

NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

NOTICE OF PROPOSED RULEMAKING

TITLE 2. ADMINISTRATION

CHAPTER 12. OFFICE OF THE SECRETARY OF STATE

PREAMBLE

- 1. Sections Affected**

	<u>Rulemaking Action</u>
R2-12-601	New Section
R2-12-602	New Section
R2-12-603	New Section
R2-12-604	New Section
R2-12-605	New Section
- 2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rule is implementing (specific):**

Authorizing statute: A.R.S. § 16-112
Implementing statutes: A.R.S. § 16-112
- 3. A list of all previous notices appearing in the Register addressing the proposed rule:**

Notice of Rulemaking Docket Opening: 7 A.A.R. 5725, December 21, 2001 (*In this issue*)
- 4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**

Name: Michael Totherow
Chief Information Officer

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1700 West Washington, 7th Floor
Phoenix, AZ 85007

Telephone: (602) 542-6170
Fax: (602) 542-1575
E-mail: mtotherow@sos.state.az.us
- 5. An explanation of the rule, including the agency's reasons for initiating the rule:**

Citizens are realizing the value of e-government in Arizona. By visiting ServiceArizona at the Arizona Department of Transportation web site, citizens can obtain a duplicate driver license, change their address, renew their vehicle registration, or order a personalized plate. These services are shining examples of e-government putting the citizen in control of the action -- self-service government.

In 1982, the Arizona Motor-Voter Act was passed, recognizing the similarities between the driver license application process and the voter registration process. The Act called for Arizona transportation authorities to work with voter registration authorities to develop a common exchange of information to better serve the citizenry. The two processes contain similar information structure, yet they remain two distinct paper filings. Currently, the Motor-Voter integration is simply the passage of a paper trail from the Motor Vehicle Division (MVD) to the county recorder. Conse-

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quently, there has been limited success in exchanging information, integrating the two application processes or getting information to the correct authorities in a timely manner.

Citizens are already aware of the benefits of electronic interaction with MVD, as evidenced by the fact that about 20% of all vehicle registrations take place on-line. These rules create a framework to enhance the objectives set out by the Motor-Voter Act. The reason for these rules is to facilitate the transfer of information from the MVD to the county recorders through the Secretary of State acting as a transient host for delivery. These rules prescribe the process by which applicants may register to vote and transfer address changes electronically, through the Internet.

This rule uses the authority granted in A.R.S. 16-112 to establish the framework and to define acceptance for electronic signatures on voter registration forms. The voter registration process is a wet signature based process because the validation of an election is completed by comparing wet signatures on ballots, or signature rosters, to the voter registration rolls of the county recorder. This electronic voter registration information framework uses the principle of unique identity within the MVD identification register to create an electronic signature of the person. That unique identification authorizes MVD to release the voter registration information, including a digitized image of the person's wet signature, to the county recorder for voter registration. This allows for the facilitation of electronic information exchange without degrading the integrity of the registration and election processes.

6. A reference to any study that the agency relied on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

None

7. 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

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

It is anticipated that the scope of these rules will cover about 70% of the paperwork filed for voter registration. Once the electronic information flow is in place, physical processes will be examined and altered to achieve even greater efficiency for the state.

This project is essential to proving effectiveness, efficiency, and functionality in a paperless government. There are over 2.2 million registered voters in the state. Maintenance of those records is time consuming and a paper exchange overload. Streamlining the flow of information from the Department of Transportation agency to the county recorder will be creating efficiency for both agencies in the transport of the information alone. In addition, with the growing population and the expected rise in voter registration, this project will help avoid future costs. The present information exchange process is a long trail of paperwork that burdens both MVD and the county recorder, without significant improvements since this law's inception. It is clear that the current method could be made substantially more efficient and effective with an electronic version of the form and process.

The rules will have a minimal impact on the Secretary of State's Office.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Michael Totherow
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Address: Office of the Secretary of State
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Fax: (602) 542-1575

E-mail: mtotherow@sos.state.az.us

10. The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

Oral and written comments will be accepted at the location listed in item #4 between 8:00 a.m. and 5:00 p.m., Monday through Friday.

An oral proceeding will be held as follows:

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Date: January 21, 2002
Time: 9:00 a.m.
Location: Secretary of State's Conference Room
State Capitol Executive Tower, 7th Floor
1700 W. Washington
Phoenix, AZ 85007

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

None

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

None

13. The full text of the rules follows:

TITLE 2. ADMINISTRATION

CHAPTER 12. OFFICE OF THE SECRETARY OF STATE

ARTICLE 6. ~~RESERVED~~ ELECTRONIC VOTER REGISTRATION

Section

<u>R2-12-601.</u>	<u>Definitions</u>
<u>R2-12-602.</u>	<u>Retention of Electronic Voter Registration Forms</u>
<u>R2-12-603.</u>	<u>Electronic Signatures for Electronic Voter Registration Forms</u>
<u>R2-12-604.</u>	<u>Acceptable Transmitters of Electronic Voter Registration Forms</u>
<u>R2-12-605.</u>	<u>Transfer of Electronic Voter Registration information</u>

ARTICLE 6. ~~RESERVED~~ ELECTRONIC VOTER REGISTRATION

R2-12-601. Definitions

In addition to the definitions provided in A.R.S. §§ 16-101, 16-111, 16-140, and 16-153, unless the context provides otherwise, the following definitions apply to this Article:

1. "Destination county recorder" means the county recorder to which the registrant's voter registration application is delivered.
2. "Electronic signature" is defined in A.R.S. § 41-132.
3. "Electronic voter registration form" means the capture and acknowledgement of statements on behalf of the registrant during the electronic voter registration process. Its contents are substantively the information prescribed by A.R.S. § 16-152.
4. "Electronic voter registration process" means the sequence of events between a registrant and a transmitter beginning with identification of the registrant up to and including submitting the registration information.
5. "Electronic voter registration, statement, or other document" means all data entered into a registration, statement, or other document that is electronically prepared and transmitted to a county recorder.
6. "Identification register" means the index of information containing registrant information maintained by a transmitter.
7. "Registrant" means a person attempting to register to vote.
8. "Transmitter" means an agency who is part of the chain of transmission of an electronic voter registration, statement, or other document from a registrant to a destination county recorder even though the agency did not receive the transmitted registration, statement, or other document directly from the registrant.
9. "Wet signature" means a physically generated signature of a person that can be compared to other physically generated signatures of the person for verification of authenticity.

R2-12-602. Retention of Electronic Voter Registration Forms

- A.** For each electronic voter registration transmitted to the Secretary of State, the Secretary of State shall keep the documents listed in A.R.S. § 16-152(B) until the next General Election or the date a county recorder confirms the registration is received, whichever is later.
- B.** For each electronic voter registration transmitted to a county recorder, the county recorder shall keep the documents listed in A.R.S. § 16-152(A) as specified by A.R.S. § 16-162.

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R2-12-603. Electronic Signatures for Electronic Voter Registration Forms

- A.** To accept the terms of the electronic voter registration process, a registrant shall electronically sign the electronic voter registration form. If a registrant uses an electronic signature, the registrant shall:
1. Declare, under penalty of perjury, that the electronic voter registration form is true, correct, and complete to the best of the registrant's knowledge; and
 2. Signify to the transmitter during the electronic voter registration process to release the electronic voter registration form to the destination county recorder.
- B.** An electronic signature for use on an electronic voter registration form shall be a separate acknowledgement statement authorizing the transmitter to transmit the information to the destination county recorder.
- C.** A registrant may use an electronic signature on an electronic voter registration form if the following conditions are true:
1. The registrant is active in the transmitter's identification register.
 2. The registrant is uniquely identified by name, physical address, and date of birth in the transmitter's identification register.
 3. A digitized image of the registrant's wet signature exists with the transmitter for the purpose of transmitting with the electronic voter registration form to the destination county recorder.
- D.** If a registrant does not electronically sign the registrant's electronic voter registration form, the registrant may complete the voter registration process on paper.

R2-12-604. Acceptable Transmitters of Electronic Voter Registration Forms

- A.** Only the following government agencies may be transmitters:
1. The Department of Transportation,
 2. The county recorders, and
 3. The Secretary of State.
- B.** Each transmitter shall enter into an intergovernmental agreement with the Secretary of State to transmit electronic voter registration information before transmitting electronic voter registration information.

R2-12-605. Transfer of Electronic Voter Registration Information

- A.** The Secretary of State, or its duly authorized third party, shall receive and deliver electronic voter registration information from an accepted transmitter to a destination county recorder.
- B.** A county recorder may:
1. Receive electronic voter registration information updates through the Secretary of State;
 2. Receive paper renditions of the electronic voter registration information on a registration form prescribed by the Secretary of State;
 3. Receive digitized images of the electronic voter registration information in a registration form prescribed by the Secretary of State.
- C.** Information collected to update a registrant's voter registration information may be transmitted electronically if the following conditions are true:
1. A registrant provides information to a transmitter for updating the registrant's name or address in the identification register [pursuant to A.R.S. § 16-112(B)(4)].
 2. The information specified in subsection (C)(1) is received from a transmitter specified in R2-12-604(C).
 3. The information specified in subsection (C)(1) is transmitted in an electronic voter registration format via an electronic manner accepted by the Secretary of State.
 4. The information specified in subsection (C)(1) uniquely identifies an elector of a county recorder's voter registration roll by name and date of birth.
- D.** Information collected for the intent of initial registration to the voter registration rolls may be transmitted electronically if:
1. The information meets the criteria of subsection (C);
 2. The information contains a digitized image of a registrant's wet signature; and
 3. The information has been electronically signed by a registrant to authorize the transmitter to release the electronic voter registration form.
- E.** Voter registration information confidentiality shall be maintained pursuant to A.R.S. § 16-153.
- F.** Driver's license information confidentiality shall be maintained pursuant to A.R.S. § 16-112.

NOTICE OF PROPOSED RULEMAKING

TITLE 3. AGRICULTURE

CHAPTER 2. DEPARTMENT OF AGRICULTURE - ANIMAL SERVICES DIVISION

PREAMBLE

- 1. Sections Affected**

	<u>Rulemaking Action</u>
R3-2-412	New Section
R3-2-413	New Section
R3-2-505	New Section
R3-2-606	Amend
R3-2-614	Amend
R3-2-615	Amend
R3-2-705	Amend
- 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. §§ 3-107(A)(1), 3-1203(B)(1)

Implementing statutes: A.R.S. §§ 3-1204, 3-1205, 3-1207
- 3. A list of all previous notices appearing in the Register addressing the adopted rule:**

Notice of Rulemaking Docket Opening: 7 A.A.R. 5258, November 23, 2001
- 4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**

Name: Sherry D. Blatner, Rules Specialist

Address: Arizona Department of Agriculture
1688 West Adams, Room 235
Phoenix, AZ 85007

Telephone: (602) 542-0962

Fax: (602) 542-5420

E-mail: sherry.blatner@agric.state.az.us
- 5. An explanation of the rule, including the agency's reasons for initiating the rule:**

This rulemaking incorporates by reference amendments to 9 CFR 54, establishing procedures for scrapie eradication, and 9 CFR 79, establishing identification requirements for interstate movement of goats and sheep. Requirements are established for identification of exhibition goats and sheep. Identification of goats and sheep to flock of birth is prescribed for intrastate movement. Language in Article 6 is clarified, health certificate requirements for equine are moved from Section R3-2-615 to Section R3-2-606(A)(7), and rules are modified to conform to the current language standards of the Office of the Secretary of State. Self-inspection requirements in Article 7 are amended to include the new requirement of animal identification to flock of birth.

The rulemaking was initiated to conform Arizona requirements for importation of goats and sheep to updated federal requirements implemented to eradicate scrapie, and to implement these same requirements to intrastate movement which is required within two years for Arizona to retain its designation as a Consistent State.
- 6. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material.**

None
- 7. 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
- 8. The preliminary summary of the economic, small business, and consumer impact:**

A. *The Arizona Department of Agriculture.*

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The Department will incur modest expenses related to training staff and educating the regulated community on the amendments.

B. Political Subdivision.

Other than the Department, no political subdivision is affected by this rulemaking.

C. Businesses Directly Affected By the Rulemaking.

Sheep and goat producers will incur minimal additional expense to individually identify each animal shipped interstate with federally approved methods. USDA-approved tags and applicators are available free of charge from the USDA. Exhibitors of most native Arizona goats and sheep will be required to provide individual identification of their animals. Exhibit officials will be required to verify health and identification documentation as prescribed by rule. Movement of native Arizona goats and sheep will require individual identification of the animals to their flock of birth, except if the first point of commingling is an auction market also acting as the owner's agent.

The Department believes that the added costs of implementing the federal guidelines for scrapie eradication and scrapie flock identification are outweighed by the benefit of enhanced disease prevention, and maintaining the state's classification as a Consistent State.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

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10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

The Department of Agriculture will schedule a public hearing if a written request for a public hearing is made to the person in item #4.

