT OF ENVIRONMENTAL QUALITY
WATER POLLUTION CONTROL

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R18-9-1001	Amend
R18-9-1002	Amend
R18-9-1003	Amend
R18-9-1004	Amend
R18-9-1005	Amend
R18-9-1006	Amend
R18-9-1007	Amend
R18-9-1008	Amend
R18-9-1011	Amend
R18-9-1013	Amend
R18-9-1014	Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 49-203, 49-255.01(B), and 49-255.03(A)

Implementing statutes: A.R.S. §§ 49-255.01 and 49-255.03

3. The effective date of the rules:

January 5, 2003

4. A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening: 8 A.A.R. 3258, August 2, 2002

Notice of Proposed Rulemaking: 8 A.A.R. 3179, August 2, 2002

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Shirley J. Conard

Address: Arizona Department of Environmental Quality
1110 W. Washington, 5420E
Phoenix, AZ 85007

Telephone: (602) 771-4632 (Metro-Phoenix area) or (800) 234-5677, ext. 4632 (other areas)

Fax: (602) 771-4674

E-mail: conard.shirley@ev.state.az.us

6. An explanation of the rule, including the agency's reasons for initiating the rule:

This rulemaking makes minor clarifications and additional corrections required for consistency with the federal program for the "Standards for the Use or Disposal of Sewage Sludge" (40 CFR 503). These changes are necessary so that EPA will approve Arizona's implementation of the program under the National Pollutant Discharge Elimination Program.

R18-9-1001. Definitions

Definitions for "Class I sludge management facility" (40 CFR 501.2) and "sewage sludge" (A.R.S. § 49-255) have been added to assist stakeholders in understanding the terms. The definition of "biosolids" was revised to clarify that sludge generated at an industrial facility is not "biosolids" even if the industrial wastewater being treated at the industrial facility included domestic sewage.

R18-9-1002. Applicability and Prohibitions

Subsection (A) has been amended to address the requirements under 40 CFR 503.1(b)(2) and 40 CFR 503.1(b)(4), by stating that this Article applies to any person who "owns or operates a sewage sludge unit," "biosolids applied to the land or placed on a surface disposal site," "land where biosolids are applied," and "a surface disposal site."

Subsection (E) has been amended to address the requirement under 40 CFR 503.20(a), by including any person who "prepares biosolids that are placed in a sewage sludge unit."

Subsection (F) has been added to address the requirements under 40 CFR 503.14(a) and 40 CFR 503.24(a), by stating that "a person shall not apply bulk biosolids to the land or place bulk biosolids in a surface disposal site if the biosolids are likely to adversely affect a threatened or endangered species listed under section 4 of the Endangered Species Act (16 U.S.C. 1533) or its designated critical habitat."

R18-9-1003. General Requirements

Subsection (A) has been amended to address the requirement under 40 CFR 503.3(b), 40 CFR 503.12(a) and 40 CFR 503.22(a), by stating that "a person shall not use or transport biosolids, ~~or~~ apply biosolids to land or place biosolids on a surface disposal site in Arizona, except as established in this Article."

Subsection (F) has been added to address the requirement under 40 CFR 503.7, by stating that "a person who prepares biosolids shall ensure that the applicable requirements in this article are met when the biosolids are applied to the land or placed on a surface disposal site."

Subsection (G) has been added to address the requirement under 40 CFR 503.5(a), 40 CFR 503.10(b)(2), and 40 CFR 503.10(c)(2), by stating that "when necessary to protect public health and the environment from any adverse effect of a pollutant in the biosolids, the Department may impose, on a case-by-case basis, requirements for the use or disposal of biosolids, including exceptional quality biosolids, in addition to or more stringent than the requirements in this Article."

Subsection (G) has been further amended to require that the Department notify the preparer, applier, or land owner of these requirements by letter and include the justification for the requirements specifying the length of time or applicability for the requirements.

R18-9-1004. Applicator Registration, Bulk Biosolids

Subsection (C)(5)(e) has been amended to reflect the numbering change in R18-9-1005.

R18-9-1005. Pollutant Concentrations

Subsection (A) has been amended to remove the selenium exemption because 40 CFR 503 does not contain an "exemption" for selenium.

Subsection (B) has been amended to apply to biosolids that are "sold or given away in a bag or other container," instead of to bulk biosolids. The existing rule applied the annual pollutant loading rate to bulk biosolids that are not exceptional quality biosolids. In 40 CFR 503.13(a)(4), biosolids that are "sold or given away in a bag or other container" must either meet the pollutant concentrations in 40 CFR 503.13, Table 3 or all the annual pollutant loading rates specified in 40 CFR 503.13, Table 4. The federal regulations do not provide the annual pollutant loading rate option for the application of bulk biosolids. For these reasons, the Department proposes to apply the provision at R18-9-1005(B) to biosolids that are "sold or given away in a bag or other container," instead of to bulk biosolids.

Subsection (C) has been added to address the requirement under 40 CFR 503.13(a)(3) and 40 CFR 503.15(a)(2), by stating that "a person shall not apply bulk biosolids to a lawn or garden that are not exceptional quality biosolids."

Subsection (D) has been amended to address the requirements under 40 CFR 503.13(a)(2). In 40 CFR 503.13(a)(2), EPA provides two options for meeting the pollutant limits for bulk biosolids that are applied to land. Subsection (D)(1) corresponds with 40 CFR 503.13(a)(2)(ii). Subsection (D)(2) corresponds with 40 CFR 503.13(a)(2)(i).

Subsection (C)(4) has been deleted because 40 CFR 503 does not contain an "exemption" for selenium.

R18-9-1006. Class A and Class B Pathogen Reduction Requirements

Subsections (C), (D)(3), and (D)(4) have been amended for clarity.

R18-9-1007. Management Practices and General Requirements, subsection (A)(13), and **R18-9-1008. Management Practices, Application of Biosolids to Reclamation Sites,** subsection (A)(12), have been amended to include a storage requirement to prevent impacts due to odors on adjacent dwellings.

R18-9-1011. Transportation

The proposed rulemaking deleted the reference to R18-13-310. However, based on public comment, the Department concluded that this citation, dealing with bulk biosolids in solid form was necessary to the rule. Subsection (B) has been further clarified to specify what each citation covers.

R18-9-1013. Recordkeeping

Subsection (A)(3) has been amended to specify the forms of nitrogen that must be analyzed and provided to the applicator to determine compliance with the agronomic rate requirement at R18-9-1007(A)(7).

R18-9-1014. Reporting

Subsection (A) has been changed to address the requirement under 40 CFR 503.12(d), 40 CFR 503.12(f), and 40 CFR 503.28, by stating that the preparer must provide any "necessary information to comply with the Article, including the concentration of pollutants listed in R18-9-1005 and the concentration of nitrogen in the biosolids."

Subsections (C) and (E) have been amended for clarity.

Subsection (F) has been amended for clarity and to address the requirements under 40 CFR 503.18. 40 CFR 503.18 requires three categories of biosolids preparers to report to EPA by February 19th of each year. The current rule requires only preparers of "exceptional quality biosolids" to report to the Department by February 19th of each year. To conform this Section with 40 CFR 503.18, the reporting requirement is amended to apply to any preparer that is a Class I Sludge Management Facility, a publicly owned treatment works (POTW) with a design flow rate equal to or greater than one million gallons per day, or a POTW that serves 10,000 people or more. Preparers of biosolids that are not exceptional quality biosolids and that fall into one or more of those three categories will be subject to this requirement.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

None

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

This rulemaking is being promulgated to comply with U.S. Environmental Protection Agency's (EPA) request for the Department to conform with the Clean Water Act. To date, the Department has not obtained EPA approval to administer the Sewage Sludge Use and Disposal program, and thus these changes will have a minimal impact on consumers or small businesses in Arizona.

A. *Estimated Costs and Benefits to the Arizona Department of Environmental Quality and other state agencies.*

The impacts to the Department from this rulemaking are minimal. The Department is already performing a land application disposal program for biosolids and had incorporated the surface disposal program into the biosolids rules in December 2001. Additional requirements imposed on the Department by these changes have to do with the review that the Department may have to perform relating to the imposition of case-by-case requirements on preparers, applicants, and/or landowners. The Department has already specified several additional management practices and a registration feature for land application based on the Arizona climate and the environment. The Department does not anticipate a great amount of additional review time for additional issues and anticipates no economic impact from adding the requirement to impose case-by-case requirements.

State agencies, such as the Department of Corrections or the State Parks, that operate wastewater treatment facilities that generate biosolids, will not be impacted because the requirements are the same as under 40 CFR 503 and the current state program.

B. *Estimated Costs and Benefits to Political Subdivisions.*

Political subdivisions that operate wastewater treatment facilities (POTWs) that prepare biosolids will not be impacted because the requirements are the same as under the federal program (40 CFR 503). However, with respect to reporting, the Department requires that all preparers of exceptional quality biosolids report on an annual basis. Based on the requirements in 40 CFR 503.18, the Department revised the reporting requirement to apply to just three categories of facilities that prepare biosolids. Any POTW that (1) does not have a pretreatment program, (2) discharges less than one million gallons per day, or (3) serves a population of less than 10,000 people benefits from this rulemaking because persons operating this type of facility will not need to report annually under the final rulemaking.

The Department is not aware, however, of any POTWs that fit these criteria. Therefore, the Department anticipates that there will be no impact from this change.