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

None

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

9 CFR 54; 66 FR 43963-44003, August 21, 2001, in R3-2-505

9 CFR 79; 66 FR 43963-44003, August 21, 2001, in R3-2-614

13. The full text of the rules follows:

TITLE 3. AGRICULTURE

CHAPTER 2. DEPARTMENT OF AGRICULTURE

ANIMAL SERVICES DIVISION

ARTICLE 4. ANIMAL DISEASE PREVENTION AND CONTROL

Section

R3-2-412. Exhibition Goats and Sheep

R3-2-413. Goats and Sheep: Intrastate Movement

ARTICLE 5. STATE-FEDERAL COOPERATIVE DISEASE CONTROL PROGRAM

Section

R3-2-505. Scrapie Procedures for Eradication

ARTICLE 6. HEALTH REQUIREMENTS GOVERNING ADMISSION OF ANIMALS

Section	
R3-2-606.	Official Health Certificate
R3-2-614.	Goats and Sheep
R3-2-615.	Equine Importation

ARTICLE 7. LIVESTOCK INSPECTION

Section	
R3-2-705.	Self-inspection for Sheep

ARTICLE 4. ANIMAL DISEASE PREVENTION AND CONTROL

R3-2-412. Exhibition Goats and Sheep

Exhibit officials shall deny entry to any goats and sheep not individually identified by the following:

1. Imported goats and sheep.
 - a. An official health certificate as prescribed in R3-2-606 that includes animal identification as required by 9 CFR 79, which is incorporated by reference at R3-2-614, and
 - b. An import permit as prescribed in R3-2-607.
2. Native Arizona goats and sheep. A method as prescribed in 9 CFR 79.2(a)(2) for non-neutered goats and sheep, and neutered goats and sheep over 18 months of age.

R3-2-413. Goats and Sheep: Intrastate Movement

A. All goats and sheep of any age not in slaughter channels and any sheep over 18 months of age must be identified to their flock of birth prior to leaving that flock, unless:

1. The first point of commingling is an auction market, and
2. The auction market acts as the owner's agent to identify the goats and sheep to their flock of birth.

B. This Section is effective January 1, 2003.

ARTICLE 5. STATE-FEDERAL COOPERATIVE DISEASE CONTROL PROGRAM

R3-2-505. Scrapie Procedures for Eradication

Procedures for scrapie control and eradication in goats and sheep shall be as prescribed in 9 CFR 54: 66 FR 43963-44003, August 21, 2001. This material is incorporated by reference, does not include any later amendments or editions, and is on file with the Department and the Office of the Secretary of State.

ARTICLE 6. HEALTH REQUIREMENTS GOVERNING ADMISSION OF ANIMALS

R3-2-606. Health Certificate

A. A health certificate is valid for not more than 30 days after the date of issue, except where otherwise noted in this Article, and shall contain:

1. The name and address of the shipper and receiver;
2. The origin of shipment;
3. The shipment's final destination;
4. Cattle.
 - a. The number of animals covered by the health certificate, and an accurate description and, except for steers, spayed heifers, or "F" branded heifers consigned to a designated feedlot identified by brand, + one of the following individual identifications:
 - i. The USDA metal eartag number;
 - ii. The registration tattoo number, or
 - iii. The registration brand of a breed association recognized by VS.
 - b. The health status of the animals, including date and result of an inspection, dipping, test, or vaccination required by Arizona; and
 - c. The method of transportation.
5. Swine.
 - a. Evidence that the swine have been inspected within 10 days before the shipment.
 - b. A statement that:
 - i. The swine have never been fed garbage, and
 - ii. The swine have not been vaccinated for pseudorabies.
 - c. Except for feeder swine consigned to a restricted swine feedlot:
 - i. A list of the individual permanent identification for each exhibition swine, using an eartag that conforms to the universal swine-eartag system or for each commercial swine, using other individual identification,

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- and the premises identification using a tattoo or producer-furnished tamper-proof eartag that conforms to the USDA National Premises Identification System;
- ii. The validated brucellosis-free herd number and last test date for swine originating from a validated brucellosis-free herd;
 - iii. The pseudorabies status of the state of origin; and
 - iv. The pseudorabies qualified negative herd number, if applicable.
- d. Except for feeder swine consigned to a restricted swine feedlot, swine moving directly to an exhibition, and swine from a farm of origin in a state recognized by ~~USDA-APHIS~~ APHIS as a pseudorabies Stage V state, a statement that the swine shall be quarantined on arrival and kept separate and apart from all other swine until tested negative for pseudorabies no sooner than 15 days nor later than 30 days after entry.
 - e. Feeder swine consigned to a restricted swine feedlot shall be identified by premises of origin using a tattoo or producer-furnished tamper-proof eartag that conforms to the USDA National Premises Identification System.
6. Sheep and goats. A statement certifying that:
- a. Individual identification as prescribed in R3-2-614;
 - b. A statement that:
 - ~~a-~~ i. The sheep or goats are not infected with bluetongue, nor exposed to scrapie or originate from a scrapie-infected or source flock;
 - b- ii. Breeding rams have been individually examined and are free of gross lesions of ram epididymitis; and
 - c. Documentation of a negative test for Brucella ovis if required by R3-2-614(B).
7. Equine.
- a. Equines shall be individually identified on the health certificate by age, sex, breed, color, name, brand, tattoo, scars, and distinctive markings.
 - b. Documentation of a negative test for EIA, as required in R3-2-615, shall be provided on the health certificate and include:
 - i. The date and results of the test;
 - ii. The name of the testing laboratory; and
 - iii. The laboratory generated accession number.
- B.** Additions, deletions, and unauthorized or uncertified changes inserted or applied to a health certificate renders the certificate void. Uncertified photocopies of health certificates are invalid.
- C.** The veterinarian issuing a health certificate shall certify that the animals shown on the health certificate are free from evidence of any infectious, contagious, or communicable disease or known exposure.
- D.** An accredited veterinarian shall inspect animals for entry into the state.
- E.** The Director may limit the period for which a health certificate is valid if advised of the occurrence of a disease which constitutes a threat to the livestock industry.

R3-2-614. Goats and Sheep

- A.** The owner of goats and sheep entering Arizona, or the owner's agent, shall comply with the requirements of:
- 1. Article 6 and pay the expenses incurred to quarantine, test, and retest the goats and sheep; and
 - 2. Animal identification prescribed in 9 CFR 79; 66 FR 43963-44003, August 21, 2001. This material is incorporated by reference, does not include any later amendments or editions, and is on file with the Department and the Office of the Secretary of State.
- B.** Breeding rams ~~6~~ six months of age and older shall test negative for Brucella ovis within 30 days of entry or originate from a certified brucellosis-free flock.

R3-2-615. Equine Importation

- A.** Except for R3-2-607, equines may enter the state as prescribed in R3-2-602 through R3-2-611.
- B.** Equines shall be individually identified on the health certificate by age, sex, breed, color, name, brand, tattoo, scars, and distinctive markings.
- ~~C.~~ **B.** Equines with fistulous withers or poll evil shall not be imported.
- ~~D.~~ **C.** All equine ~~6~~ six months of age or older shall, using a test established in R3-2-407(A), be tested negative for EIA within 12 months before entry. Testing expenses shall be paid by the owner. ~~The health certificate shall contain:~~
- 1. ~~The date and results of the test;~~
 - 2. ~~The name of the testing laboratory; and~~
 - 3. ~~The laboratory generated accession number.~~

R3-2-705. Self-inspection for Sheep

- A.** An owner or operator applying for a self-inspection certificate book for sheep movement shall obtain an application from the livestock officer or inspector and submit it with the following information to the Department:
- 1. The name, business or home address, telephone number, social security number, and signature of the applicant;
 - 2. The date of the application; and

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3. The signature and badge number of the livestock officer or inspector assigned in the inspection area.
- B.** An owner or operator shall provide the following information on a self-inspection certificate whenever sheep are being moved:
 1. The name, business or home address, telephone number, and signature of the owner;
 2. The date of the shipment;
 3. The name, address, and telephone number of the person purchasing the sheep, if applicable;
 4. The location from which the sheep are being moved;
 5. The name of the trucker;
 6. The location to which the sheep are being moved, including the name of the pasture, auction, exhibit, or slaughter establishment;
 7. The number of sheep being moved; ~~and~~
 8. The brand location and ear marks; and
 9. The flock of birth identification prescribed in R3-2-413.

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TITLE 3. AGRICULTURE

CHAPTER 2. DEPARTMENT OF AGRICULTURE - ANIMAL SERVICES DIVISION

PREAMBLE

1. Sections Affected

Rulemaking Action

R3-2-301	Amend
R3-2-302	Amend
R3-2-401	Amend
R3-2-406	Amend
R3-2-407	Amend
R3-2-601	Amend
R3-2-602	Amend
R3-2-603	Amend
R3-2-604	Amend
R3-2-608	Amend
R3-2-609	Amend
R3-2-610	Amend
R3-2-617	Amend
R3-2-618	Amend
R3-2-620	Amend
Article 10	Amend
R3-2-1002	Amend
R3-2-1003	Amend
R3-2-1010	Amend

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. §§ 3-107(A)(1), 3-1203(B)(1)

Implementing statutes: A.R.S. §§ 3-1205(A), 3-1455, 3-2046, 3-2662, 3-2903, 3-2907, 3-2908

3. A list of all previous notices appearing in the Register addressing the adopted rule:

Notice of Rulemaking Docket Opening: 7 A.A.R. 1776, April 27, 2001

Notice of Rulemaking Docket Opening: 7 A.A.R. 5489, December 14, 2001

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

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Arizona Administrative Register
Notices of Proposed Rulemaking

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

In Article 3, this rulemaking advises operators of beef cattle feedlots that they may be regulated by the Department, as well as the U.S. Environmental Protection Agency and the Arizona Department of Environmental Quality.

In Article 4, definitions are added for "designated feedlot", "equine infectious anemia" or "EIA", and "restricted feeding pen". The definition for "free area" is deleted. R3-2-406 had regulated brucellosis control in feedlots and auction markets, the rule now regulates disease control in feedlots. If an equine tests positive for EIA, the testing laboratory may now also advise the State Veterinarian by means of facsimile.

In Article 6, R3-2-601 expands the definition of "permit number" to be interchangeable with the term "permit". Both phrases have been used interchangeably in the Article. R3-2-618, establishes specific health requirements for a psittacine bird to enter Arizona. R3-2-620(C) includes a reference to the licensing requirements of the Game and Fish Commission for importation and exhibit of zoo animals.

In Article 10, R3-2-1002(A) sets forth the aquaculture licensing fees. R3-2-1010(F) prescribes the circumstances in which an imported aquaculture shipment may be quarantined and/or destroyed.

Generally, this rulemaking clarifies existing language, removes language that is duplicative of information provided in statute, and conforms the rules to the current language standards in use by the Office of the Secretary of State.

This rulemaking evolves from procedural initiatives of the Department and changes proposed by the Division in its last Five-Year Review Report.

6. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material.

None

7. 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

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

A. The Arizona Department of Agriculture.

The Department will incur modest expenses related to training staff and educating the regulated community on the amendments.

B. Political Subdivision.

Other than the Department of Agriculture, this rulemaking will not impact any other political subdivision.

C. Businesses Directly Affected By the Rulemaking

Operators of feedlots will need to become familiar with the new terms set forth in definitions and comply with the requirements of signage and movement of cattle into and out of a restricted feeding pen.

Importers of psittacine birds will need to follow the specific regulations to ensure the health of birds brought into the state.

The Department believes that the costs connected to the implementation of this rulemaking are minor. The benefit to the state in regulating these animal health issues outweighs any related costs.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Sherry D. Blatner
Address: Arizona Department of Agriculture
1688 West Adams, Room 235
Phoenix, AZ 85007
Telephone: (602) 542-0962

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Fax: (602) 542-5420
E-mail: sherry.blatner@agric.state.az.us

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

The Department of Agriculture will schedule a public hearing if a written request for a public hearing is made to the person in item #4.