C. ***Businesses Directly Affected By the Rulemaking.***

Businesses that deal with the disposal of bulk biosolids by land application may be impacted by the requirements in R18-9-1007(A)(13) and R18-9-1008(A)(12), which prohibit the storage of bulk biosolids within 1000 feet of a dwelling. The rule language in R18-9-1007(A)(12) and R18-9-1008(A)(11) implied that, to reduce odors and other nuisance impacts to residents in close proximity, applicators cannot leave bulk biosolids on the ground if there is a dwelling within 1000 feet. If the rule requires that bulk biosolids be applied (incorporated or injected) within 10 hours, then longer term storage of bulk biosolids on land that is within 1000 feet of a dwelling would not be acceptable. The rules have been amended so that it is clear that no person may store bulk biosolids within 1000 feet of a dwelling, unless the person obtains permission from the dwelling owner or lessee.

D. ***Estimated Costs and Benefits to Consumers and the Public.***

There will be no impact on consumers. The small percentage of the public that resides next to land application sites will benefit from the clarification that biosolids may not be stored within 1000 feet of a dwelling, because that person will be notified and must provide permission before the storage is allowed.

E. ***Estimated Costs and Benefits to State Revenues.***

This rulemaking should have no impact on state general funding revenues.

Requirements of A.R.S. § 41-1035

1. Establish less stringent compliance and reporting requirements for small businesses.

   The changes to these rules do not impact the existing compliance and reporting requirements for small businesses. HB 2426, passed in the 2001 legislative session, specifies that the AZPDES program shall be consistent with, but not more stringent than the National Pollutant Discharge Elimination System (NPDES) program and the requirements of 405(a) (disposal and use of sewage sludge) (33 U.S.C. 1345). (A.R.S. § 49-255.01(B).) The compliance and reporting requirements are consistent with the requirements under the federal program.

2. Establish less stringent compliance or reporting schedules or deadlines for small businesses.

   The change to R18-9-1014(F) meets this requirement by eliminating the requirement to report for some preparers of exceptional quality biosolids that do not fall into the three categories specified.

3. Consolidate or simplify the rule's compliance and reporting requirements for small businesses.

   The rules follow the requirements of EPA's disposal and use of sewage sludge program.

4. Establish performance standards for small businesses to replace design and operational standards.

   The federal program for the disposal and use of sewage sludge is primarily a "performance-based" program. The performance targets are dependant on a variety of factors including the extent of treatment for biosolids and the characteristics of the disposal site. The rules follow the requirements of EPA's disposal and use of sewage sludge program and therefore provide the "performance standards" approach.

5. Exempt small businesses from any or all requirements of the rule.

   The rules follow the requirements of EPA's disposal and use of sewage sludge program. The Department is not able to provide any exemptions that are not already in the federal program.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

General

Rulemaking changes made as a result of responses to comments are described in item #11, a summary of the principal comments and the agency response to them.

Grammatical and clarification rule changes were made at the request of Council staff.

R18-9-1007. Management Practices and General Requirements

R18-9-1008. Management Practices, Application of Biosolids to Reclamation Sites

Subsections (A) in R18-9-1007 and R18-9-1008 establish that both rules deal with requirements for bulk biosolids. The term "bulk" however, was not used consistently throughout the two rules, rather its use was implied. The term "bulk" has been added throughout R18-9-1007(A) and R18-9-1008(A) to clarify that these Sections deal only with requirements for bulk biosolids. R18-9-1008(B) was changed as follows to clarify that this subsection deals with biosolids placed in a bag or other container.

The requirements of R18-9-1007(B) apply if biosolids placed in a bag or other container are used to reclaim a site.

R18-9-1014. Reporting

This Section deals with reporting requirements for land application. In the proposed rulemaking under subsection (A), however, the Department included reporting requirements for surface disposal. Reporting requirements for surface disposal are covered in 40 CFR 503, subpart C, which is incorporated by reference under R18-9-A905(A)(9), therefore the requirements do not need to be mentioned in this rule. The following sentence in subsection (A) has been deleted:

The person who prepares biosolids for surface disposal shall comply with 40 CFR 503.28 which is incorporated by reference in R18-9-A905(A)(9).

The following language was inadvertently included in the proposed rulemaking and is duplicative of the initial statement in subsection (F). This duplicative language has been deleted.

On February 19 of each year, a person preparing exceptional quality biosolids that is applied to land shall, by letter or on a form provided by the Department, report to the Department all the following applicable information regarding their activities during the previous calendar year:

11. A summary of the comments made regarding the rule and the agency response to them:

R18-9-1001. Definitions

Comment: A commenter requested that additional verbiage be added to the definition of "reclamation" to clarify that both active and closed mining sites fall within the definition.

Response: The Department agrees that this additional language will clarify that all mining sites are covered, whether active or closed. Subsection (36) has been amended as follows:

"Reclamation" means the use of biosolids to restore or repair ~~mining or~~ construction sites, active or closed mining sites, landfill caps, or other drastically disturbed land.

R18-9-1002. Applicability and Prohibitions

Comment: Proposed R18-9-1002(F) largely parallels the text of several portions of the federal regulations, including 40 CFR 503.14(a), and prohibits application or disposal of biosolids if the application or disposal of biosolids is likely to adversely affect a listed species or its habitat. The commenter requests that ADEQ strike this provision from the rule because there is no legal basis for its inclusion and the provision is not required for EPA to approve Arizona's implementation of the NPDES program or certify administrative completeness pursuant to 40 CFR Part 501. If the provision is retained, it should be modified consistent with language from EPA guidance addressing the management standards in Part 503.

The commenter questions the need for inclusion of this provision at all. The "likely to adversely affect" standard comes from the Endangered Species Act ("ESA") consultation process, and is used to determine when federal agencies must consult with the Fish and Wildlife Service ("FWS") before taking action. In that context it does *not* serve as a bar to taking action, as it does in the proposed rule.

Moreover, as ADEQ is well aware, ESA requirements apply only to federal agencies taking action, not to state agencies. The requirements for state sludge programs are set forth in the Clean Water Act ("CWA") and the corresponding rules. CWA § 405(c) allows states to administer a sludge program in accordance with § 402, and says nothing about ESA issues; § 402(b) lists the requirements for state program approval but is silent on the ESA and does not contain any special procedures for the sludge program. Finally, the state statute on biosolids simply requires consistency with §§ 402 and 405 of the CWA, which as noted above are silent with respect to ESA issues. *See* A.R.S. § 49-255.03(A).

The corresponding federal rules are equally silent. 40 CFR 123 lists the federal rules that must be complied with to obtain program approval of a permit program and does not mention the ESA sections of the biosolids rules; instead, it states that the requirements that a state sludge program must meet for approval are set forth in 40 CFR 501. *See* 40 CFR 123.1(a). 40 CFR 501 does not specifically mandate that states adopt the portions of the federal rules mentioning ESA concerns. The commenter does not see any legal basis for including an ESA requirement in the biosolids section.

Furthermore, removal of R18-9-1002(F) from the proposed rule does not provide EPA with a legal basis to deny that ADEQ's submission is administratively complete pursuant to 40 CFR 501 (*see* 40 CFR 501.11(a) (stating the five elements of an approvable program submission)).

As noted above, the standard contained in the proposed rule is a version of the trigger used to require consultation when Section 7 of the ESA is applicable because a federal action is being taken. Nowhere in the ESA is the "likely to adversely affect" standard used to bar an activity, as it would be here. If any ESA-type provision is to be included in these rules, the standard ought to be more akin to that used to prohibit take under the ESA. Specifically, the commenter suggests that the standard be a prohibition on harm to a listed species or the destruction or adverse modification to designated critical habitat (both terms have definitions in the ESA regulations at 50 CFR 402.02).

EPA guidance on the biosolids program appears to confirm that this is the correct standard to be used when assessing endangered species impacts caused by biosolids application. *See* excerpts from *A Plain English Guide to the EPA*

Part 503 Biosolids Rule (EPA 1994). In addition, in the recent Texas adoption of a state NPDES program, the state (presumably with EPA's approval) added clarifying language to this effect in its sludge rules. *See* 30 T.A.C. § 312.44(a). The commenter suggests that if this provision is retained, similar language be included as follows:

> F. A person shall not apply bulk biosolids to the land or place bulk biosolids in a surface disposal site if the biosolids are likely to HARM ~~adversely affect~~ a threatened or endangered species listed under section 4 of the Endangered Species Act or RESULT IN THE DESTRUCTION OR ADVERSE MODIFICATION OF its designated critical habitat.

If this provision is to be left in the regulations, ADEQ should explain in the preamble to the final rule: (1) who will make the determination (will ADEQ contact the Arizona Game and Fish Department ("AGFD")); (2) when will the determination be made (the commenter suggests at the time the original registration is provided, or subsequently only if there is a change in application or disposal practices); and (3) what criteria will be used in making the determination?

Response: During discussions with U.S. EPA Region 9, EPA stressed that Department rules must include a prohibition similar to the ones at 40 CFR 503.14(a) and 503.24(a). The rules already incorporated 40 CFR 503.24(a) by reference in R18-9-A905(A)(9), so the Department created R18-9-1002(F) to comply with EPA's requirement and for consistency with 40 CFR 503.24(a). EPA maintains that the Department program must contain this type of provision in order to be administratively complete. As the commenter mentioned, the Texas Pollutant Discharge Elimination System (TPDES) has a similar provision.

The Department reviewed the suggested language changes, the rule language from the TPDES program rules, and consulted with EPA Region 9 regarding the suggested changes. EPA reminded the Department that 40 CFR 501.1(c)(1) requires that a state sludge management program shall have "the authority to require compliance by any person who uses or disposes of sewage sludge with standards for sludge use or disposal issued under section 405(d) of the CWA, including compliance by federal facilities." 40 CFR 503 are the "standards for sludge use or disposal issued under section 405(d) of the CWA." EPA Region 9 disagrees that "harm" is the same as "adversely affect." EPA indicated that replacing "adversely affect" with "harm" makes the provision inconsistent with 40 CFR 503.14(a) and that this change would cause the Department program to not meet the minimum standards under 40 CFR 501.1(c)(1). If the Department submits the program with the commenter's suggested changes, EPA would not approve the Department's biosolids management program. The Department will retain the language as proposed to maintain consistency with 40 CFR 503.14(a) and also 40 CFR 503.24(a), which is incorporated by reference.

In response to the commenter's last question regarding who will make the determination, when will the determination be made, and under what criteria, the Department plans to implement this provision in a manner that is similar to EPA's approach. Land owners, preparers, and applicators are responsible for complying with this provision. This provision is self-implementing. If biosolids that are land applied or placed in a surface disposal site adversely affect a threatened or endangered species or its critical habitat, the Department has the authority to take enforcement action pursuant to its enforcement authorities in A.R.S. Title 49, Chapter 2, Article 4.

The most effective means to implement this measure is for the Department to remind or to advise applicants about this provision and to direct them to work with the Arizona Game and Fish Department and the U.S. Fish and Wildlife Service to determine whether the land application activity will adversely impact a threatened or endangered species or its critical habitat. The Department will modify the web site to provide links to these agencies' web sites. The Department anticipates that when it receives information regarding a potential impact to threatened or endangered species or a designated habitat, the Department will use a variety of means to make the determination, including obtaining information from the Arizona Game and Fish Department. The Department will make the determination when it receives information on these activities, either through an outside party or through its inspection program.

R18-9-1003. General Requirements

Comment: In order to be consistent with the federal sewage sludge regulations at Part 503 (*see* 40 CFR 503.5(a), 503.10(b)(2), and 503.10(c)(2)), proposed R18-9-1003(G) should be revised to provide that the imposition of additional or more stringent requirements on the use or disposal of biosolids when necessary to protect public health and the environment from an adverse effect of a pollutant in biosolids can occur *only* on a "case-by-case basis." As currently drafted, the first sentence in particular could be read to allow ADEQ to apply the additional requirements to multiple parties generating, applying or transporting biosolids via a single action. The clear intent of the federal rule is to allow for the imposition of the additional or more stringent requirements in an individual case based on an examination of the circumstances of that individual case. Such an approach is implied by the second sentence of proposed R18-9-1003(G), but even that sentence does not make the point unambiguously. Addition of the phrase "on a case-by-case basis" in the first sentence would provide the appropriate clarification.

It also is unclear what is meant by a "reasonably anticipated" adverse effect of a pollutant in biosolids. Although this phrase is used in 40 CFR 503.10(b)(2) and 503.10(c)(2), which provisions apply only to certain instances during the management of bulk sewage sludge or bulk material, the phrase is not used in the more general provision (*see* 40 CFR 503.5(a)) regarding the ability of the permitting authority to impose additional or more stringent requirements. The additional phrase appears to have the effect of expanding ADEQ's authority in this regard. It is appropriate that

before ADEQ be allowed to exercise this broad authority, there be more than a reasonable anticipation of an adverse effect.

In accordance with the above discussion, proposed R18-9-1003(G) should be revised as follows:

G. When necessary to protect public health and the environment from any ~~reasonably anticipated~~ adverse effect of a pollutant in the biosolids, the Department may impose, ON A CASE-BY-CASE BASIS, requirements for the use or disposal of biosolids, including exceptional quality biosolids, in addition to, or more stringent than, the requirements in this Article. The Department shall notify the preparer, applier, or land owner of these requirements by letter and include the justification for the requirements and the length of time or applicability for the requirements.

Response: The Department believes that the suggested changes maintain the intent of the requirements in 40 CFR 503.5(a), 40 CFR 503.10(b)(2) and 503.10(c)(2) and made the revisions to subsection (G) as suggested.

Comment: Subsection (G) gives ADEQ authority to "impose requirements for the use or disposal of biosolids, including exceptional quality biosolids, in addition to, or more stringent than, the requirements in this Article," when ADEQ believes it is necessary to protect public health and the environment. This section of the proposed rule does not provide any specific procedures or guidance which explain how ADEQ staff will come to a determination that biosolids application may present a threat to public health and the environment. The proposed rule also does not specify any limitations on what ADEQ can require or limitations on the length of time a requirement may be imposed. In total, the proposed rules specify many requirements that the regulated community must follow in order to safely use or dispose of biosolids within Arizona. If the regulated community complies with these rules, then application of biosolids should not cause harm to public health or the environment. If biosolids are being used or disposed of in a manner that is not consistent with the rules, then ADEQ has legal authority to impose requirements that will bring the regulated community back into compliance, or ADEQ may impose a cease and desist order to completely halt the activity. ADEQ also has legal authority to impose fines, require clean-up of contaminated sites and recover costs. Because of this, the commenter believes that the proposed rule in this subsection is arbitrary and capricious and is unnecessarily broad in its scope and authority. ADEQ already has all the authority and tools it needs to adequately regulate biosolids without inclusion of this proposed subsection of the rule. Because of this, the commenter requests that ADEQ withdraw this section of the rule. If this is unacceptable, the commenter requests that ADEQ withdraw this subsection of the rule until such time when ADEQ develops and codifies procedures that specify the steps that ADEQ will follow to determine if application of biosolids will have an adverse impact on public health and the environment, and what requirements ADEQ may impose to mitigate an impact.

Response: During discussions with U.S. EPA Region 9, EPA stressed that Department rules must include authority to impose additional requirements on a case-by-case basis. EPA did not agree that the Department's existing rule provisions or the authority in A.R.S. §§ 49-141 to 49-144 was adequate. EPA's authority is broad. The regulated community is subject to EPA imposing requirements on a case-by-case basis under the existing federal program. EPA will not approve the Department program without the Department having additional authority to impose case-by-case requirements on the disposal of biosolids.

The language conforms with the federal requirements at 40 CFR 503.5(a), 503.10(b)(2) and 503.10(c)(2). The federal provisions do not specify the exact process that EPA will use. As mentioned in the response to the previous comment, the Department will revise the language of this provision to emphasize that this authority is applied on a case-by-case basis.

The Department specified its plan for implementing the case-by-case requirements by including a requirement to notify the parties of the additional requirement(s). The Department proposed to include in the notification, the specific additional requirements, the justification for the requirements and the length of time the requirements apply to the land application or surface disposal activity. The party may appeal the notification as any other final agency action. In addition to the process of notifying parties about additional case-by-case requirements, the Department may choose to transfer the requirements into a permit issued under R18-9-A902(C).

R18-9-1006. Class A and Class B Pathogen Reduction Requirements

Comment: Subsection (B) can be interpreted to mean that biosolids that are sold or given away in a bag or other container, must under all circumstances meet Class A pathogen reduction requirements. The commenter believes it was the intention of the regulation that this only apply to biosolids that are sold or given away to be used for home lawn or garden uses. A requirement to meet Class A pathogen reduction should not apply to Class B biosolids that are sold or given away in a bag or other container for application to a sewage sludge unit which meets all Class B biosolids land application restrictions. Because of this, the commenter suggests that this subsection be modified to read "Biosolids that are sold or given away in a bag or other container which are applied on a lawn or home garden, shall meet the Class A pathogen reduction requirements established in subsection (D)."

Response: The Department understands that the current rule language in R18-9-1006(B) may restrict the preparers of Class B biosolids from distributing biosolids in a container for placement in a sewage sludge unit. Based on the fact

that this section needs to apply to both land application and surface disposal activities and the Department has already incorporated the language in 40 CFR 503.25(a) and 503.33(b)(11) by reference in R18-9-A905(A)(9), R18-9-1006(A) and (B) have been amended as follows:

A. An applicator shall ensure that all biosolids applied to land meet Class A or Class B pathogen reduction requirements at the time the biosolids are:

1. Placed on an active sewage sludge unit unless the biosolids are covered with soil or other material at the end of each operating day, or

2. ~~land~~ Land applied.

B. Biosolids that are sold or given away in a bag or other container for land application, or that are applied on a lawn or home garden, shall meet the Class A pathogen reduction requirements established in subsection (D).

R18-9-1007. Management Practices and General Requirements

Comment: R18-9-1007(A)(12) requires that no biosolids can be stored within 1000 feet of a dwelling and usually the dwelling closest to the field is the farmer's own dwelling. This requirement won't allow a farmer to store biosolids next to his house because he may smell it when he would rather have the free fertilizer. We're talking almost a quarter mile distance here. This is a tremendous economic impact on the farmer. In this case, injection or incorporation isn't just convenience of whether the farmer discs today or tomorrow. Many times it's an excellent conservation practice as well as an economic scenario. Many times farmers will land apply biosolids on an existing growing crop, such as alfalfa or Bermuda grass. There is a 30-day harvest restriction which usually means that they would have to do this in the wintertime when there is a greater interval between cutting of alfalfa, but it is a very sound best management practice (BMP). This BMP means that you have a crop that is immediately growing and immediately uptakes the nitrogen so you minimize the chance of leachate down through the soil into the groundwater. It also reduces the chance of wind and water erosion.

The commenter suggests using language similar to that used in the reclamation sites, "unless the applicator receives permission to apply biosolids from the land owner or lessee" of the occupant or a dwelling. If a person likes to smell biosolids, he can have the biosolids, if he doesn't then applicators won't put it within a thousand feet.