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

None

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

None

13. The full text of the rules follows:

TITLE 3. AGRICULTURE

**CHAPTER 2. DEPARTMENT OF AGRICULTURE
ANIMAL SERVICES DIVISION**

ARTICLE 3. FEEDING OF ANIMALS

Section

R3-2-301. Operation of ~~beef cattle feedlots~~ Beef Cattle Feedlots
R3-2-302. ~~Requirements for permit to feed garbage to swine~~ Permit to Feed Garbage to Swine: Requirements

ARTICLE 4. ANIMAL DISEASE PREVENTION AND CONTROL

Section

R3-2-401. Definitions
R3-2-406. ~~Bruce~~ Bruce ~~ellosis Disease Control -- ; Feedlots and Auction Markets~~
R3-2-407. Equine Infectious Anemia

ARTICLE 6. HEALTH REQUIREMENTS GOVERNING ADMISSION OF ANIMALS

Section

R3-2-601. Definitions
R3-2-602. ~~Requirements for Importation~~ Requirements
R3-2-603. Importation of Diseased Animals
R3-2-604. ~~Permit Required for Livestock~~ Permit Requirements: Exceptions
R3-2-608. Consignment of Animals
R3-2-609. ~~Diversion~~ Diversion; Prohibitions
R3-2-610. ~~Test -- ; Official Confirmation~~
R3-2-617. Poultry
R3-2-618. Psittacine birds
R3-2-620. Zoo Animals

ARTICLE 10. AQUACULTURE RULES

Section

R3-2-1002. Fees for Licenses; Inspection Authorization and Fees
R3-2-1003. General Licensing Provisions
R3-2-1010. Importation of Aquatic Animals

ARTICLE 3. FEEDING OF ANIMALS

R3-2-301. Operation of ~~beef cattle feedlots~~ Beef Cattle Feedlots

A. Feedlot categories

1. The following categories are established:

- a. Category A: ~~Those feedlots~~ Feedlots located in, or immediately adjacent to, areas where feedlot operations may adversely affect considerable numbers of people, public improvements or safety ~~as determined by the Board.~~

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- b. ~~Category B: Those feedlots which are~~ Feedlots located in rural areas where feedlot operations may adversely affect public improvements or safety, ~~such as highways or streams,~~ but do not affect considerable numbers of people, ~~as determined by the Board.~~
 - c. ~~Category C: Those feedlots~~ Feedlots located in rural areas where feedlot operations do not affect considerable numbers of people or public improvements ~~such as highways, or streams, as determined by the Board.~~
 2. Regarding the determination of categories of feedlots, the ~~Board~~ Department shall assign each feedlot to a specific category in accordance with the above subsection. The assigned categories are reviewable and reassignments may be made by the ~~Board~~ Department.
 3. In addition to the requirements set forth in A.R.S. Title 3, Ch. 11, Article 9 and in this Section, feedlots may be required to comply with the standards prescribed in the U.S. Environmental Protection Agency administered permit program, The National Pollutant Discharge Elimination System, and the Arizona Department of Environmental Quality rule R18-9-403.
- B. Performance and code Standards of operation**
1. Category A feedlots shall:
 - a. ~~Take such steps as necessary and required as determined by the Board, to prevent any~~ Prevent dust from arising and spreading from any feedlot ~~which shall be dangerous that creates a danger to the public health or offensive to the a public generally nuisance.~~
 - b. Use reodorants, deodorants or other ~~effective and economically practical means in the pen area so that to control~~ offensive odors ~~from the feedlots are kept to limits that are determined satisfactory by the Board.~~
 - c. Remove manure and clean all pens at least ~~3~~ three times per year or more often if ~~the need be determined~~ required by the ~~Board~~ Department. ~~In enforcing this provision, consideration shall be given to the effect of inclement weather which might preclude removal.~~
 - d. Keep stacked manure, after removal from pens, to a minimum and in as dry ~~a condition as possible. Where stacking after removal is necessary, the stack shall be kept and handled in as and~~ odor free condition as practical.
 - e. Employ methods of operation ~~which are~~ designed to eliminate stagnant water in feedlots.
 - f. ~~Employ such measures as are necessary for the control of flies and other insects.~~
 2. Category B feedlots shall:
 - a. Remove manure and clean all pens at least ~~once~~ twice a year or more often if ~~need be determined~~ required by the ~~Board~~ Department.
 - b. ~~Take necessary measures to prevent waste water from contaminating streams, ponds, lakes or the underground water table.~~
 - e.b. ~~Take such measures to control~~ Control movement of dust from the feedlot operations ~~as are determined to be necessary by the Board.~~
 3. Category C feedlots shall:
 - a. ~~Take necessary measures to prevent waste water from contaminating streams, ponds, lakes, or the underground water tables.~~
 - b. ~~Remove~~ remove manure and clean all pens at least once a year ~~or more often if required by the Department.~~
- C. Rules procedure**
1. The Board shall hear and decide cases pertaining to feedlot complaints according to the following method:
 - a. ~~Receive complaints regarding feedlots. All complaints shall be in writing signed by complainant and dated.~~
 - b. ~~Make or cause to be made an investigation to determine the conditions that do exist and whether or not the complaint is justifiable. Such investigation shall be commenced within 10 days after receipt of complaint.~~
 - e. ~~Direct the complaint to the proper agency if the matter is outside the jurisdiction of the Board.~~
 - d. If the complaint is within the jurisdiction of the Board, the Board will evaluate the performance of the feedlot according to the standards or codes of operation as they exist at the time of the complaint and take 1 of the following steps:
 - i. ~~Dismiss the complaint if unjustified.~~
 - ii. ~~Issue a written notice to the offending party describing the violation and imposing a reasonable time limit for correction and compliance with the existing standards or codes.~~
 - iii. ~~Consult with the complainant and feedlot operator together with necessary third parties, technical consultants or other members of the community, when inadequate standards exist or where no standards exist, in order to establish requirements which will bring conditions to within limits to the satisfaction of the Board.~~
 - iv. ~~Notify the complainant in writing of final disposition of complaint.~~
 2. The Board shall take such action as is necessary which shall be final and conclusive on all parties served with notice of such action, unless parties filed with Board notice of appeal within 5 days after decision or prior to the expiration of any compliance order, whichever period is shorter.
 3. The Board shall be responsible for enforcement of all performance standards and codes.
 4. The Board shall conduct hearings.

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5. ~~The Board shall maintain records of proceedings including documents, testimony, summary, and decisions of the Board with number of affirmative votes on each decision.~~
6. ~~The Board shall institute regular inspection for all licensed feedlots to see that they are being operated according to Section V of these regulations and make a record of all inspections.~~

R3-2-302. Requirements for permit to feed garbage to swine Permit to Feed garbage to Swine; Requirements

A swine garbage feeding permit ~~holder~~ holder or applicant for a permit to feed garbage to swine must be in compliance with the following requirements:

1. ~~An approved cooker capable of adequately processing garbage as required by law must be installed and in operating condition on the premise premises, and fenced off from all swine.~~
2. ~~An approved~~ A concrete slab, trough, ~~or other equally effective~~ easily cleanable area, ~~or~~ and equipment for feeding garbage must be provided.
3. ~~Premise~~ Premises to be utilized for swine garbage feeding must be reasonably clean, free of litter, adequately drained, and ~~reasonable methods provided~~ provide for removal of animal excrement and garbage not consumed ~~or used~~.
4. Individually operated swine garbage feeding premises must be separated from ~~another other~~ another swine feeding ~~premise~~ premises by a minimum distance of 200 feet in all directions and ~~so~~ constructed to prevent the escape of any swine.

ARTICLE 4. ANIMAL DISEASE PREVENTION AND CONTROL

R3-2-401. Definitions

The following terms apply to this Article:

“Accredited veterinarian” means a veterinarian approved by the State Veterinarian and the Deputy Administrator of VS, APHS, USDA, to perform functions required by cooperative State-Federal animal disease control and eradication programs.

“Biologicals” means medical preparations made from living organisms and their products, including serums, vaccines, antigens, and antitoxins.

“Designated feedlot” means a confined drylot area under state quarantine that is approved and licensed by the State Veterinarian, containing restricted feeding pens, and is maintained for finish feeding of cattle or bison that do not meet the brucellosis or tuberculosis import test requirements.

“Equine infectious anemia” or “EIA” means a viral disease, also known as Swamp Fever, of members of the family equidae.

“Free area” means a feedlot pen that is separate from all restricted feeding pens, and all facilities and equipment used in the free area are separate from all facilities and equipment used in a restricted feeding pen.

“Restricted feeding pen” means a confined area in a designated feedlot, located at least eight feet from other pens, where cattle are maintained for feeding in a drylot without provisions for pasturing or grazing.

R3-2-406. ~~Brucellosis Disease Control~~; Feedlots and Auction Markets

A. ~~Brucellosis rules and regulations governing feedlots~~

1. ~~Free Area feed pens or lots~~ Restricted feeding pens shall be areas which are isolated from all other ~~quarantined~~ feed pens, ~~having~~ have separate loading and unloading chutes, alleys and handling facilities. They must not share water or feeding facilities accessible to ~~quarantine~~ other areas. They must be posted at all corners with permanently affixed signs stating “Free Area” “Restricted Feeding Area” ~~and contain only free area cattle.~~ There must be a minimum of eight feet between ~~quarantined~~ restricted and ~~free area other pens and facilities,~~ no common fences or gates may be used, and this area cannot be used for the handling of cattle.
 - a. ~~Cattle in free area pens or lots must retain their identity and be documented as such cattle.~~
 - b. ~~To enter free area pens or lots, they must comply with 1 of the following:~~
 - i. ~~Native Arizona cattle properly identified as non-quarantined cattle with Arizona brand inspection certificate.~~
 - ii. ~~Imported steers which are accompanied by a permit number and an official health certificate.~~
 - iii. ~~Imported beef breed calves under 6 months of age properly identified and accompanied by a permit number and official health certificate.~~
 - iv. ~~Imported dairy cattle or beef breeding cattle going into free area feedlots or pens must comply with Arizona importation regulations and be accompanied by a permit number and an official health certificate showing proper identification.~~
 - e. ~~Free area feed pens or lots shall not handle improperly identified cattle or cattle whose health status is questionable.~~
 - d. ~~Any violation will remove the facilities from free area to quarantine status.~~
2. ~~A quarantined feedlot shall be a confined area where cattle are maintained for feeding in a drylot without provisions for pasturing or grazing, except for small contiguous green pastures isolated as is the said feedlot.~~

B. Requirements for cattle to enter and leave a restricted feeding pen are:

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1. All cattle, except steers and spayed heifers, shall be identified with an "F" brand, at least two inches in height, on the jaw or adjacent to the tailhead prior to entering the pen.
- ~~a.2.~~ Imported cattle, any age and from any area may enter if accompanied by a permit number and an official health certificate, ~~no brucellosis or tuberculosis testing required.~~
- ~~b.3.~~ Any native cattle accompanied by an Arizona livestock inspection certificate.
- ~~e.4.~~ All animals, except steers and spayed heifers, ~~leaving such feedlot~~ shall ~~move~~ be moved only to slaughter, another quarantined designated feedlot or a specifically approved auction market for sale to slaughter.
5. Steers and spayed heifers may be moved anywhere.

B. Brucellosis rules and regulations governing auction sales

1. ~~Free Area Pens shall be located so they are isolated from all other pens, having separate loading and unloading chutes, alleys and handling facilities. They must not contain any common water or feeding facilities which are accessible to quarantine pens. Only free area cattle are allowed in these pens. All cattle in these pens must be identified and retain their identity as long as they remain in this area.~~
 - a. ~~Cattle requirements to enter free area pens and facilities are:~~
 - i. ~~Native Arizona cattle which are properly identified as non-restricted cattle with an Arizona livestock inspection certificate.~~
 - ii. ~~Imported steers accompanied by a permit number and official health certificate.~~
 - iii. ~~Imported beef breed calves under 6 months of age properly identified and accompanied by a permit number and an official health certificate.~~
 - iv. ~~Imported dairy or beef breeding cattle must comply with Arizona importation regulations and show proper identification.~~
 - b. ~~Any violation will remove the facilities from free area to quarantine status.~~
2. ~~Quarantined pens shall be a confined area where cattle are maintained away from all free area facilities. They shall contain their own loading and unloading chutes, with separate driving alleys and handling facilities.~~
 - a. ~~These pens must be so identified by signs on gates and corners of total quarantine area.~~
 - b. ~~Quarantine cattle are to be sold after the free area cattle have all been sold.~~
 - c. ~~The sale ring is to be cleaned and disinfected before the next sale date.~~

R3-2-407. Equine Infectious Anemia

- A. The Arizona official test for EIA equine infectious anemia, known as Swamp Fever or EIA, is either the agar-gel immunodiffusion test, known as the Coggins Test, or the Competitive Enzyme-Linked Immunosorbent Assay test, known as the CELISA test. The test shall be performed in a laboratory approved by APHIS and required samples shall be drawn by an accredited veterinarian, the State Veterinarian, the State Veterinarian's designee, or ~~a USDA~~ an APHIS veterinarian.
- B. Disposal of equine testing positive.
 1. When an Arizona equine tests positive to EIA, the testing laboratory shall immediately notify the State Veterinarian by telephone or facsimile.
 2. The EIA-positive equine shall be quarantined to the premises where tested, segregated from other equine, and shall not be moved unless authorized by the State Veterinarian. The equine shall be retested by the State Veterinarian, the State Veterinarian's designee, or ~~a USDA~~ an APHIS veterinarian within 2 two weeks of the notification.
 3. Within 14 days of being notified by the testing laboratory of a positive test conducted under subsection (B)(2), the State Veterinarian or the State Veterinarian's designee shall brand the equine on the left side of its neck with "86A" not less than 2 two inches in height.
 4. Within 10 days after being branded, the EIA-positive equine shall be:
 - a. ~~Humanely destroyed, or~~
 - b. Confined to a screened stall marked "EIA Quarantine" that is at least 200 yards from other equine, or
 - c. Consigned to slaughter at a slaughtering establishment. If consigned to slaughter, the equine shall be accompanied by a Permit for Movement of Restricted Animals, VS 1-27, issued by the State Veterinarian, the State Veterinarian's designee, or ~~a USDA~~ an APHIS veterinarian.
 5. Offspring of mares testing EIA-positive shall be quarantined, segregated from other equine, and tested at 6 six months of age. Offspring testing positive shall be handled as prescribed in ~~subsection~~ subsections (B)(3) and (B)(4).
 6. If an EIA-positive equine is located on premises other than those of the owner at the time a quarantine under this Section is effective, the State Veterinarian may authorize movement of the EIA-positive equine to the owner's premises. If the owner lives in another state, the owner may move the equine to that state with the permission of the Chief livestock health official of the state and ~~USDA~~ APHIS.
- C. The State Veterinarian ~~shall~~ may require testing of any equine located in the same facility as the EIA-positive equine or any equine considered exposed to the EIA-positive equine. The owner of the equine shall pay the expenses for the testing.
- D. The owner of any equine found to be positive for EIA-positive shall not be indemnified by the state for any loss caused by the destruction ~~and~~ or loss of value of the equine.