The commenter also suggests that the odor from stored biosolids should be much less than from the application of biosolids because of smaller amount of surface area. In addition, when dealing with little wastewater treatment plants, it may take six months to get enough material for one field. This is a problem and an alternative is necessary.

Comment: In some cases, farm dwellings are located near farm fields and the persons who live in the farm dwelling approve of biosolids application closer than 1000 feet. Under this circumstance, the proposed rule should make provisions for this to happen. The commenter requests that ADEQ insert language to subsection (A)(12) that allows application and storage of biosolids closer than 1000 feet to a dwelling if the person living within the dwelling approves.

Response: The Department understands the comments and has deleted "or store biosolids within 1000 feet (305 meters) of a dwelling" from R18-9-1007(A)(12) and R18-9-1008(A)(11) and added the following language to both Sections under R18-9-1007(A)(13) and R18-9-1008(A)(12):

Store bulk biosolids within 1000 feet (305 meters) of a dwelling unless the applicator obtains permission from the dwelling owner or lessee to store the biosolids at a shorter distance from the dwelling. If the dwelling owner or lessee changes, the applicator shall obtain permission from the new dwelling owner or lessee to continue to store the bulk biosolids within 1000 feet of the dwelling or move the biosolids to a location at least 1000 feet from the dwelling.

R18-9-1008. Management Practices, Application of Biosolids to Reclamation Sites

Comment: Section R18-9-1007 discusses general requirements and management practices for application of bulk biosolids that are not exceptional quality at land application sites. Under R18-9-1007(A)(6), the biosolids must not be applied within 25 feet (7.62 meters) of a public right-of-way or private property line unless the applicator receives permission to apply biosolids from the land owner or lessee of the adjoining property. The proposed R18-9-1007(A)(12) states in order to minimize odors, biosolids should not be applied within 1000 feet (305 meters) of a dwelling unless the biosolids are injected or incorporated into the soil within 10 hours of being applied or stored within 1000 feet (305) meters of a dwelling.

Section R18-9-1008 discusses general requirements and management practices for application of bulk biosolids that are not exceptional quality at reclamation sites. R18-9-1008(A)(11) contains the same provision as R18-9-1007(A)(12) regarding setbacks distances from dwellings; however, the setback distance requirement under R18-9-1008(A)(6) for public rights-of-way or private property lines is 1000 feet instead of the 25 feet requirement found in R18-9-1007(A)(6). Both sections of rule contain the 1000 foot setback requirement from dwellings in order to minimize odors. It is inconsistent and unnecessary however, that the rules regulating reclamation sites should have a setback distance from private property lines which is 975 feet longer than that for other bulk biosolids application sites.

The commenter suggests that to be consistent with R18-9-1007(A)(6), and because adjoining properties next to reclamation sites will be protected from nuisance odors by R18-9-1008(A)(11), that R18-9-1008(A)(6) be revised to read "Store or apply biosolids within 25 feet (7.62) meters of a public right-of-way or private property line unless the applicator receives permission to apply biosolids from the land owner or lessee of the adjoining property."

Response: The Department understands the request for consistency between Sections on potentially common issues. One major difference between Sections R18-9-1007 and R18-9-1008 is that the loading rate allowed under R18-9-1008(A)(7) (up to 150 tons per acre) is much greater than that allowed under R18-9-1007(A)(10) (at the agronomic rate for the crop or vegetation in pounds per acre). The current language in R18-9-1008(A)(6) provides a mechanism for the applicator to request a shorter "set-back" distance from the public right-a-way or property line. The Department believes that because of the greater loading rate, the language in R18-9-1008(A)(6) is appropriate. No change has been made to the rule.

R18-9-1011. Transportation

Comment: The Department proposed to delete the reference to R18-13-310 from R18-9-1011(B).

R18-8-612 is not applicable to vehicles hauling solid sewage sludge. The rule was clearly written for vehicles hauling human excreta in a liquid or semi-solid state. 40 CFR 503.9(w) defines sewage sludge as solid, semi-solid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Solid biosolids cannot be placed in leak-proof, fly-tight containers via suction pump and hose commonly found on vacuum trucks, tankers, and septic tank pumpers as required in R18-8-612. Most biosolids produced at sewage treatment works within the area of concern intended for land application are in solid form. Solid biosolids are commonly loaded with construction type equipment into open top trailers or containers normally used to transport solid waste and secured with tarpaulin type covers to prevent spillage. Vehicles used for the transportation of solid waste are strictly regulated in R18-13-310.

The commenter recommends the reference to R18-13-310 not be removed from R18-9-1011(B) and that R18-13-312(G) be amended to include "sludge from a wastewater treatment plant." In accordance with 40 CFR 258.2, sludge from a wastewater treatment plant is included in the definition of solid waste.

If the proposed rule change is implemented as currently written, the commenter may not be able to adequately enforce the requirements in R18-8-612 when applied to the transportation of solid sewage sludge or biosolids. Transporting biosolids in unregulated vehicles has the potential to severely impact public health and cause harm to the environment.

Response: The Department agrees that both references are necessary. The reference to R18-8-612 pertains to liquid or semisolid biosolids that are pumped from a tank. The reference to R18-13-310 applies to solid biosolids that need to be loaded with construction-type equipment. In order to clarify the applicability for each provision, R18-9-1011(B) has been changed as follows:

A transporter of bulk biosolids in liquid or semisolid form, including domestic septage, into and within Arizona shall comply with all the requirements in A.A.C. R18-8-612. ~~or~~ A transporter of bulk biosolids in solid form into and within Arizona shall comply with all the requirements in A.A.C. R18-13-310.

R18-9-1014. Reporting

Comment: Subsections (E) and (F) require that certain information be reported to the Arizona Department of Environmental Quality on February 19 of each year. Given the difficulty that the regulated community may experience in trying to time the reporting of information on one particular day of the year, the commenter suggest that the words "or before" be added to these subsections of the regulations, directly after the word "on" to allow greater flexibility regarding the reporting of information.

Response: The language in these subsections are derived from 40 CFR 503.18. However, the Department agrees with the commenter that requiring applicants and preparers to submit reports only on February 19 of each year is onerous. Subsections (E) and (F) have been changed to allow an applicant or preparer to submit the report on or before February 19th.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None

13. Incorporations by reference and their location in the rules:

None

14. Was this rule previously adopted as an emergency rule?

No

15. The full text of the rules follows:

TITLE 18. ENVIRONMENTAL QUALITY

**CHAPTER 9. DEPARTMENT OF ENVIRONMENTAL QUALITY
WATER POLLUTION CONTROL**

**ARTICLE 10. ARIZONA POLLUTANT DISCHARGE ELIMINATION SYSTEM
DISPOSAL, USE, AND TRANSPORTATION OF BIOSOLIDS**

Section
R18-9-1001. Definitions
R18-9-1002. Applicability and Prohibitions
R18-9-1003. General Requirements
R18-9-1004. Applicator Registration, Bulk Biosolids
R18-9-1005. Pollutant Concentrations
R18-9-1006. Class A and Class B Pathogen Reduction Requirements
R18-9-1007. Management Practices and General Requirements
R18-9-1008. Management Practices, Application of Biosolids to Reclamation Sites
R18-9-1011. Transportation
R18-9-1013. Recordkeeping
R18-9-1014. Reporting

**ARTICLE 10. ARIZONA POLLUTANT DISCHARGE ELIMINATION SYSTEM
DISPOSAL, USE, AND TRANSPORTATION OF BIOSOLIDS**

R18-9-1001. Definitions

In addition to the definitions in A.R.S. § 49-255 and R18-9-A901, the following terms apply to this Article:

1. "Aerobic digestion" means the biochemical decomposition of organic matter in biosolids into carbon dioxide and water by microorganisms in the presence of air.
2. "Agronomic rate" means the whole biosolids application rate on a dry-weight basis that meets the following conditions:
   a. The amount of nitrogen needed by existing vegetation or a planned or actual crop has been provided, and
   b. The amount of nitrogen that passes below the root zone of the crop or vegetation is minimized.
3. "Anaerobic digestion" means the biochemical decomposition of organic matter in biosolids into methane gas and carbon dioxide by microorganisms in the absence of air.
4. "Annual biosolids application rate" means the maximum amount of biosolids (dry-weight basis) that can be applied to an acre or hectare of land during a 365-day period.
5. "Annual pollutant loading rate" means the maximum amount of a pollutant that can be applied to an acre or hectare of land during a 365-day period.
6. "Applicator" means ~~the~~ a person who arranges for and controls the site-specific land application of biosolids in Arizona.
7. "Biosolids" means sewage sludge, including exceptional quality biosolids, that is placed on, or applied to the land to use the beneficial properties of the material as a soil amendment, conditioner, or fertilizer. Biosolids do not include any of the following:
   a. Sludge determined to be hazardous under A.R.S. Title 49, Chapter 5, Article 2 and 40 CFR 261;
   b. Sludge with a concentration of polychlorinated biphenyls (PCBs) equal to or greater than 50 milligrams per kilogram of total solids (dry-weight basis);
   c. Grit (for example, sand, gravel, cinders, or other materials with a high specific gravity) or screenings generated during preliminary treatment of domestic sewage by a treatment works;
   d. Sludge generated during the treatment of either surface water or groundwater used for drinking water;
   e. Sludge generated ~~by~~ at an industrial facility during the treatment of industrial wastewater, ~~or~~ including industrial wastewater combined with domestic sewage;
   f. Commercial septage, industrial septage, or domestic septage combined with commercial or industrial septage; or
   g. Special wastes~~,~~ as defined and controlled under A.R.S. Title 49, Chapter 4, Article 9.
8. "Bulk biosolids" means biosolids that are transported and land-applied in a manner other than in a bag or other container holding biosolids of 1.102 short tons or 1 metric ton or less.
9. "Class I sludge management facility" means any POTW identified under 40 CFR 403.8(a) as being required to have an approved pretreatment program (including a POTW for which the Department assumes local program responsibilities under 40 CFR 403.10(e)) and any other treatment works treating domestic sewage classified as a Class I sludge

management facility by the regional administrator in conjunction with the Director or by the Director because of the potential for its sludge use or disposal practices to adversely affect public health or the environment.