ARTICLE 6. HEALTH REQUIREMENTS GOVERNING ADMISSION OF ANIMALS

R3-2-601. Definitions

The following terms apply to this Article:

1. "Animal" means livestock, feral swine, ratite, bison, water buffalo, oxen, llama, and any exotic mammal not regulated as restricted live wildlife by the Arizona Game and Fish Department.
2. "Breeding swine" means any swine having the potential to breed, and includes gilts, sows, and boars.
3. "Cervidae" means a family of cervids that includes deer, moose, elk, reindeer, and caribou.
4. "Dairy cattle" means cattle of dairy breeds or dairy types used for the production of milk or milk products for human consumption.
5. "Designated feedlot" means a confined drylot area under state quarantine that is approved and licensed by the State Veterinarian, containing restricted feeding pens, and is maintained for finish feeding of cattle or bison that do not meet the brucellosis or tuberculosis import test requirements.
6. "Health certificate" means a legible record that is issued by a VS animal health official, state animal health official, or accredited veterinarian at the point of origin of a shipment of animals, conforms to the requirements of R3-2-606, and is written on a form approved by the chief animal health official of the state of origin or an equivalent form of the USDA attesting that the animal described has been inspected and found to meet the Arizona entry requirements.
7. "Macaque" means any monkey of the genus *Macaca* in the family *Ceropithecidae*.
8. "Permit number" or "permit" means a serialized number issued by the State Veterinarian's Office that conforms to the requirements of R3-2-607 and allows the regulated movement of certain animals into Arizona.
9. "Specifically approved stockyard" means a stockyard specifically approved by VS and the State Veterinarian for receiving from other states cattle and bison that are not brucellosis-reactor, brucellosis-suspect, or brucellosis-exposed cattle or bison.

R3-2-602. Requirements for Importation Requirements

Unless otherwise specifically provided in this Article, all animals and poultry transported or moved into the state of Arizona must be accompanied by an official health certificate from the state of origin or a permit, or both, which must be attached to the waybill or be in the possession of the driver of the vehicle or person in charge of the animals. When a single health certificate and permit number is issued for animals being moved in more than ~~±~~ one vehicle, the driver of each vehicle shall ~~have in his possession~~ retain the original or a certified copy of the health certificate and permit number. (See R3-2-606(B).)

R3-2-603. Importation of Diseased Animals

- A. No animals affected with or ~~which have been~~ recently exposed to any infectious, contagious or communicable disease, or which originate in a state or ~~federally quarantined~~ federal quarantine area, may be transported or moved into the state of Arizona unless a permit for such entry is first obtained from the Arizona State Veterinarian's Office. ~~In addition, all~~ All conditions for the movement of animals from a quarantined area established by the quarantining authority or ~~U.S. Department of Agriculture~~ APHIS must also be met.
- B. If any animal in a lot presented for shipment or movement into Arizona shows a suspicious or positive reaction to any test required for admission to Arizona, no animal from that lot or from the herd in which the animal reacting to the test originates may enter the state of Arizona without ~~special~~ prior permission from the State Veterinarian ~~or his agent~~.

R3-2-604. Permit Required for Livestock Permit Requirements: Exceptions

- A. Livestock may not enter the state of Arizona unless accompanied by an Arizona permit. This requirement applies regardless of the species, breed, sex, class, age, point of origin, place of destination, or purpose of the movement of the livestock entering the state.
- B. Exceptions:
 1. Horses, mules and asses.
 2. Livestock consigned directly to slaughter at ~~an approved~~ a state or federally licensed slaughter establishment.

R3-2-608. Consignment of Animals

- A. All animals transported or moved into the state of Arizona must be consigned to or in the care of an Arizona resident, or to ~~a legal an entity and address authorized by law~~ to do business in the state of Arizona. ~~(Excluding exhibition or show animals.)~~
- B. Exceptions:
 1. Exhibition, or
 2. Show animals.

R3-2-609. Diversions Diversion: Prohibitions

No person consigning, transporting, or receiving animals into the state of Arizona may authorize, order or carry out diversion of ~~such the~~ animals to a destination or consignee other than as set forth on the health certificate or and permit, if required, without first obtaining permission from the State Veterinarian ~~of Arizona authorizing such diversion~~.

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R3-2-610. Tests -- Official Confirmation

All tests of animals required by Arizona or federal authorities as a condition for entry into Arizona must be ~~made performed~~ or confirmed by state or federal animal diagnostic laboratories, or labs approved by APHIS.

R3-2-617. Poultry

The ~~Livestock Board~~ Department has no entry requirements on poultry provided they are apparently healthy, ~~and~~ do not originate from a poultry quarantine area, and comply with all interstate requirements of ~~A.P.H.I.S. of the U.S.D.A.~~ APHIS.

R3-2-618. Psittacine Birds

~~Psittacine birds entering Arizona must comply with import regulations of the United States Public Health Service and not originate from a quarantined area.~~

A psittacine bird shall be accompanied by a health certificate issued by an accredited veterinarian within 30 days of entry, certifying:

1. The bird is not infected with Chlamydia psittaci, and
2. The bird was not exposed to birds known to be infected with avian chlamydiosis within the past 30 days.

R3-2-620. Zoo Animals

A. Zoo animals may be transported or moved into the state of Arizona when accompanied by an official health certificate, consigned to a zoo, in the charge of a circus or show ~~arrangement, etc., so long as~~ if importation produces no undue hazard to livestock or public health.

B. Animals in "Petting Zoos" ~~shall have been tested~~ require a negative test for tuberculosis within ~~the past~~ 12 months prior to importation.

C. Businesses transporting and exhibiting zoo animals must be licensed by the Arizona Game and Fish Department.

ARTICLE 10. AQUACULTURE RULES

R3-2-1002. Fees for Licenses; Inspection Authorization and Fees

A. License fees are established as follows:

1. Aquaculture facility: \$100 annually.
2. Fee fishing facility: \$100 annually.
3. Aquaculture processor: \$100 annually.
4. Aquaculture transporter: \$100 annually.
5. Special licenses: \$10 annually.

~~A.B.~~ An expired license may be renewed within 90 days following after expiration by payment of an additional \$50.00 a \$50 late fee.

~~B.C.~~ Upon request of the licensee, the Department may certify that a facility is free from restrictive infectious diseases and causative agents listed in R3-2-1009 prior to issuing a certificate of aquatic health Certificate of Aquatic Health pursuant to R3-2-1009. The Department may deputize certified inspectors, pursuant to A.R.S. § 3-2905(B), to perform the certification inspection on the Department's behalf. All expenses properly incurred in the certification procedure of the inspection, including but not limited to time, travel and laboratory expenses, shall be paid to the Department by the licensee requesting certification prescribed in A.R.S. § 3-2905(B).

R3-2-1003. General Licensing Provisions

A. Applicants for a license to operate an aquaculture facility, a fee fishing facility, or to operate as an aquaculture processor or aquaculture transporter shall provide the following information on a form furnished by the Department:

1. Whether the application is for an individual, corporation, partnership, cooperative, association, or other type of organization.
2. The name and address of the licensee.
3. Corporations shall specify the date and state of incorporation.
4. The principal name of the business, and all other business names which may be used.
5. The name, mailing address, and telephone number of the licensee's authorized agent.
6. The street address or legal description of the location of the facility to be licensed.
- ~~7. Gross sales for the year prior to application.~~
- ~~8.~~ 7. The signature of the person designated in subsection (A)(5), and the date the application is completed for submission to the Department.

B. The licensee shall advise the Department in writing of any change in the information provided on the application during the license year. This information shall be provided within 30 calendar days of the change.

C. ~~To ensure compliance with~~ prevent the spread of diseases and causative agents listed in R3-2-1009, the Department may inspect and take samples from any facility or shipment being transported. A licensee aware of the presence of any disease or causative agent as set forth listed in R3-2-1009 shall notify the Department within 72 hours. Aquatic animals found to be infected are prohibited from interstate or intrastate movement without prior written Department approval.

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- D. The Department may quarantine or seize aquatic animals, alive or dead, plants, or products for examination or diagnostic study when there is a potential for spread of a disease or causative agents as prescribed agent listed in R3-2-1009, or any other disease or causative agent that could constitute a threat to aquatic animals or plants of the state. The Department shall issue a written notice to the licensee specifying:
 - 1. The reason for the ~~Department~~ Department's action; and
 - 2. The licensee's ~~responsibilities, obligations, and options to the action~~ right to request a hearing as prescribed in A.R.S. § 3-2906.
- E. All quarantined aquatic products and quarantined areas shall be conspicuously marked by the licensee in a manner specified by the Department.
- F. Diagnostic, quarantine, and destruction costs shall be at the expense of the licensee.
- G. When all conditions are satisfactorily met, the Department shall grant the license and assign a Department establishment number identifying each facility.
- H. All licenses, ~~except special licenses~~, expire on December 31 for the year issued.

R3-2-1010. Importation of Aquatic Animals

- A. Live aquatic animals imported into the state shall be accompanied by the following:
 - 1. A Certificate of Aquatic Health as defined in R3-2-1001, based upon ~~a physical~~ an inspection of the originating facility within the 12 months preceding the shipment;
 - 2. ~~Transporter~~ A transporter license issued pursuant to R3-2-1007; and
 - 3. ~~Import~~ An import permit number issued by the Department pursuant to this rule, legibly written or typed on the certificate of aquatic health.
- B. Imported live aquatic animals must be consigned to or in the care of an Arizona resident or legal entity licensed by the Department, ~~or a holder of an aquatic wildlife stocking permit issued by the Arizona Game and Fish Department,~~ or a holder of a license issued by the Arizona Game and Fish Department.
- C. An import permit number may be obtained from the Department, Office of the State Veterinarian, by providing the following information:
 - 1. Consignor's name, address, and telephone number;
 - 2. Consignee's name, address, and telephone number;
 - 3. Consignee's Department establishment number issued by the Department or a copy of an aquatic wildlife stocking permit or the permit number issued by the Arizona Game and Fish Department;
 - 4. Origin of the shipment;
 - 5. Genus, species and common name of aquatic animals to be imported; and
 - 6. Quantity and size classification of aquatic animals to be imported.
- D. The import permit number shall remain valid for 15 calendar days from the date of issuance by the Department.
- E. The Department may refuse entry to any shipment not in compliance with this rule.
- F. The Department may quarantine and require destruction of any shipment, after its arrival, that is determined to be infected with or previously exposed to any causative agent or disease listed in R3-2-1009.

NOTICE OF PROPOSED RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 6. DEPARTMENT OF HEALTH SERVICES

COMMUNICABLE DISEASES

PREAMBLE

1. Sections Affected

R9-6-101
R9-6-102
R9-6-103
R9-6-104
R9-6-202
R9-6-308
R9-6-309
R9-6-323
R9-6-330
R9-6-331

Rulemaking Action

Amend
Amend
Amend
Repeal
Amend
Amend
Amend
Amend
Amend
Amend

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R9-6-360	Amend
Article 4	Amend
R9-6-401	Renumber
R9-6-401	New Section
R9-6-402	Renumber
R9-6-402	Amend
R9-6-403	Renumber
R9-6-403	Amend
R9-6-404	Renumber
R9-6-404	Amend
R9-6-405	Renumber
R9-6-405	Amend
R9-6-406	Renumber
R9-6-406	Amend
R9-6-407	Repeal
R9-6-407	Renumber
R9-6-407	Amend
R9-6-408	Renumber
R9-6-408	New Section
R9-6-409	Renumber
R9-6-409	Amend
Exhibit A	Renumber
Exhibit B	Renumber
R9-6-410	Renumber
Article 9	New Article
R9-6-901	New Section
R9-6-902	Renumber
R9-6-902	Amend
Exhibit A	Renumber
Exhibit A	Amend
Exhibit B	Renumber
Exhibit B	Amend

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. §§ 36-136(A)(7), 36-136(F)

Implementing statutes: A.R.S. §§ 8-341(Q), 13-1210, 13-1415, 32-1483, 36-136(H)(1), 36-136(H)(14), 36-136(H)(15), 36-136(L), 36-663, 36-664(K)

3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 7 A.A.R. 1385, March 30, 2001

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

Name: Judy A. Norton
Address: Arizona Department of Health Services
Office of HIV/STD
3815 N. Black Canyon Highway
Phoenix, AZ 85015
Telephone: (602) 230-5840
Fax: (602) 230-5973
E-mail: jnorton@hs.state.az.us

or

Name: Kathleen Phillips
Address: Arizona Department of Health Services
Office of Administrative Rules
1740 W. Adams, Room 102

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Phoenix, AZ 85007

Telephone: (602) 542-1264

Fax: (602) 364-1150

E-mail: kphilli@hs.state.az.us

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

In December 1999, the Department completed a five-year review report for 9 A.A.C. 6. The five-year review report was approved by the Governor's Regulatory Review Council in March 2000. As a result of the review process, the Department identified a number of changes that needed to be made in 9 A.A.C. 6. The Department also determined that those changes should be made in three separate rule packages. This is the first of those rule packages.

This rule package amends the general definitions Section within Article 1 and the definitions Sections for Articles 2 and 3, which shall remain in Article 1 until the third rule package, to implement the changes recommended in the five-year-review report. This rule package also repeals the definitions Section for Article 4 that is currently located in Article 1 and replaces it with a new definitions Section within Article 4.

In Article 2, this rule package clarifies the clinical laboratory reporting requirement for HIV and adds a clinical laboratory reporting requirement for laboratory findings of CD₄-T-lymphocyte counts of fewer than 200 per microliter of whole blood or CD₄-T-lymphocyte percentages of total lymphocytes of less than 14%. The addition of this reporting requirement is consistent with the Centers for Disease Control and Prevention's definition of AIDS and will improve the Department's ability to track the number of AIDS cases in Arizona.

In Article 3, this rule package amends the Sections that pertain to sexually transmitted diseases by describing required treatment; eliminating use of the terms "suspect case", "suspect carrier", and "special control measure"; eliminating the requirement to obtain a waiver when a parent refuses administration of antibiotic eye ointment to a newborn to prevent gonorrheal ophthalmia; updating the material incorporated by reference in R9-6-331; clarifying the rules; and conforming the rules to current rulemaking format and style requirements. In addition, the Department is eliminating the requirement that local health agencies obtain identification and assure notification of individuals who may have been exposed to chlamydia infection or gonorrhea through sexual contact with a case. Rather, the diagnosing health care provider shall counsel the case about the importance of notifying such individuals of possible exposure and of the need to seek treatment. Then, if such an individual seeks treatment from the local health agency, the local health agency shall offer or arrange for treatment. The Department is changing the notification requirement to a counseling requirement because of the number of annual cases of chlamydia infection and gonorrhea. In a typical year, more than 11,000 cases of chlamydia infection and more than 4,000 cases of gonorrhea are reported in the State of Arizona. Local health agencies have been unable to comply with the rules as written, because to do so would be overly burdensome. For the same reasons, the rules eliminate the requirement that the local health agency conduct an epidemiologic investigation of each case of chlamydia infection or gonorrhea. To ensure that follow-up is provided where needed, the chlamydia infection and gonorrhea rules add a requirement that the Department review each case report for completeness, accuracy, and the need for follow-up.

The Department is removing the parental waiver requirement in the gonorrhea rule because it is not really a case control measure, but rather serves to protect the individual attending a birth from liability. Thus, it is more appropriate to leave the issue of obtaining a waiver to the discretion of the individual attending a birth.

This rule package divides the current Article 4 into 2 Articles. The revised Article 4 includes only the rules pertaining to the AIDS Drug Assistance Program (ADAP), and the new Article 9 includes only the rules pertaining to HIV-related testing. Article 4 is thus redesignated "AIDS Drug Assistance Program (ADAP)," and the new Article 9 is named "HIV-Related Testing."

The rules for ADAP are revised to clarify the rules; to update the program due to changes in drug therapy, HIV-related testing, and other areas; to add time-frames for the application process; and to conform to current rulemaking format and style requirements.

The rules concerning HIV-related testing, which are moved from Article 4 to the new Article 9, are amended to reflect statutory change; to update information in the Exhibits; to reflect changes in HIV-related testing; to clarify the rules; and to conform to current rulemaking format and style changes.

6. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material:

Not applicable

7. 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

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

The Department anticipates that the proposed rule changes in Article 2 will minimally¹ burden clinical laboratories, which will newly be required to report CD₄-T-lymphocyte counts of fewer than 200 per microliter of whole blood or CD₄-T-lymphocyte percentages of total lymphocytes of less than 14%. Because clinical laboratory directors are already required by Article 2 to make regular reports of numerous laboratory results, the addition of this reporting requirement should result in only a minimal burden. The clarification of the HIV reporting requirement should result in a minimal benefit to clinical laboratories because it should resolve any existing confusion about what HIV-related test results are required to be reported.

[¹As used in this Summary, minimal means less than \$1,000, moderate means between \$1,000 and \$9,999, and substantial means \$10,000 or greater.]

The Department anticipates that the proposed rule changes in Article 3 will substantially benefit local health agencies and minimally benefit and minimally burden health care providers. Specifically, the changes to the rules for chlamydia infection and gonorrhea should benefit local health agencies. The current rules require local health agencies to notify all identified individuals potentially exposed through sexual contact with a case and to offer or arrange for treatment. The proposed rules do not require local health agencies to provide this notification. Instead, the proposed rules require the diagnosing health care provider to counsel the case about the importance of notifying individuals who may have been exposed through sexual contact of their possible exposure and of the need to seek medical treatment. The current rules also require the local health agency to conduct an epidemiologic investigation of each reported case of chlamydia infection or gonorrhea. The proposed rules eliminate this requirement as well. Because there are more than 11,000 cases of chlamydia and more than 4,000 cases of gonorrhea reported in a typical year, the changes in the chlamydia rule should result in a substantial benefit and the changes in the gonorrhea rule should result in a substantial benefit to local health agencies.

Diagnosing health care providers should incur a minimal cost per case as a result of the new requirement to counsel each case of chlamydia infection or gonorrhea about the importance of notifying individuals who may have been exposed through sexual contact of their exposure and of the need to seek treatment. The Department believes that this information is likely already provided by diagnosing health care providers. But, even for those diagnosing health care providers who do not already provide this information, the new requirement will result in only a few additional moments spent counseling each case.

The Department will incur at most a minimal cost per case as a result of the requirement to review each case report of chlamydia infection or gonorrhea for completeness, accuracy, and the need for follow-up. In reality, although not required to do so by the rules, the Department has been conducting reviews of these case reports for some time.

In addition, the proposed rules will no longer require a physician or other individual attending a birth to obtain a parental waiver if a parent refuses administration of antibiotic eye ointment to the newborn to prevent gonorrheal ophthalmia. This could result in a minimal benefit for each health care provider or midwife who attends births, because these individuals will no longer be required to take the time to have the waiver completed. Realistically, however, the Department anticipates that, due to liability concerns, many of these individuals may choose to obtain a waiver even if it is not required.

The proposed changes to the counseling requirements for a case with herpes genitalis may result in a minimal additional burden per case for diagnosing health care providers. The proposed rules require that a case be informed of treatment options and chemoprophylaxis and other measures to prevent transmission. This may take several minutes more than was spent previously in counseling a case. It is likely, however, that this information was already being provided in spite of its not being required by the rules.

In the proposed HIV rule, ethnicity is added as a field of epidemiological information to be collected from individuals who opt for anonymous testing. The addition of this field should result in a minimal burden for anonymous testing subjects, who will have to check an additional box on a form. The change may also result in a minimal burden for each anonymous testing site, because the forms currently used may have to be changed to add ethnicity.

In addition, the proposed HIV rule updates the material incorporated by reference as the standard for school district personnel who handle blood or bodily fluids. The new reference costs \$27 in hard copy or \$12 in microfiche. Each school district will thus be minimally impacted by the need to purchase at least one copy of the reference.

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The renaming of Article 4 should minimally benefit each individual interested in the AIDS Drug Assistance Program (ADAP) because the rules will be easier to find². Previously, the name of the program itself did not appear in the rules, and the rules for ADAP were combined in an Article that also included HIV-related testing provisions and Exhibits.

[²In June 2001, ADAP had 1,025 enrolled individuals, provided services to 716 enrolled individuals, and enrolled 44 individuals. The average amount ADAP expended for each of the 716 individuals was \$745. These numbers fluctuate from month to month, and individuals cycle into and out of ADAP as their eligibility changes. It is impossible to estimate how many additional individuals might be interested in applying for ADAP.]

The proposed rules for Article 4 revise the ADAP rules by eliminating the waiting list for ADAP, which should result in a minimal-to-moderate benefit to the Department due to a savings in administrative time spent maintaining the waiting list. Additionally, the proposed rules will benefit individuals who may have believed that they were ineligible for ADAP because the current rules state specific dollar amounts for maximum income and specific HIV-related conditions or test results necessary to be eligible. The proposed rules reflect the eligibility standards currently used by ADAP for income and HIV status: 300% of the federal poverty level and a medical diagnosis of HIV disease or infection.

The proposed rules also reflect the changes made to ADAP as the result of a July 2000 policy issued by the United States Department of Health & Human Services, HIV/AIDS Bureau, requiring Ryan White CARE Act grant recipients to provide benefits to American Indians or Alaska Natives who are otherwise eligible for program benefits even if those individuals could obtain the same benefits through Indian Health Services. The economic impact of these changes is not the result of the rules, but rather is the result of the federal policy.

Each ADAP applicant or enrolled individual may also realize a minimal benefit from the use of the term “primary care provider” rather than “physician” for purposes of diagnosis, completion of forms, and prescription of drugs for ADAP participation. The proposed rules reflect the Department’s awareness that an individual’s primary care provider is not always a physician, but may be a registered nurse practitioner or a physician assistant.

The proposed ADAP rules also require the primary care provider portion of the follow-up application to be completed only after every 24 months of continuous enrollment, rather than every six months as is currently required. This could save each individual enrolled for a continuous 24-month period three special trips to the primary care provider just to complete follow-up applications and would also save each primary care provider the time of doing that portion of the follow-up application on those three occasions, resulting in a minimal benefit to the primary care provider for each patient enrolled in ADAP and to each individual enrolled in ADAP. Additionally, the proposed rules allow submission of the most recent HIV-related tests rather than requiring submission of specific HIV-related tests. This may minimally benefit each individual applying for or enrolled in ADAP who thus may not pay for a test that was previously required for ADAP but that otherwise would not have been ordered.

Also, rather than having an eligibility determination last for only one year, the proposed ADAP rules have an eligibility determination last indefinitely, based on submission of a follow-up application and current proof of income after every six months and of the primary care provider portion of the follow-up application after every 24 continuous months. This will result in a minimal benefit to each enrolled individual and a minimal-to-moderate benefit to the Department, because less paperwork will be required to remain eligible for and to administer ADAP. In the same vein, the proposed rules will no longer limit a prescription to a one-month supply with five refills. Rather, the proposed rules do not limit the number of refills and require that the prescription be written for the quantity in the manufacturer’s original packaging. This should be more convenient for each primary care provider and enrolled individual and for the Department and should minimally benefit each.

Finally, the proposed ADAP rules add a time-frames Section and expressly require ADAP to comply with the Administrative Procedure Act (APA) rather than the appeals Section, which is being repealed. The addition of time-frames will result in a moderate burden on the Department. ADAP has not always provided notice in writing and will now do so. The repeal of the appeals Section should not burden any party, because ADAP was already following the APA for appeals.

The creation of a new Article 9 for HIV-Related Testing should minimally benefit individuals who seek to use these rules. It was difficult to find the rules in Article 4 because they were located at the end of the Article, which primarily dealt with ADAP, not HIV-related testing. The proposed rule changes to the consent Section and to the Exhibits should not result in any economic impact other than the need for individuals who order HIV-related tests to copy and use the revised Exhibits. This cost should be minimal for each individual who orders tests.

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The changes to the Section on court-ordered HIV-related testing should result in a minimal economic benefit to clinical laboratories that run HIV-related tests, to health care providers that order HIV-related tests, and to individuals who pay for HIV-related tests. Rather than requiring use of the enzyme immunoassay test, a retest of reactive blood in duplicate, and a test of repeatedly reactive blood with the Western blot test, the proposed rules allow use of any licensed test for HIV screening and require retesting of a repeatedly reactive sample with a licensed supplemental or confirmatory test or as recommended by the original test manufacturer's package insert. This gives health care providers who order HIV-related tests and clinical laboratories that run HIV-related tests a great deal of freedom in the tests that are used and should also allow the individuals paying for HIV-related tests some choice in the tests used. Additionally, the proposed rule will allow testing of bodily substances other than blood, thereby permitting use of additional tests and of new technologies as they are licensed by the FDA.

The Department will incur the costs of the rulemaking process, which are moderate.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact summary:

Name: Judy A. Norton
 Address: Arizona Department of Health Services
 Office of HIV/STD
 3815 N. Black Canyon Highway
 Phoenix, AZ 85015
 Telephone: (602) 230-5840
 Fax: (602) 230-5973
 E-mail: jnorton@hs.state.az.us

or

Name: Kathleen Phillips
 Address: Arizona Department of Health Services
 Office of Administrative Rules
 1740 W. Adams, Room 102
 Phoenix, AZ 85007
 Telephone: (602) 542-1264
 Fax: (602) 364-1150
 E-mail: kphilli@hs.state.az.us

10. The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

The Department has scheduled the following oral proceedings:

Date:	January 22, 2002	January 23, 2002	January 24, 2002
Time:	9:30 a.m.	9:00 a.m.	12:30 p.m.
Location:	Tucson State Complex Room 222 400 W. Congress Tucson, AZ 85701	Arizona Department of Health Services Division of Assurance and Licensure Services Hearing Room 1647 E. Morten Ave. Phoenix, AZ 85020	Flagstaff City/Coconino County Public Library Program Room 300 W. Aspen Flagstaff, AZ 86001
Nature:	Oral Proceeding	Oral Proceeding	Oral Proceeding

Written comments on the proposed rulemaking or the preliminary economic, small business, and consumer impact summary may be submitted to the individuals listed in items #4 and #9 until the close of record at 5:00 p.m. on January 24, 2002.