~~9.~~10. *"Clean water act" means the federal water pollution control act amendments of 1972, as amended (P.L. 92-500; 86 Stat. 816; 33 United States Code sections 1251 through 1376).* A.R.S. 49-201(6).

~~10.~~11. "Coarse fragments" means rock particles in the gravel-size range or larger.

~~11.~~12. "Coarse or medium sands" means a soil mixture of which more than 50% of the sand fraction is retained on a No. 40 (0.425 mm) sieve.

~~12.~~13. "Cumulative pollutant loading rate" means the maximum amount of a pollutant applied to a land application site.

~~13.~~14. "Domestic septage" means the liquid or solid material removed from a septic tank, cesspool, portable toilet, marine sanitation device, or similar system or device that receives only domestic sewage. Domestic septage does not include commercial or industrial wastewater or restaurant grease-trap wastes.

~~14.~~15. "Domestic sewage" means waste or wastewater from humans or household operations that is discharged to a publicly or privately owned treatment works. Domestic sewage also includes commercial and industrial wastewaters that are discharged into a publicly-owned or privately-owned treatment works if the industrial or commercial wastewater combines with human excreta and other household and nonindustrial wastewaters before treatment.

~~15.~~16. "Dry-weight basis" means the weight of biosolids calculated after the material has been dried at 105° C until reaching a constant mass.

~~16.~~17. "Exceptional quality biosolids" means biosolids certified under R18-9-1013(A)(6) as meeting the pollutant concentrations in R18-9-1005 Table 2, Class A pathogen reduction in R18-9-1006, and one of the vector attraction reduction requirements in subsections R18-9-1010(A)(1) through R18-9-1010(A)(8).

~~17.~~18. "Feed crops" means crops produced for animal consumption.

~~18.~~19. "Fiber crops" means crops grown for their physical characteristics. Fiber crops, including flax and cotton, are not produced for human or animal consumption.

~~19.~~20. "Food crops" means crops produced for human consumption.

~~20.~~21. "Gravel" means soil predominantly composed of rock particles that will pass through a 3-inch (75 mm) sieve and be retained on a No. 4 (4.75 mm) sieve.

~~21.~~22. "Industrial wastewater" means wastewater that is generated in a commercial or industrial process.

~~22.~~23. "Land application," "apply biosolids," or "biosolids applied to the land" means spraying or spreading biosolids on the surface of the land, injecting biosolids below the land's surface, or incorporating biosolids into the soil to amend, condition, or fertilize the soil.

~~23.~~24. "Monthly average" means the arithmetic mean of all measurements taken during a calendar month.

~~24.~~25. "Municipality" means a city, town, county, district, association, or other public body, including an intergovernmental agency of two or more of the foregoing entities created by or under state law. The term includes special districts such as a water district, sewer district, sanitary district, utility district, drainage district, or similar entity that has as one of its principal responsibilities, the treatment, transport, use, or disposal of biosolids.

~~25.~~26. *"Navigable waters" means the waters of the United States as defined by section 502(7) of the clean water act (33 United States Code section 1362(7)).* A.R.S. § 49-201(21).

~~26.~~27. "Other container" means a bucket, bin, box, carton, trailer, pickup truck bed, or a tanker vehicle or an open or closed receptacle with a load capacity of 1.102 short tons or one metric ton or less.

~~27.~~28. "Pathogen" means a disease-causing organism.

~~28.~~29. *"Person" means an individual, employee, officer, managing body, trust, firm, joint stock company, consortium, public or private corporation, including a government corporation, partnership, association or state, a political subdivision of this state, a commission, the United States government or a federal facility, interstate body or other entity.* A.R.S. § 49-201(26).

~~29.~~30. "Person who prepares biosolids" means ~~the~~ a person who generates biosolids during the treatment of domestic sewage in a treatment works, packages biosolids, or derives a new product from biosolids either through processing or by combining it with another material, including blending several biosolids together.

~~30.~~31. "pH" means the logarithm of the reciprocal of the hydrogen ion concentration.

~~31.~~32. "Pollutant" means an organic substance, an inorganic substance, a combination of organic and inorganic substances, or a pathogenic organism that, after release into the environment and upon exposure, ingestion, inhalation, or assimilation into an organism, either directly from the environment or indirectly by ingestion through the food chain, could cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunction in reproduction), or physical deformities in either organisms or reproduced offspring.

~~32.~~33. "Pollutant limit" means:

a. A numerical value that describes the quantity of a pollutant allowed in a unit of biosolids such as milligrams per kilogram of total solids,
b. The quantity of a pollutant that can be applied to a unit area of land such as kilograms per hectare, or
c. The volume of biosolids that can be applied to a unit area of land such as gallons per acre.

~~33.~~34. "Privately owned treatment works" means a device or system owned by a non-governmental entity used to treat, recycle, or reclaim, either domestic sewage or a combination of domestic sewage and industrial waste that is generated off-site.

~~34.~~35. "Public contact site" means a park, sports field, cemetery, golf course, plant nursery, or other land with a high potential for public exposure to biosolids.

~~35.~~36. "Reclamation" means the use of biosolids to restore or repair ~~mining or~~ construction sites, active or closed mining sites, landfill caps, or other drastically disturbed land.

~~36.~~37. "Responsible official" means a principal corporate officer, general partner, proprietor, or, in the case of a municipality, a principal executive official or any duly authorized agent.

~~37.~~38. "Runoff" means rainwater, leachate, or other liquid that drains over any part of a land surface and runs off of the land surface.

~~38.~~39. "Sand" means soil that contains more than 85% grains in the size range that will pass through a No. 4 (4.75 mm) sieve and be retained on a No. 200 (0.075 mm) sieve.

40. *"Sewage sludge":*
   (a) Means solid, semisolid or liquid residue that is generated during the treatment of domestic sewage in a treatment works.
   (b) Includes domestic septage, scum or solids that are removed in primary, secondary or advanced wastewater treatment processes, and any material derived from sewage sludge.
   (c) Does not include ash that is generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings that are generated during preliminary treatment of domestic sewage in a treatment works. A.R.S. 49-255(6).

~~39.~~41. "Sewage sludge unit" means land on which only sewage sludge is placed for final disposal. This does not include land on which sewage sludge is either stored or treated. Land does not include navigable waters.

~~40.~~42. "Specific oxygen uptake rate (SOUR)" means the mass of oxygen consumed per unit time per unit mass of total solids (dry-weight basis) in biosolids.

~~41.~~43. "Store biosolids" or "storage of biosolids" means the temporary holding or placement of biosolids on land before land application.

~~42.~~44. "Surface disposal site" means an area of land that contains one or more active sewage sludge units.

~~43.~~45. "Ton" means a net weight of 2000 pounds and is known as a short ton.

~~44.~~46. "Total solids" means the biosolids material that remains when sewage sludge is dried at 103° C to 105° C.

~~45.~~47. "Treatment of biosolids" means the thickening, stabilization, dewatering, and other preparation of biosolids for land application. Storage is not a treatment of biosolids.

~~46.~~48. "Unstabilized solids" means the organic matter in biosolids that has not been treated or reduced through an aerobic or anaerobic process.

~~47.~~49. "Vectors" means rodents, flies, mosquitos, or other organisms capable of transporting pathogens.

~~48.~~50. "Volatile solids" means the amount of total solids lost when biosolids are combusted at 550° C in the presence of excess air.

~~49.~~51. "Wetlands" means those areas that are inundated or saturated by surface water or groundwater at a frequency and duration to support, and do under normal circumstances support, a prevalence of vegetation typically adapted for life in saturated soil conditions. Wetlands generally include swamps, marshes, bogs, cienegas, tinajas, and similar areas.

R18-9-1002. Applicability and Prohibitions

A. This Article applies to ~~any person who~~:

1. Any person who:
   ~~1.~~a. Prepares biosolids for land application or disposal in a sewage sludge unit,
   ~~2.~~b. Transports biosolids for land application or disposal in a sewage sludge unit,
   ~~3.~~c. Applies biosolids ~~for soil amendment or disposes of biosolids in a sewage sludge unit, or~~ to the land,
   d. Owns or operates a sewage sludge unit, or
   ~~4.~~e. Owns or leases land to which biosolids are applied ~~or placed for disposal in a sewage sludge unit.~~,
2. Biosolids applied to the land or placed on a surface disposal site,
3. Land where biosolids are applied, and
4. A surface disposal site.

B. The land application of biosolids in a manner consistent with this Article is exempt from the requirements of the aquifer protection program established under A.R.S. Title 49, Chapter 2, Article 3 and 18 A.A.C. 9, Articles 1, 2, and 3.

C. Except as provided in subsection (D), the land application of biosolids in a manner that is not consistent with Articles 9 and 10 of this Chapter is prohibited.

D. The Department may permit the land application of biosolids in a manner that differs from the requirements in R18-9-1007 and R18-9-1008 if the land application is permitted under the aquifer protection permit program established under A.R.S. Title 49, Chapter 2, Article 3, and 18 A.A.C. 9, Articles 1, 2, and 3.