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

Not applicable

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

R9-6-331: Elizabeth A. Bolyard et al., *Guideline for Infection Control in Health Care Personnel*, 1998 (1998)

13. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 6. DEPARTMENT OF HEALTH SERVICES

COMMUNICABLE DISEASES

ARTICLE 1. DEFINITIONS

Section

- R9-6-101. General Definitions
R9-6-102. Communicable Disease Control
R9-6-103. Control Measures for Communicable Diseases
R9-6-104. ~~Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS)~~ Repealed

ARTICLE 2. COMMUNICABLE DISEASE REPORTING

Section

- R9-6-202. Special Reporting Requirements

ARTICLE 3. CONTROL MEASURES FOR COMMUNICABLE AND PREVENTABLE DISEASES

Section

- R9-6-308. Chancroid (*Haemophilus ducreyi*)
R9-6-309. Chlamydia Infection
R9-6-323. Gonorrhea
R9-6-330. Herpes Genitalis
R9-6-331. Human Immunodeficiency Virus (HIV) Infection and Related Disease
R9-6-360. Syphilis

ARTICLE 4. ~~HUMAN IMMUNODEFICIENCY VIRUS (HIV) / ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)~~ AIDS DRUG ASSISTANCE PROGRAM (ADAP)

Section

- R9-6-401. Definitions
~~R9-6-401~~~~R9-6-402.~~ Limitations and Termination of Program
~~R9-6-402~~~~R9-6-403.~~ Eligibility
~~R9-6-403~~~~R9-6-404.~~ Application Process
~~R9-6-404~~~~R9-6-405.~~ Enrollment Process
~~R9-6-405~~~~R9-6-406.~~ Continuing Enrollment
~~R9-6-407.~~ Appeal
~~R9-6-406~~~~R9-6-407.~~ Distribution Requirements
R9-6-408. Time-frames
~~R9-6-409.~~ Consent for HIV-related Testing
~~R9-6-408~~~~R9-6-409.~~ Confidentiality
Exhibit A. Consent for HIV Testing Renumbered
Exhibit B. Consentimiento Para la Prueba de VIH Renumbered
R9-6-410. Human Immunodeficiency Virus Testing Renumbered

ARTICLE 9. HIV-RELATED TESTING

Section

- R9-6-901. Definitions
~~R9-6-409~~~~R9-6-902.~~ Consent for HIV-related Testing
~~Exhibit A~~~~Exhibit A.~~ Consent for HIV-related Testing
~~Exhibit B~~~~Exhibit B.~~ Consentimiento Para la Prueba de VIH
~~R9-6-410~~~~R9-6-903.~~ Human Immunodeficiency Virus Court-ordered HIV-related Testing

ARTICLE 1. DEFINITIONS

R9-6-101. General Definitions

In this Chapter, unless the context otherwise requires specified:

1. "AIDS" means Acquired Immunodeficiency Syndrome.
- ~~1-2.~~ No change
- ~~2-3.~~ No change
4. "Body fluid" means semen, vaginal secretion, tissue, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, urine, blood, or saliva.
- ~~3-5.~~ "Carrier" means an infected person who harbors an infectious agent in the absence of clinical disease and who serves as a potential source of infection individual with an asymptomatic infection that can be transmitted to a susceptible individual.
- ~~4-6.~~ "Case" means a person an individual with a clinical syndrome of a communicable disease whose condition is documented:
 - a. ~~by~~ By laboratory results ~~which that~~ support the presence of the causative agent; ~~;~~
 - b. ~~or by~~ By a ~~physician's~~ health care provider's diagnosis based on clinical observation; ~~;~~ or
 - c. ~~by~~ By epidemiologic associations with communicable disease, the causative agent, or its toxic products.
- ~~5-7.~~ "Communicable disease" means an illness caused by an infectious agent or its toxic products ~~which that~~ arises through the transmission of that agent or its products to a susceptible host, either directly or indirectly.
- ~~6-8.~~ No change
9. "Dentist" means an individual licensed under A.R.S. Title 32, Chapter 11, Article 2.
10. "Department" means the Arizona Department of Health Services.
- ~~7-11.~~ No change
- ~~8-12.~~ "Epidemiologic investigation" means the application of scientific methods to verify the diagnosis, identify risk factors for the disease, determine the potential for spread, institute ~~appropriate~~ control measures, and complete requisite communicable disease and case investigation reports.
- ~~9-13.~~ No change
- ~~10-14.~~ No change
- ~~11-15.~~ No change
16. "Health care provider" means a physician, physician assistant, registered nurse practitioner, or dentist.
17. "HIV" means Human Immunodeficiency Virus.
18. "HIV-related test" has the same meaning as in A.R.S. § 36-661.
- ~~12-19.~~ No change
- ~~13-20.~~ "Local health agency" means a county ~~public~~ health department, a public health services district, a tribal health unit, or a United States Public Health Service Indian Health Service Unit.
- ~~14-21.~~ No change
22. "Physician" means an individual licensed as a doctor of:
 - a. Allopathic medicine under A.R.S. Title 32, Chapter 13;
 - b. Naturopathic medicine under A.R.S. Title 32, Chapter 14;
 - c. Osteopathic medicine under A.R.S. Title 32, Chapter 17; or
 - d. Homeopathic medicine under A.R.S. Title 32, Chapter 29.
23. "Physician assistant" has the same meaning as in A.R.S. § 32-2501.
- ~~15-24.~~ No change
25. "Registered nurse practitioner" has the same meaning as in A.R.S. § 32-1601.
16. "Syndrome" means a pattern of signs and symptoms characteristic of a specific disease.
- ~~17-26.~~ No change
27. "Subject" means an individual whose blood or other body fluid has been tested or is to be tested.
18. "Suspect carrier" means a person without clinical symptoms of disease but who tests positive for HIV by culture, antigen, antibodies to the virus, or viral genetic sequence detection.
- ~~19-28.~~ "Suspect case" means a person an individual whose medical history, signs, or symptoms indicate that ~~person the~~ individual may have or is developing a communicable disease.
29. "Syndrome" means a pattern of signs and symptoms characteristic of a specific disease.

R9-6-102. Communicable Disease Reporting

In Article 2, unless the context otherwise requires specified:

1. No change
2. "Health care provider" means any physician, nurse, aide, therapist, dentist, or dental hygienist, whether paid or a volunteer.
- ~~3-2.~~ No change

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R9-6-103. Control Measures for Communicable Diseases

In Article 3, unless the context otherwise requires specified:

1. No change
2. No change
3. ~~“Body fluid” means semen, vaginal secretion, tissue, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, urine, blood, or saliva.~~
3. “Blood bank” means a facility where human whole blood or a blood component is collected, prepared, tested, processed, or stored, or from which human whole blood or a blood component is distributed.
4. “Blood center” means a mobile or stationary facility that procures human whole blood or a blood component that is transported to a blood bank.
5. “Blood component” means any part of a single donor unit of blood separated by physical or mechanical means.
- 4-6. ~~“Concurrent disinfection” means the application of disinfective measures to inanimate objects or surfaces after the discharge of blood or body fluids from the body of an infected person, individual or after the contamination of articles with blood or body fluids.~~
5. ~~“Contact precautions” means, in addition to Standard precautions, the use of barriers to prevent infection spread by direct contact.~~
- 6-7. ~~“Contaminated” means to have come in contact with a disease-causing agent or toxin.~~
- 7-8. ~~“Counseling and testing site” means a health facility offering clients HIV counseling and HIV-related testing which that meets the standards established in the Centers for Disease Control, “HIV Counseling, Testing, and Referral, Standards and Guidelines,” HIV Counseling, Testing, and Referral Standards and Guidelines (May 1994), incorporated by reference, on file with the Department and the Office of the Secretary of State, and available from Centers for Disease Control, 1600 Clifton Road, N.E., Atlanta, GA 30333, incorporated by reference and on file with the Department and Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.~~
- 8-9. No change
- 9-10. No change
- 10-11. No change
12. “Drug” means a chemical substance licensed by the United States Food and Drug Administration.
- 11-13. ~~“Follow-up” means the practice of investigating and monitoring cases, carriers, contacts, or suspect cases; to detect, treat, or prevent disease.~~
14. “Guardian” means an individual who has been invested with the authority and charged with the duty of caring for a minor by a court of competent jurisdiction.
15. “Identified individual” means an individual named by a case as an individual who may have been exposed through sexual contact with the case and for whom a case provides information that enables the local health agency to locate the individual.
16. “Midwife” has the same meaning as in A.R.S. § 36-751.
17. “Milk bank” means a facility that procures, processes, stores, or distributes human breast milk.
18. “Organ bank” means a facility that procures, processes, stores, or distributes human kidneys, livers, hearts, lungs, or pancreases.
19. “Parent” means a natural or adoptive mother or father.
20. “Plasma center” means a facility where the process of plasmapheresis or another form of apheresis is conducted.
21. “Pupil” means a student attending a school.
22. “School district personnel” means individuals who work for a school district, as defined by A.R.S. § 15-101, whether within a classroom or other setting and whether as employees, contractors, or volunteers.
23. “Sexual contact” means vaginal intercourse, anal intercourse, fellatio, or cunnilingus.
- 12-24. No change
25. “Tissue bank” means a facility that procures, processes, stores, or distributes corneas, bones, semen, or other specialized human cells for the purpose of injecting, transfusing, or transplanting the cells into a human body.
26. “Whole blood” means human blood from which plasma, erythrocytes, leukocytes, and thrombocytes have not been separated.

R9-6-104. Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS) Repealed

In Article 4, unless the context otherwise requires:

1. ~~“AHCCCS” means the Arizona Health Care Cost Containment System.~~
2. ~~“Clinical trial study” means the Treatment IND (investigative new drug) trial of zidovudine conducted by Burroughs-Wellcome Company between October 11, 1986, and April 30, 1987.~~
3. ~~“Enrolled” means eligible for and being provided therapeutic assistance by the Department.~~
4. ~~“Family” means a group of two or more persons related by birth, marriage, or adoption who reside together; all such related persons are considered members of one family. If a household includes more than one family and/or more~~

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than one unrelated individual, the poverty guidelines are applied separately to each family and/or unrelated individual, and not to the household as a whole.

5. "Family unit of size one" means an unrelated individual, that is, a person 15 years old or older (other than an inmate of an institution) who is not living with relatives. An unrelated individual may be the sole occupant of a housing unit, or may be residing in a housing unit, including a rooming house, in which one or more persons also reside who are not related to the individual in question by birth, marriage, or adoption.
6. "Income" means the total annual cash receipts before taxes from all sources; it may consist of data for the most recent 12 months or an annualized figure derived by computation from less than 12 months' data. Income includes money, wages and salaries before any deductions, but does not include food or rent received in lieu of wages. Income also includes net receipts from nonfarm or farm self-employment, net of business or farm expenses. Income includes regular payments from social security, railroad retirement, unemployment compensation, workers' compensation, strike benefits from union funds, veterans' benefits, public assistance (including Aid to Families with Dependent Children, Supplemental Security Income, and non-Federally-funded General Assistance or General Relief money payments), training stipends, alimony, child support, and military family allotments or other regular support from an absent family member or someone not living in the household, private and government employee pensions, and regular insurance or annuity payments, and income from dividends, interest, rents, royalties, or periodic receipts from estates or trusts. For eligibility purposes, income does not include: capital gains, any assets drawn down as withdrawals from a bank, proceeds from the sale of property, a house, or a car; tax refunds, gifts, lump-sum inheritances, one-time insurance payments, or compensation for injury. Also excluded are noncash benefits, such as the employer-paid or union-paid portion of health insurance and other employee fringe benefits; the value of food and fuel produced and consumed on farms, the imputed value of rent from owner-occupied nonfarm or farm housing, and federal programs such as Medicare, Medicaid, food stamps, school lunches, and public housing.
7. "SSI" means Supplemental Security Income, a program of the Social Security Administration.
8. "Symptomatic HIV infection" means illness either within the case definition of the Centers for Disease Control for acquired immunodeficiency syndrome (AIDS) or generally recognized as AIDS related complex (ARC). Incorporated by reference herein and on file with the Office of the Secretary of State is Morbidity and Mortality Weekly Report: Revision of the CDC Surveillance Case Definition for Acquired Immunodeficiency Syndrome, Centers for Disease Control, Atlanta, Georgia, Vol. 36, No. 15, August 14, 1987.
9. "Therapeutic agents" means drugs determined by the United States Food and Drug Administration to prolong the life of individuals with symptomatic HIV infection.
10. "Zidovudine" means azidothymidine (AZT).

ARTICLE 2. COMMUNICABLE DISEASE REPORTING

R9-6-202. Special Reporting Requirements

- A.** No change
 1. No change
 2. No change
 3. No change
 4. No change
 5. No change
 6. No change
 7. No change
 8. No change
 9. No change
 10. No change
 11. No change
 12. No change
 13. No change
 14. No change
 15. No change
- B.** No change
 1. No change
 2. No change
 3. No change
 4. No change
 5. No change
 6. No change
 7. No change

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- 8. No change
- C. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
 - 6. No change
 - 7. No change
 - 8. No change
 - 9. No change
 - 10. No change
 - 11. No change
- D. A clinical laboratory director, ~~or authorized representative,~~ either personally or through a representative, shall submit to the Department a weekly written, or electronic report of the following:
 - 1. ~~positive~~ Positive laboratory findings for the following communicable disease pathogens:
 - 1-~~a.~~ No change
 - 2-~~b.~~ No change
 - 3-~~c.~~ No change
 - 4-~~d.~~ No change
 - 5-~~e.~~ No change
 - 6-~~f.~~ No change
 - 7-~~g.~~ No change
 - 8-~~h.~~ No change
 - 9-~~i.~~ No change
 - 10-~~j.~~ No change
 - 11-~~k.~~ No change
 - 12-~~l.~~ No change
 - 13-~~m.~~ No change
 - 14-~~n.~~ No change
 - 15-~~o.~~ No change
 - 16-~~p.~~ Human Immunodeficiency Virus (HIV) (by culture, antigen, antibodies to the virus, or viral genetic sequence detection);
 - 17-~~q.~~ No change
 - 18-~~r.~~ No change
 - 19-~~s.~~ No change
 - 20-~~t.~~ No change
 - 21-~~u.~~ No change
 - 22-~~v.~~ No change
 - 23-~~w.~~ No change
 - 24-~~x.~~ No change
 - 25-~~y.~~ No change
 - 26-~~z.~~ No change
 - 27-~~aa.~~ No change
 - 28-~~bb.~~ No change
 - 29-~~cc.~~ No change
 - 30-~~dd.~~ Yersinia sp.; and
 - 2. Laboratory findings of CD4-T-lymphocyte counts of fewer than 200 per microliter of whole blood or CD4-T-lymphocyte percentages of total lymphocytes of less than 14%.
- E. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
 - 6. No change
 - 7. No change
 - 8. No change
- F. No change

1. No change
2. No change
3. No change
4. No change
5. No change
6. No change

ARTICLE 3. CONTROL MEASURES FOR COMMUNICABLE AND PREVENTABLE DISEASES

R9-6-308. Chancroid (*Haemophilus ducreyi*)

A. Case control measures:

1. ~~The A~~ diagnosing health care provider or authorized representative shall treat prescribe drugs to render a case noninfectious and counsel or arrange for a the case to be counseled:
 - a. ~~to~~ To abstain from sexual contact until lesions are healed during drug treatment and for at least seven days after drug treatment is completed; and
 - b. About the following:
 - i. The characteristics of chancroid.
 - ii. The syndrome caused by chancroid.
 - iii. Measures to reduce the likelihood of transmitting chancroid to others, and
 - iv. The need to notify individuals with whom the case has had sexual contact within a time period determined based upon the stage of the disease; and
2. The local health agency shall conduct an epidemiologic investigation of each reported case, confirming the stage of the disease.

B. Contact control measures: The local health agency shall;

1. notify sexual contacts of exposure and Notify identified individuals of their exposure;
2. offer Offer or arrange for treatment of identified individuals; and
3. Counsel identified individuals about the following:
 - a. The characteristics of chancroid.
 - b. The syndrome caused by chancroid.
 - c. Measures to reduce the likelihood of transmitting chancroid to others, and
 - d. The need to notify individuals with whom the identified individual has had sexual contact within a time period determined based upon the stage of the disease.

R9-6-309. Chlamydia Infection

~~A. Reports: Suspect cases include clinically diagnosed cases of nongonococcal urethritis and epididymitis in men under age 35 years, and pelvic inflammatory disease and nongonococcal mucopurulent cervicitis in women.~~

~~B.A.~~ **Case control measures:**

1. ~~The A~~ diagnosing health care provider or authorized representative shall:
 - a. Prescribe drugs to render a case noninfectious.
 - b. ~~counsel a~~ Counsel or arrange for the case to be counseled to abstain from sexual contact until during drug treatment and for at least seven days after drug treatment is complete completed, and
 - c. Counsel or arrange for the case to be counseled about the importance of notifying individuals who may have been exposed through sexual contact of their exposure and of the need to seek medical treatment.
2. The Department shall review each case report for completeness, accuracy, and need for follow-up.

~~C.B.~~ **Contact control measures: The** If an individual who may have been exposed through sexual contact with the case seeks treatment from the local health agency, the local health agency shall notify identified sexual contacts and offer or arrange for treatment.

~~D.~~ **Special control measures: The local health agency shall conduct or direct an epidemiologic investigation of each reported case:**

R9-6-323. Gonorrhea

A. Case control measures:

1. ~~The A~~ diagnosing health care provider shall:
 - a. Prescribe drugs to render a case noninfectious.
 - b. ~~counsel~~ Counsel or arrange for the case to be counseled to abstain from sexual contact during drug treatment and for 7 at least seven days after drug treatment is completed, and
 - c. Counsel or arrange for the case to be counseled about the importance of notifying individuals who may have been exposed through sexual contact of their exposure and of the need to seek medical treatment.
2. The Department shall review each case report for completeness, accuracy, and need for follow-up.

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3. For the prevention of gonorrheal ophthalmia, a health care provider or midwife attending the birth of an infant in Arizona shall treat the eyes of the infant immediately after the birth with one of the following, unless treatment is refused by a parent or guardian:
 - a. Erythromycin ophthalmic ointment 0.5%, or
 - b. Tetracycline ophthalmic ointment 1%.
- ~~B.~~ Contact control measures: ~~The~~ If an individual who may have been exposed through sexual contact with the case seeks treatment from the local health agency, the local health agency shall assure identification and notification and shall offer or arrange for treatment to sexual contacts.
- ~~C.~~ Special control measures:
 1. For the prevention of gonorrheal ophthalmia, the physician or person attending the birth of any newborn in Arizona shall treat the eyes of the baby immediately after the birth with 1 of the following medications:
 - a. Erythromycin ophthalmic ointment 0.5%,
 - b. Tetracycline ophthalmic ointment 1%,
 - e. Silver nitrate aqueous solution 1%.
 2. A parent or guardian may refuse the treatment set forth in subsection (C)(1) by signing a written statement, witnessed by the physician or person attending the birth, stating that the parent or guardian has been informed of the potential risks and benefits of waiving the prescribed treatment and is refusing to allow its application. The physician or person attending the birth shall maintain a copy of the written refusal in the newborn's medical record.
 3. The local health agency shall conduct or direct an epidemiologic investigation of each reported case.

R9-6-330. Herpes Genitalis

Case control measures: ~~The~~ A diagnosing health care provider or authorized representative shall counsel or arrange for a case to be counseled:

- ~~1.~~ To abstain from sexual contact until lesions are healed,
2. About available treatment, and
3. About chemoprophylaxis and other measures to prevent transmission.

R9-6-331. Human Immunodeficiency Virus (HIV) Infection and Related Disease

~~A.~~ Reports: As directed by Article 2, a person shall report a case, suspect case, or suspect carrier except for the suspect carrier requesting anonymity pursuant to subsection (D)(4).

~~B.~~ A. Case control measures:

1. A health care provider or operator of a blood bank, blood center, plasma center, tissue bank, organ bank, or milk bank shall not utilize use donated blood or blood components, plasma, milk, body organs, sperm semen, or other tissue from a case, suspect case, or suspect carrier for transfusion, transplantation, or consumption.
2. A health care provider or operator of a blood bank, blood center, plasma center, tissue bank, organ bank, or milk bank who orders or administers a test for HIV or HIV antibodies and receives a test result that the health care provider or operator interprets as positive for HIV or HIV antibodies shall notify the subject or arrange for the subject to be notified of the test result within 30 days after receiving the test result.
3. A health care provider or operator of a blood bank, blood center, plasma center, tissue bank, organ bank, or milk bank shall provide or arrange for subject counseling at the time of notification that includes the following information:
 - a. The characteristics of HIV;
 - b. The syndrome caused by HIV and its symptoms;
 - c. The measures that are effective in reducing the likelihood of transmitting HIV to others;
 - d. The need to notify individuals, including a spouse, with whom the subject has had sexual contact or has shared needles of their exposure to HIV; and
 - e. The availability of assistance from local health agencies in notifying those individuals described in subsection (A)(3)(d).
4. The local health agency shall conduct an epidemiologic investigation of each reported case or carrier within 30 days after receiving a report. Upon completion of the epidemiologic investigation, the local health agency shall not retain any personal identifying information about the case or carrier.
5. A counseling and testing site supervised by the Department or by a local health agency shall offer an anonymous testing option. The Department or local health agency shall collect the following epidemiologic information about each individual opting for anonymous testing:
 - a. Age.
 - b. Race and ethnicity.
 - c. Sex.
 - d. County of residence, and
 - e. HIV-associated risk behaviors.

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6. The Department shall confidentially notify an identifiable third party reported to be at risk of HIV infection under A.R.S. § 36-664(K) if all of the following conditions are met:
 - a. The Department received the report of risk in a writing that included the following:
 - i. The name and address of the identifiable third party.
 - ii. The name and address of the individual placing the identifiable third party at risk.
 - iii. The name and address of the individual making the report, and
 - iv. The type of exposure placing the identifiable third party at risk;
 - b. The individual making the report is in possession of confidential HIV-related information; and
 - c. The Department determines that the information provided in the report is accurate and sufficient to warrant notification of the identifiable third party.
7. As authorized under A.R.S. § 36-136(L), a local health agency shall notify the superintendent of a school district, as defined in A.R.S. § 15-101, in a confidential writing that a pupil of the school district is a case or carrier of HIV if the following criteria are met:
 - a. The local health agency has determined by consulting with the Department that the pupil places others in the school setting at risk for HIV infection; and
 - b. The school district has an HIV policy that includes the following provisions:
 - i. That a school shall not exclude an infected pupil from attending school or school functions or from participating in school activities solely due to HIV infection;
 - ii. That the school district shall establish a group to determine on a case-by-case basis whether an infected pupil should be permitted to attend school by considering the risks and benefits to the pupil and to others if the pupil attends school;
 - iii. That the group described in subsection (A)(7)(b)(ii) shall include the superintendent of the school district, the parents or guardians of a minor pupil, the pupil if the pupil is not a minor or is emancipated, the pupil's physician, and the local health officer and may include a school administrator, a school nurse, and a teacher or counselor of the pupil;
 - iv. That school district personnel who are informed of the pupil's HIV infection shall keep that information confidential;
 - v. That the school district shall provide HIV education programs to pupils, parents or guardians of pupils, and school district personnel through age-appropriate curricula, workshops, or in-service training sessions; and
 - vi. That school district personnel who handle blood or body fluids shall comply with Elizabeth A. Bolyard et al., Guideline for Infection Control in Health Care Personnel, 1998 (1998), incorporated by reference, on file with the Department and the Office of the Secretary of State, and available from National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. This incorporation by reference includes no future editions or amendments.

~~**C.B.** Environmental control measures: The diagnosing An employer, as defined under A.R.S. § 23-401, or health care provider or authorized representative shall ensure concurrent disinfection of equipment or other surfaces contaminated with blood, semen, vaginal fluids, or other body fluids containing visible blood of cases, suspect cases, or suspect carriers comply with 29 CFR 1910.1030, as required by A.R.S. § 23-403 and A.A.C. R20-5-602.~~

~~**D.** Special control measures:~~

- ~~1. Any physician, hospital administrator, or other person, including operators of blood or plasma centers, tissue or sperm banks, who orders, administers or interprets as positive a test for HIV or antibodies to the virus shall, in addition to meeting the reporting requirements specified, use all reasonable means to notify the person on whom the test was performed within 30 days of receiving the test result.~~
- ~~2. At the time of notification, the physician, hospital administrator or other person shall provide or arrange for counseling which includes factual information regarding the virus, the syndrome and its symptoms, measures which are effective in reducing the likelihood of transmitting the virus to others, the need to notify sex and/or needle-sharing partners of their exposure to the virus and the availability of assistance from local health agencies in partner notification procedures.~~
- ~~3. The local health agency shall conduct or direct an epidemiologic investigation of each reported case, suspected case, or suspect carrier within 30 days of the initial report. Upon completion of the epidemiologic investigation, the local health department shall not retain any personal identifying information on the case, suspect case, or suspect carrier.~~
- ~~4. Counseling and testing sites supervised by the Department or by local health agencies shall offer an anonymous testing option. Epidemiologic information including age, race, sex, county of residence, and associated risk behaviors shall be collected on individuals opting for anonymous testing.~~
- ~~5. The Department shall confidentially notify an identifiable 3rd party reported to be at risk of HIV infection pursuant to A.R.S. § 36-664(K) if all of the following conditions are met:~~
 - ~~a. The report of risk is made to the Department in writing and includes the name and address of the identifiable 3rd party, the name and address of the person placing the identifiable 3rd party at risk, the type of exposure placing the identifiable 3rd party at risk, and the name and address of the person making the report;~~

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- b. The report is made by a person in possession of confidential HIV-related information;
 - e. The Department determines that the above information is both accurate and sufficient to warrant notification of the 3rd party at risk.
6. The local health department shall notify the school district superintendent in a writing which shall be kept confidential that a school district pupil is reported as a case, suspect case, or suspect carrier of HIV infection when all of the following criteria are met:
- a. The infected pupil places others in the school setting at risk for HIV infection. The local health department shall make this determination in consultation with the Department.
 - b. The school district has established a communicable disease policy which consists of the following criteria:
 - i. A school shall not exclude an infected pupil from school or school functions solely due to HIV infection.
 - ii. The school district superintendent, the pupil, or parents or legal guardians of a minor pupil, the pupil's physician, and the local health officer shall make decisions regarding the educational setting for HIV-infected pupils on a case-by-case basis. In addition to the aforementioned individuals, the school district superintendent may also include the following individuals in this decision-making process: the school administrator, school nurse, and principal teacher or counselor. In making this decision, these individuals shall consider the risks and benefits to the pupil and others of maintaining the pupil in the school setting.
 - iii. School district personnel informed of the pupil's HIV infection shall maintain that information as confidential.
 - iv. School district personnel who handle blood or body fluids shall comply with the "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health Care Settings", June 1988, Centers for Disease Control, 1600 Clifton Road, N.E., Atlanta, GA 30333, incorporated by reference and no other amendments and on file with the Office of the Secretary of State.
 - v. AIDS educational programs shall be made available to pupils, parents, and staff through age-appropriate curricula, workshops, or in-service training sessions.