E. Surface disposal site.
1. Any person who prepares biosolids that are placed in a sewage sludge unit, or places biosolids in a sewage sludge unit, or who owns or operates a biosolids surface disposal site shall comply with 40 CFR 503, Subpart C, which is incorporated by reference in R18-9-A905(A)(9), and
   a. The pathogen reduction requirements in R18-9-1006, and
   b. The vector attraction reduction requirements in R18-9-1010.
2. In addition to the requirements under subsection (E)(1), any person who owns or operates a biosolids surface disposal site shall apply for, and obtain, a permit under 18 A.A.C. 9, Articles 1 and 2.

F. A person shall not apply bulk biosolids to the land or place bulk biosolids in a surface disposal site if the biosolids are likely to adversely affect a threatened or endangered species as listed under section 4 of the Endangered Species Act (16 U.S.C. 1533), or its designated critical habitat as defined in 16 U.S.C. 1532.

~~F.~~**G.** The incineration of biosolids is prohibited.

R18-9-1003. General Requirements

A. A person shall not use or transport biosolids, ~~or~~ apply biosolids to land, or place biosolids on a surface disposal site in Arizona, except as established in this Article.

B. The management practices in R18-9-1007 and R18-9-1008 do not apply if biosolids are exceptional quality biosolids.

C. The applicator shall obtain, submit to the Department, and maintain the ~~necessary~~ information ~~needed~~ required to comply with the requirements of this Article.

D. The applicator shall not receive bulk biosolids without prior written confirmation of the filing of a "Request for Registration" under R18-9-1004.

E. The land owner or lessee of land on which bulk biosolids, that are not exceptional quality biosolids, have been applied shall notify any subsequent land owner and lessee of all previous land applications of biosolids and shall disclose any site restrictions listed in R18-9-1009 that are in effect at the time the property is transferred.

F. A person who prepares biosolids shall ensure that the applicable requirements in this Article are met when the biosolids are applied to the land or placed on a surface disposal site.

G. If necessary to protect public health and the environment from any adverse effect of a pollutant in the biosolids, the Department may impose, on a case-by-case basis, requirements for the use or disposal of biosolids, including exceptional quality biosolids, in addition to, or more stringent than, the requirements in this Article. The Department shall notify the preparer, applier, or land owner of these requirements by letter and include the justification for the requirements and the length of time or applicability for the requirements.

R18-9-1004. Applicator Registration, Bulk Biosolids

A. Any person intending to land-apply bulk biosolids in Arizona shall submit, on a form provided by the Department, a completed "Request for Registration."

B. An applicator shall not engage in land application of bulk biosolids, unless the applicator has obtained a prior written acknowledgment of the ~~request for registration~~ Request for Registration or a supplemental request from the Department.

C. The Request for Registration for all biosolids, except exceptional quality biosolids, shall include:
1. The name, address, and telephone number of the applicator and any agent of the applicator;
2. The name and telephone number of a primary contact person who has specific knowledge of the land application activities of the applicator;
3. Whether the applicator holds a NPDES or AZPDES permit, and, if so, the permit number;
4. The identity of the person, if different from the applicator, including the NPDES or AZPDES permit number, who will prepare the biosolids for land application; and
5. The following information, unless the information is already on file at the Department as part of an approved land application plan, for each site on which application is anticipated to take place:
   a. The name, mailing address, and telephone number of the land owner and lessee, if any;
   b. The physical location of the site by county;
   c. The legal description of the site, including township, range, and section, or latitude and longitude at the center of each site;
   d. The number of acres or hectares at each site to be used;
   e. Except for sites described in ~~R18-9-1005(C)(3)~~ R18-9-1005(D)(2)(c), background concentrations of the pollutants listed in Table 4 of R18-9-1005 from representative soil samples;
   f. The location of any portion of the site having a slope greater than 6%; and
   g. Public notice. Proof of placement of a public notice announcing the potential use of the site for the application of biosolids when a site has not previously received biosolids, or when a site has not been used for land application for at least three consecutive years.
      i. The notice shall appear at least once each week for at least two consecutive weeks in the largest newspaper in general circulation in the area in which the site is located.

ii. If a site is not used for land application for at least three consecutive years, the applicator shall renotice the site following the process described in subsection (C)(5)(g)(i) before its reuse.

D. The Request for Registration for exceptional quality biosolids shall include the information in subsections (C)(1) through (C)(4).

E. A responsible official of the applicator shall sign the Request for Registration.

F. The Department shall mail a written acknowledgment of a Request for Registration~~, including~~ or supplemental ~~requests~~ request, within 15 business days of receipt of the request.

G. An applicator wishing to use a site that has not been identified in a Request for Registration shall file a supplemental request with the Department before using the new site. Public notice requirements under R18-9-1004(C)(5)(g) apply.

R18-9-1005. Pollutant Concentrations

A. A person shall not apply biosolids with pollutant concentrations that exceed any of the ceiling concentrations established in Table 1. ~~Biosolids placed on public contact sites with a low potential for child occupancy are exempt from the selenium limit in Table 1.~~

B. A person shall not apply ~~bulk~~ biosolids sold or given away in a bag or other container that are not exceptional quality biosolids to a site if any annual pollutant loading rate in Table 3 will be exceeded. A person shall determine annual application rates using the methodology established in Appendix A.

C. A person shall not apply bulk biosolids to a lawn or garden unless the biosolids are exceptional quality biosolids.

~~C.~~D. ~~A~~ Unless using exceptional quality biosolids, a person shall not apply bulk biosolids ~~that are not exceptional quality biosolids~~ to a site ~~if~~ when:

1. The pollutant concentrations exceed the levels in Table 2, or
2. Any cumulative pollutant loading rate in Table 4 will be exceeded. A person shall determine compliance with the site cumulative pollutant loading rates using the following:

~~1.~~a. By ~~calculating~~ identifying all known biosolids application events and information relevant to a site since September 13, 1979.

~~2.~~b. By calculating the existing cumulative level of the pollutants established in Table 4 using actual analytical data from the application events or if actual analytical data from application events before April 1996 are not available, background concentrations determined by taking representative soil samples of the site, if it is known that the site received biosolids before April 1996.

~~3.~~c. Background soil tests are not required for those sites that have not received biosolids before April 23, 1996.

~~4. Biosolids placed on public contact sites with a low potential for child-occupancy are exempt from the selenium limit in Table 4.~~

Table 1. Ceiling Concentrations

Pollutant	Ceiling concentrations (milligrams per kilogram) (1)
Arsenic	75.0
Cadmium	85.0
Chromium	3000.0
Copper	4300.0
Lead	840.0
Mercury	57.0
Molybdenum	75.0
Nickel	420.0
Selenium	100.0
Zinc	7500.0

(1) Dry-weight basis.

Table 2. Monthly Average Pollutant Concentrations

Pollutant	Concentration limits (milligrams per kilogram) (1)
Arsenic	41.0
Cadmium	39.0
Copper	1500.0
Lead	300.0
Mercury	17.0
Nickel	420.0
Selenium	100.0
Zinc	2800.0

(1) Dry-weight basis.

Table 3. Annual Pollutant Loading Rates

Pollutant	Annual pollutant loading rates (in kilograms per hectare)
Arsenic	2.0
Cadmium	1.9
Copper	75.0
Lead	15.0
Mercury	0.85
Nickel	21.0
Selenium	5.0
Zinc	140.0

Table 4. Cumulative Pollutant Loading Rates

Pollutant	Cumulative pollutant loading rates (in kilograms per hectare)
Arsenic	41.0
Cadmium	39.0
Copper	1500.0
Lead	300.0
Mercury	17.0
Nickel	420.0
Selenium	100.0
Zinc	2800.0

R18-9-1006. Class A and Class B Pathogen Reduction Requirements

A. An applicator shall ensure that all biosolids applied to land meet Class A or Class B pathogen reduction requirements at the time the biosolids are:

1. Placed on an active sewage sludge unit unless the biosolids are covered with soil or other material at the end of each operating day, or
2. ~~land~~ Land applied.

B. Biosolids that are sold or given away in a bag or other container for land application, or that are applied on a lawn or home garden, shall meet the Class A pathogen reduction requirements established in subsection (D).

C. Land on which biosolids with Class B pathogen reduction requirements are applied is subject to the use restrictions established in R18-9-1009.

D. Biosolids satisfy the Class A pathogen reduction requirements when the density of fecal coliform is less than 1000 Most Probable Number per gram of total solids (dry-weight basis), or the density of *Salmonella sp.* bacteria is less than three Most Probable Number per four grams of total solids (dry-weight basis), and any one of the following alternative pathogen treatment options is used:

1. Alternative 1. The pathogen treatment process meets one of the following time and temperature requirements:
   a. When the percent solids of the biosolids are seven percent or greater, the temperature of the biosolids shall be held at 50° C or higher for at least 20 minutes. The temperature and time period is determined using the equation in subsection (D)(1)(b), except when small particles of the biosolids are heated by either warmed gases or an immiscible liquid;
   b. When the percent solids of the biosolids are seven percent or greater, and small particles of the biosolids are heated by either warmed gases or an immiscible liquid, a temperature of 50° C or higher shall be held for 15 seconds or longer. The temperature and time period is determined using the following equation:

      $$D = \frac{131{,}700{,}000}{10^{[0.1400t]}}$$

      D = time in days and t = temperature in degrees Celsius;
   c. When the percent solids of the biosolids are less than seven percent, the temperature of the biosolids is 50° C or higher and the time period is 30 minutes or longer. The temperature and time period shall be determined using the following equation:

      $$D = \frac{50{,}070{,}000}{10^{[0.1400t]}}$$

      D = time in days and t = temperature in degrees Celsius; or
   d. When the percent solids of the biosolids are less than seven percent, and the time of heating is at least 15 seconds, but less than 30 minutes, the time and temperature is determined using the following equation:

      $$D = \frac{131{,}700{,}000}{10^{[0.1400t]}}$$

      D = time in days~~,~~ and t = temperature in degrees Celsius.
2. Alternative 2. The pathogen treatment process meets all the following parameters:
   a. The pH of the quantity of biosolids treated is raised to 12 or higher and held at least 72 hours;
   b. During the period that the pH is above 12, the temperature of the biosolids is held above 52° C for at least 12 hours; and
   c. At the end of the 72-hour period during which the pH is above 12, the biosolids are air dried to achieve a percent solids in the biosolids greater than 50%.
3. Alternative 3. ~~If the following are met~~ The following conditions are met:
   a. The biosolids, before pathogen treatment and until the next monitoring event, have an enteric virus density less than one plaque-forming unit for four grams of total solids (dry-weight basis);
   b. The biosolids, before pathogen treatment and until the next monitoring event, have a viable helminth ova density less than one for four grams of total solids (dry-weight basis); and
   c. Once the density requirements in subsections (D)(3)(a) and (D)(3)(b) are consistently met after pathogen treatment and the values and ranges of the pathogen treatment process used are documented, the biosolids continue to be Class A with respect to enteric viruses and viable helminth ova when the values for the pathogen treatment process operating parameters are consistent with the previously documented values or ranges of values.
4. Alternative 4. ~~If the~~ The following ~~additional~~ requirements are met at the time the biosolids are used or disposed or at the time the biosolids are prepared for sale or given away in a bag or other container for application to the land:
   a. The biosolids have an enteric virus density less than one plaque-forming unit for four grams of total solids (dry-weight basis), and
   b. The biosolids have a viable helminth ova density less than one for four grams of total solids (dry-weight basis).
5. Alternative 5. Composting.
   a. Use either the within-vessel or the static-aerated-pile composting method, maintaining the temperature of the biosolids at 55° C or higher for three days; or
   b. Use the windrow composting method, maintaining the temperature of the biosolids at 55° C or higher for at least 15 days. The windrow shall be turned at least five times when the compost is maintained at 55° C or higher.
6. Alternative 6. Heat drying. The biosolids are dried by direct or indirect contact with hot gases to reduce the moisture content to 10% or lower by weight. During the process:

a. The temperature of the sewage sludge particles shall exceed 80° C, or
b. The wet bulb temperature of the gas as the biosolids leave the dryer shall exceed 80° C.

7. Alternative 7. Heat treatment. The quantity of liquid biosolids treated are heated to a temperature of 180° C or higher for at least 30 minutes.
8. Alternative 8. Thermophilic aerobic digestion. Liquid biosolids are agitated with air or oxygen to maintain aerobic conditions and the mean cell residence time of the biosolids is 10 days at 55° to 60° C.
9. Alternative 9. Beta ray irradiation. Biosolids are irradiated with beta rays from an accelerator at dosages of at least 1.0 megarad at room temperature (approximately 20° C).
10. Alternative 10. Gamma ray irradiation. Biosolids are irradiated with gamma rays from certain isotopes, such as ^{60}Cobalt and ^{137}Cesium at dosages of at least 1.0 megarad at room temperature (approximately 20° C).
11. Alternative 11. Pasteurization. The temperature of the biosolids is maintained at 70° C or higher for at least 30 minutes.
12. Alternative 12. The Director shall approve another process if the process is equivalent to a Process to Further Reduce Pathogens specified in subsections (D)(5) through (D)(11), as determined by the EPA Pathogen Equivalency Committee.

E. Biosolids satisfy the Class B pathogen reduction requirements when the biosolids meet any one of the following options:

1. Alternative 1. The geometric mean of the density of fecal coliform in seven representative samples is less than either 2,000,000 Most Probable Number per gram of total solids (dry-weight basis), or 2,000,000 colony forming units per gram of total solids (dry-weight basis);
2. Alternative 2. Air drying. The biosolids are dried on sand beds or paved or unpaved basins for at least ~~3~~ three months. During at least two of the three months, the ambient average daily temperature is above 0° C;
3. Alternative 3. Lime stabilization. Sufficient lime is added to the biosolids to raise the pH of the biosolids to 12 after at least two hours of contact;
4. Alternative 4. Aerobic digestion. The biosolids are agitated with air or oxygen to maintain aerobic conditions for a specific mean cell residence time at a specific temperature between 40 days at 20° C and 60 days at 15° C;
5. Alternative 5. Anaerobic digestion. The biosolids are treated in the absence of air for a specific mean cell residence time at a specific temperature between 15 days at 35° C to 55° C and 60 days at 20° C;
6. Alternative 6. Composting. Using the within-vessel, static-aerated-pile or windrow composting methods, the temperature of the biosolids is raised to 40° C or higher for five consecutive days. For at least four hours during the five days, the temperature in the compost pile exceeds 55° C; or
7. Alternative 7. The Director shall approve another process if it is equivalent to a Process to Significantly Reduce Pathogens specified in subsections (E)(2) through (E)(6), as determined by the EPA Pathogen Equivalency Committee.

R18-9-1007. Management Practices and General Requirements

A. An applicator of bulk biosolids that are not exceptional quality biosolids shall comply with the following management practices at each land application site, except a site where bulk biosolids are applied for reclamation. The applicator shall not:

1. Apply bulk biosolids to soil with a pH less than 6.5 at the time of the application, unless the biosolids are treated under one of the procedures in subsections R18-9-1006(D)(2), R18-9-1006(E)(3), or R18-9-1010(A)(6), or the soil and biosolids mixture has a pH of 6.5 or higher immediately after land application;
2. Apply bulk biosolids to land with slopes greater than 6%, unless the site is operating under an AZPDES permit or a permit issued under section 402 of the Clean Water Act (33 U.S.C. 1342);
3. Apply bulk biosolids to land under the following conditions:
   a. ~~Biosolids~~ Bulk biosolids with Class A pathogen reduction. If the depth to groundwater is five feet (1.52 meters) or less;
   b. ~~Biosolids~~ Bulk biosolids with Class B pathogen reduction.
      i. If the depth to groundwater is 10 feet (3.04 meters) or less; or
      ii. To gravel, coarse or medium sands, ~~and~~ or sands with less than 15% coarse fragments, if the depth to groundwater is 40 feet (12.2 meters) or less from the point of application of biosolids;
4. Apply bulk biosolids to land that is 32.8 feet (10 meters) or less from navigable waters;
5. Store or apply bulk biosolids closer than 1000 feet (305 meters) from a public or semi-public drinking water supply well ~~and~~ or no closer than 250 feet (76.2 meters) from any other water well;
6. Store or apply bulk biosolids within 25 feet (7.62 meters) of a public right-of-way or private property line unless the applicator receives permission to apply bulk biosolids from the land owner or lessee of the adjoining property;
7. Apply bulk biosolids at an application rate greater than the agronomic rate of the vegetation or crop grown on the site;
8. Apply domestic septage or any other bulk biosolids with less than 10% solids at a rate that exceeds the annual application rate, calculated in gallons per acre for a 365-day period by dividing the amount of nitrogen needed by the crop or vegetation grown on the land, in pounds per acre per 365-day period, by 0.0026;

9. Apply bulk biosolids to land that is flooded, frozen, or snow-covered, so that the bulk biosolids enter a wetland or other navigable waters, except as provided in an AZPDES permit or a permit issued under section 402 of the Clean Water Act (33 U.S.C. 1342);
10. Apply any additional bulk biosolids before a crop is grown on the site if the site has received biosolids containing nitrogen at the equivalent of the agronomic rate appropriate for that crop;
11. Exceed the irrigation needs of the crop of an application site; ~~and~~
12. To minimize odors, apply bulk biosolids within ~~1,000~~ 1000 feet (305 meters) of a dwelling unless the biosolids are injected or incorporated into the soil within 10 hours of being applied~~.~~; or
13. Store bulk biosolids within 1000 feet (305 meters) of a dwelling unless the applicator obtains permission from the dwelling owner or lessee to store the biosolids at a shorter distance from the dwelling. If the dwelling owner or lessee changes, the applicator shall obtain permission from the new dwelling owner or lessee to continue to store the bulk biosolids within 1000 feet of the dwelling or move the biosolids to a location at least 1000 feet from the dwelling.

B. If biosolids are placed in a bag or other container, the person who prepares the biosolids shall distribute a label or information sheet to the person receiving the material. This label or information sheet shall, at a minimum, contain the following information:
1. The identity and address of the person who prepared the biosolids;
2. Instructions on the proper use of the material, including agronomic rates and an annual application rate that ensures that the annual pollutant rates established in R18-9-1005 are not exceeded; and
3. A statement that application of biosolids to the land shall not exceed application rates described in the instructions on the label or information sheet.

R18-9-1008. Management Practices, Application of Biosolids to Reclamation Sites

A. An applicator of bulk biosolids that are not exceptional quality biosolids shall comply with the following management practices at each land application site where the bulk biosolids are applied for reclamation. The applicator shall not:
1. Apply bulk biosolids unless the soil and biosolids mixture has a pH of 5.0 or higher immediately after land application;
2. Apply bulk biosolids to land with slopes greater than 6% unless:
   a. The site is operating under an AZPDES permit or a permit issued under section 402 (33 U.S.C. 1342) or 404 (33 U.S.C. 1344) of the Clean Water Act;
   b. The site is reclaimed as specified under A.R.S. Title 27, Chapter 5, and controls are in place to prevent runoff from leaving the application area; or
   c. Runoff from the site does not reach navigable waters;
3. Apply bulk biosolids to land under the following conditions:
   a. ~~Biosolids~~ Bulk biosolids with Class A pathogen reduction. To land if the depth to groundwater is 5 feet (1.52 meters) or less;
   b. ~~Biosolids~~ Bulk biosolids with Class B pathogen reduction.
      i. To land if the depth to groundwater is 10 feet (3.04 meters) or less; and
      ii. To gravel, coarse or medium sands, ~~and~~ or sands with less than 15% coarse fragments if the depth to groundwater is 40 feet (12.2 meters) or less from the point of application of biosolids;
4. Apply bulk biosolids to land that is 32.8 feet (10 meters) or less from navigable waters;
5. Store or apply bulk biosolids closer than 1000 feet (305 meters) from a public or semi-public drinking water supply well, unless the applicator justifies and the Department approves a shorter distance, ~~and~~ or apply bulk biosolids closer than 250 feet (76.2 meters) from any other water well;
6. Store or apply bulk biosolids within ~~1,000~~ 1000 feet (305 meters) of a public right-of-way or private property line unless the applicator receives permission to apply bulk biosolids from the land owner or lessee of the adjoining property;
7. Exceed a total of 150 dry tons per acre to any portion of a reclamation site if bulk biosolids are applied;
8. Apply bulk biosolids with less than 10% solids;
9. Apply bulk biosolids to land that is flooded, frozen, or snow-covered so that the bulk biosolids enter a wetland or other navigable waters, except as provided in an AZPDES permit or a permit issued under section 402 (33 U.S.C. 1342) or 404 (33 U.S.C. 1344) of the Clean Water Act;
10. Apply more water than necessary to control dust and establish vegetation; and
11. Apply bulk biosolids within ~~1,000~~ 1000 feet (305 meters) of a dwelling unless the biosolids are injected or incorporated into the soil within 10 hours of being applied.
12. Store bulk biosolids within 1000 feet (305 meters) of a dwelling unless the applicator obtains permission from the dwelling owner or lessee to store the biosolids at a shorter distance from the dwelling. If the dwelling owner or lessee changes, the applicator shall obtain permission from the new dwelling owner or lessee to continue to store the bulk biosolids within 1000 feet of the dwelling or move the biosolids to a location at least 1000 feet from the dwelling.

B. The requirements of R18-9-1007(B) apply if biosolids placed in a bag or other container are used to reclaim a site.

R18-9-1011. Transportation

A. A transporter of bulk biosolids into and within Arizona shall use covered trucks, trailers, rail-cars, or other vehicles that are leakproof.

B. A transporter of bulk biosolids in liquid or semisolid form, including domestic septage, into and within Arizona shall comply with the requirements in A.A.C. R18-8-612. ~~or~~ A transporter of bulk biosolids in solid form into and within Arizona shall comply with the requirements in A.A.C. R18-13-310.

C. A transporter of biosolids shall clean any truck, trailer, rail-car, or other vehicle used to transport biosolids to prevent odors or insect breeding. A transporter shall clean any tank vessel used to transport commercial or industrial septage~~,~~ or restaurant grease-trap wastes, ~~which~~ that is also used to haul domestic septage, before loading the domestic septage to ensure that mixing of wastes does not occur.

D. If bulk biosolids are spilled while being transported, the transporter shall:

1. Immediately pick up any spillage, including any visibly discolored soil, unless otherwise determined by the Department on a case-by-case basis;
2. Within 24 hours after the spill, notify the Department of the spill and submit written notification of the spill within seven days. The written notification shall include the location of the spill, the reason it occurred, the amount of biosolids spilled, and the steps taken to clean up the spill.

R18-9-1013. Recordkeeping

A. A person who prepares biosolids shall collect and retain the following information for at least five years:

1. The date, time, and method used for each sampling activity and the identity of the person collecting the sample;
2. The date, time, and method used for each sample analysis and the identity of the person conducting the analysis;
3. The results of all analyses of pollutants regulated under R18-9-1005 and organic and ammonium nitrogen to comply with R18-9-1007(A)(7);
4. The results of all pathogen density analyses and applicable descriptions of the methods used for pathogen treatment in R18-9-1006;
5. A description of the methods used, if any, and the operating values and ranges observed in any pre-land application, vector attraction reduction activities required in R18-9-1010(A); and
6. ~~The~~ For the records described in subsections (A)(1) through (A)(5), ~~accompanied by~~ the following certification statement signed by a responsible official of the person who prepares the biosolids:
   "I certify, under penalty of law, that the pollutant analyses and the description of pathogen treatment and vector attraction reduction activities have been made under my direction and supervision and under a system designed to ensure that qualified personnel properly gather and evaluate the information used to determine whether the applicable biosolids requirements have been met. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

B. An applicator of bulk biosolids, except exceptional quality biosolids, shall collect the following information for each land application site, and, except as indicated in subsection (B)(6), shall retain this information for at least five years:

1. The location of each site, by either street address or latitude and longitude;
2. The number of acres or hectares;
3. The date and time the biosolids were applied;
4. The amount of biosolids (in dry metric tons);
5. The biosolids loading rates for domestic septage and other biosolids with less than 10 percent solids in tons or kilograms of biosolids per acre or hectare and in gallons per acre and the biosolids loading rates for other biosolids in tons or kilograms of biosolids per acre or hectare;
6. The cumulative pollutant levels of each regulated pollutant (in tons or kilograms per acre or hectare). The applicator shall retain these records permanently;
7. The results of all pathogen density analyses and applicable descriptions of the methods used for pathogen treatment in R18-9-1006;
8. A description of the activities and measures used to ensure compliance with the management practices in R18-9-1007 and R18-9-1008, including information regarding the amount of nitrogen required for the crop grown on each site;
9. If vector attraction reduction was not met by the person who prepares the biosolids, a description of the vector attraction reduction activities used by the applicator to ensure compliance with the requirements in R18-9-1010;
10. A description of any applicable site restriction imposed by in R18-9-1009~~,~~ if biosolids with Class B pathogen reduction have been applied~~,~~ and documentation that the applicator has notified the land owner and lessee of these restrictions;
11. ~~The~~ For the records described in subsections (B)(1) through (B)(8), ~~accompanied by~~ the following certification statement signed by a responsible official of the applicator of the biosolids:
    "I certify, under penalty of law, that the information and descriptions, have been made under my direction and supervision and under a system designed to ensure that qualified personnel properly gather and evaluate the information used to determine whether the applicable biosolids requirements have been met. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

12. The information in subsections (A)(1) through (A)(6) if the person who prepares the biosolids is not located in this state.

C. All records required for retention under this Section are subject to periodic inspection and copying by the Department.

D. If there is unresolved litigation, including enforcement, concerning the activities documented by the records required in this Section, the period of record retention shall be extended pending final resolution of the litigation.

R18-9-1014. Reporting

A. A person who prepares biosolids for application shall provide the applicator ~~written notification of the pollutant concentrations as necessary for the applicator to comply with R18-9-1003(C),~~ with the necessary information to comply with this Article including the concentration of pollutants listed in R18-9-1005 and the concentration of nitrogen in the biosolids.

B. A transporter shall report spills to the Department under R18-9-1011(D).

C. A bulk applicator of biosolids other than exceptional quality biosolids shall provide the land owner and lessee of land application sites with information on the ~~pollutant~~ concentrations of the pollutants listed in R18-9-1005 and loading rates of biosolids applied to that site, and any applicable site restrictions under R18-9-1009.

D. A bulk applicator of biosolids other than exceptional quality biosolids shall report to the Department if 90% or more of any cumulative pollutant loading rate has been used at a site.

E. On or before February 19 of each year, any person land-applying bulk biosolids that are not exceptional quality biosolids shall, by letter or on a form provided by the Department, report to the Department the following applicable information for the previous calendar year:

1. The actual sites used; and
2. For each site used, the following information:
   a. The amount of biosolids applied (in tons or kilograms per acre or hectare);
   b. The application loading rates (in tons or kilograms per acre or hectare, and gallons per acre for domestic septage);
   c. The ~~pollutant~~ concentrations of the pollutants listed in R18-9-1005 (in milligrams per kilogram of biosolids on a dry-weight basis);
   d. The pathogen treatment methodologies used during the year and the results; and
   e. The vector attraction reduction methodologies used during the year and the results.

F. On or before February 19 of each year, a person preparing ~~exceptional quality~~ biosolids in a Class I Sludge Management Facility, POTW with a design flow rate equal to or greater than one million gallons per day, or POTW that serves 10,000 people or more, that are applied to land, shall, by letter or on a form provided by the Department, report to the Department all the following applicable information regarding their activities during the previous calendar year:

1. The amount of biosolids received if the preparer purchased or received the biosolids from another preparer or source;
2. The amount of ~~exceptional quality~~ biosolids produced (tons or kilograms);
3. The amount of ~~exceptional quality~~ biosolids distributed;
4. The ~~pollutant~~ concentrations of the pollutants listed in R18-9-1005 (in milligrams per kilogram of biosolids on a dry-weight basis);
5. The pathogen treatment methodologies used during the year, including the results; and
6. The vector attraction reduction methodologies used during the year, including the results.

G. All annual self-monitoring reports shall contain the following certification statement signed by a responsible official:

"I certify, under penalty of law, that the information and descriptions, have been made under my direction and supervision and under a system designed to ensure that qualified personnel properly gather and evaluate the information used to determine whether the applicable biosolids requirements have been met. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."