R9-6-360. Syphilis

A. Case control measures:

- 1. A diagnosing health care provider shall prescribe drugs to render a case noninfectious and counsel or arrange for the case to be counseled:
 - a. To abstain from sexual contact during drug treatment and for at least seven days after drug treatment is completed; and
 - b. About the following:
 - i. The characteristics of syphilis.
 - ii. The syndromes caused by syphilis.
 - iii. Measures to reduce the likelihood of transmitting syphilis to others, and
 - iv. The need to notify individuals with whom the case has had sexual contact within a time period determined based upon the stage of the disease.
- 2. A case shall be subject to obtain serologic testing at 3 three months and 6 six months following after initiation of drug treatment.
- 3. A health care provider or operator of a blood bank, blood center, or plasma center, tissue bank, or organ bank shall not utilize use blood, plasma blood components, sperm, body organs, or tissue from a case for injection, transfusion, or transplantation. The diagnosing health care provider or authorized representative shall counsel the case to abstain from sexual contact for 7 days after completion of treatment.
- 4. An operator of a blood bank, blood center, plasma center, tissue bank, or organ bank who interprets as positive a test for the syphilis antigen or antibody shall notify the subject of the test within 30 days after interpreting the test.
- 5. The local health agency shall conduct an epidemiologic investigation of each reported case, confirming the stage of the disease.

B. Contact control measures: The local health agency shall;

- 1. ~~identify~~ Notify identified individuals of their exposure;
- 2. ~~and offer~~ Offer or arrange for serologic testing and treatment of identified individuals to sexual contacts; and
- 3. Counsel identified individuals about the following:
 - a. The characteristics of syphilis.
 - b. The syndromes caused by syphilis.
 - c. Measures to reduce the likelihood of transmitting syphilis to others, and
 - d. The need to notify individuals with whom the identified individual has had sexual contact within a time period determined based upon the stage of the disease.

C. Special control measures:-

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1. Any person operating a blood or plasma center who interprets a positive test for the syphilis antigen or antibody shall, in addition to meeting the reporting requirements specified, notify or cause to be notified the person on whom the test was performed within 30 days of interpreting the test.
2. The local health agency shall conduct or direct an epidemiologic investigation of each reported case.

**ARTICLE 4. ~~HUMAN IMMUNODEFICIENCY VIRUS (HIV) / ACQUIRED IMMUNODEFICIENCY SYNDROME~~
(~~AIDS~~) AIDS DRUG ASSISTANCE PROGRAM (ADAP)**

R9-6-401. Definitions

In this Article, unless otherwise specified:

1. “ADAP” means the AIDS Drug Assistance Program.
2. “AHCCCS” means the Arizona Health Care Cost Containment System.
3. “Applicant” means an individual who submits an application for ADAP to the Department.
4. “Diagnosis” means an identification of a disease by an individual authorized by law to make the identification.
5. “Drug” means a chemical substance determined by the United States Food and Drug Administration to be useful in the treatment of individuals with HIV infection.
6. “Earned income” means payments received by an individual as a result of work performed, including:
 - a. Wages,
 - b. Commissions and fees,
 - c. Salaries and tips,
 - d. Profit from self-employment,
 - e. Profit from rent received from a tenant or boarder, and
 - f. Any other monetary payments received by an individual for work performed.
7. “Family income” means the combined gross earned income and unearned income of all individuals within the family unit.
8. “Family unit” means:
 - a. A group of individuals residing together who are related by birth, marriage, or adoption; or
 - b. An individual who does not reside with any individual to whom the individual is related by birth, marriage, or adoption.
9. “Outpatient” means in an ambulatory setting.
10. “Poverty level” means the annual income for a family unit of a particular size included in the poverty guidelines updated annually in the Federal Register by the United States Department of Health and Human Services.
11. “Primary care provider” means a physician, registered nurse practitioner, or physician assistant who is treating an applicant or enrolled individual for HIV disease or HIV infection.
12. “Public assistance” means a government program that provides benefits to individuals based on need, such as Aid to Families with Dependent Children, SSI, or non-federally funded general assistance.
13. “Resident” means an individual who has a place of habitation in Arizona and lives in Arizona as other than a tourist.
14. “SSI” means Supplemental Security Income, a program of the Social Security Administration.
15. “Unearned income” means non-gift payments received by an individual that are unrelated to work performed by the individual, including:
 - a. Unemployment insurance;
 - b. Workers’ compensation;
 - c. Disability payments;
 - d. Social security payments;
 - e. Public assistance payments;
 - f. Periodic insurance or annuity payments;
 - g. Retirement or pension payments;
 - h. Strike benefits from union funds;
 - i. Training stipends;
 - j. Child support payments;
 - k. Alimony payments;
 - l. Military family allotments or other regular support payments from a relative or other individual not residing in the household;
 - m. Investment income;
 - n. Royalty payments;
 - o. Periodic payments from estates or trusts; and
 - p. Any other non-gift monetary payments received by an individual that are unrelated to work performed by the individual and that are not capital gains, lump-sum inheritance or insurance payments, or payments made to compensate for personal injury.

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~~R9-6-401~~, R9-6-402. Limitations and Termination of Program

- ~~A.~~ This program shall provide zidovudine and any other drug which has been determined by the FDA to prolong the life of a person with AIDS or related conditions to the extent of funding made available for that purpose.
- ~~B.~~ Therapeutic assistance shall be available only to certain low-income individuals not covered under AHCCCS or by any third-party payor.
- ~~C.~~ Therapeutic assistance shall be allocated to the maximum number of eligible persons derived by dividing the available funds by the cost of treatment for one person with zidovudine or other life-prolonging drug for a period concurrent with and ending in accordance with the fiscal year for which such funds are authorized. All others shall be placed on a waiting list; the Department may revise the maximum number of persons upward or downward, according to its actual experience with the availability of the therapeutic agent. Those on the waiting list shall have therapeutic assistance afforded them only if the maximum number of persons is raised or one or more persons receiving assistance leave the program. Upon the occurrence of such vacancy, the person at the top of the waiting list shall be enrolled for the period of time remaining in the fiscal year.
- ~~D.~~ All therapeutic assistance shall terminate upon the exhaustion or termination of available funding expressly authorized for this purpose. ADAP ceases to provide drugs when available funding is exhausted or terminated. This program shall ADAP is not constitute an entitlement program for any person or and does not create a right to assistance absent continued available funding.

~~R9-6-402~~, R9-6-403. Eligibility

- A. To establish financial eligibility, an applicant shall comply with the following An individual is eligible to participate in ADAP if the individual:
 - 1. Provide a copy of one of the following Has applied for enrollment in AHCCCS and possesses one of the following:
 - a. Application A letter from AHCCCS showing that an application for eligibility determination as filed with AHCCCS or SSI, bearing their stamp of the date processed, for which a determination of eligibility has not yet been made; is pending, or
 - b. Letter A letter from AHCCCS denying eligibility under AHCCCS or SSI;
 - 2. Certify that Has no or inadequate health insurance is in effect for the applicant which covers to cover the cost of the therapeutic agents drugs that are or may become available under this Article from ADAP on an outpatient basis- or is an American Indian or Alaska Native who is eligible for but chooses not to use Indian Health Services;
 - 3. To establish financial eligibility for HIV/AIDS therapy assistance, income shall not exceed the following allowable family income levels: Has annual family income that is less than or equal to 300% of the poverty level:

ALLOWABLE INCOME LIMITS

Size of Family Unit	Upper Limit Annual Income
1	\$13,240
2	\$17,760
3	\$22,280
4	\$26,800
5	\$31,320
6	\$35,840
7	\$40,360
8	\$44,880

- ~~B.~~ To establish medical eligibility, an applicant 13 years of age or over shall have one of the following conditions:
 - 1. A medical history of cytologically confirmed Pneumocystis carinii pneumonia, or
 - 2. A diagnosis of HIV infection which includes serologic or virologic evidence of HIV infection and an absolute CD4 (T4 helper/inducer) lymphocyte count of less than 500/mm³ in the peripheral blood before the initiation of therapy.
- ~~C.~~ To establish medical eligibility, an applicant more than three months but less than 13 years of age shall have one of the following conditions:
 - 1. A diagnosis of HIV-related illness, or
 - 2. A diagnosis of HIV infection with laboratory values indicating HIV-related immunosuppression.
 - 4. Is ineligible for Veterans' Administration benefits;
 - 5. Has a medical diagnosis of HIV disease or HIV infection; and
- ~~D.~~ 6. The applicant shall be Is a resident of Arizona.
- ~~B.~~ For purposes of ADAP application, an individual may report annual family income using actual family income for the most recent 12 months or estimated annual family income determined by multiplying the current monthly family income by 12.

~~R9-6-403~~, R9-6-404. Application Process

- ~~A.~~ Application shall be made on a form prescribed by An applicant shall submit to the Department containing the following documents:

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1. ~~Personal and other information:~~ An application completed by the applicant, on a form provided by the Department, including the following:
 - a. ~~Name~~ The applicant's name, date of birth, and sex;
 - b. ~~Address~~ The applicant's address;
 - c. ~~Telephone~~ The applicant's telephone number;
 - d. ~~Number of persons in household~~ The number of individuals in the applicant's family unit;
 - e. ~~Income~~ The applicant's annual family income; and
 - f. ~~The identification number, if a subject in the clinical trial study of zidovudine;~~ applicant's social security number;
 - g. The applicant's residency;
 - h. The applicant's race and ethnicity;
 - i. The applicant's employment status;
 - j. Whether the applicant is receiving benefits from SSI or AHCCCS;
 - k. Whether the applicant is eligible to receive benefits from the Veterans' Administration;
 - l. Whether the applicant has health insurance that would pay for drugs and, if so, to what extent;
 - m. The applicant's scheduled AHCCCS eligibility appointment date, if any;
 - n. A statement by the applicant or the parent or guardian of a minor applicant that:
 - i. The information on the form is true and complete;
 - ii. The applicant does not have health insurance coverage for the requested drugs or is an American Indian or Alaska Native who is eligible for but chooses not to use Indian Health Services;
 - iii. The applicant, or the parent or guardian of a minor applicant, understands that eligibility does not create an entitlement; and
 - iv. The applicant, or the parent or guardian of a minor applicant, grants permission to the Department to discuss the applicant's application with AHCCCS for purposes of determining AHCCCS eligibility; and
 - o. The signature of the applicant or the parent or guardian of a minor applicant and the date of signature;
2. ~~Medical information:~~ An application completed by the applicant's primary care provider, on a form provided by the Department, including the following:
 - a. ~~A medical history of cytologically confirmed Pneumocystis carinii pneumonia~~ The applicant's name; or
 - b. ~~A confirmed diagnosis of symptomatic HIV infection, and evidence that the applicant's CD4 (T4 helper/inducer) lymphocyte count is above or below 400/mm³ in the peripheral blood prior to the initiation of therapy, the date of testing, and the name and address of the laboratory performing the testing~~ The primary care provider's name and business address, telephone number, and facsimile number; and
 - c. ~~The name, address and telephone number of the applicant's physician.~~ A statement that the applicant has been diagnosed with HIV disease or HIV infection;
 - d. The dates, results, and laboratory names and addresses for the most recent HIV-related tests conducted for the applicant;
 - e. The drug or drugs prescribed by the primary care provider for the applicant;
 - f. A statement by the primary care provider that the information presented on the application is true and complete; and
 - g. The signature of the primary care provider and the date of signature;
3. ~~Certification statements:~~
 - a. ~~The applicant, or the applicant's parent, if the applicant is a minor, or legal guardian shall certify the following:~~

~~"I, _____, certify that to the best of my knowledge and belief, all statements made herein regarding personal and other nonmedical information are true and accurate. I certify that I am or my child or ward is not covered by any health insurance plan that would provide the support for which I am or my child or ward is applying. I understand that eligibility does not guarantee that the Arizona Department of Health Services will be able to provide support and that such support, if begun, may be terminated without notice."~~
 - b. ~~The applicant's physician shall sign the certificate attesting to the following:~~

~~"I certify that to the best of my knowledge and belief all medical information presented by me in this application is true and accurate."~~
 - e. ~~Failure by the applicant or the physician to provide the certification shall result in a denial of eligibility by the Department.~~
3. An original prescription signed by the primary care provider for each drug indicated as prescribed on the primary care provider's application;
4. A copy of one of the following:
 - a. A letter from AHCCCS showing that an application for eligibility is pending, or
 - b. A letter from AHCCCS denying eligibility; and
5. Proof of annual family income, including the following items, as applicable:
 - a. The most recent paycheck stub, or a statement from the employer listing gross wages, from each job;

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- b. Business records showing net income from self-employment;
- c. A letter describing any monetary award received by a student to cover non-tuition expenses;
- d. A letter describing each public assistance award; and
- e. Documentation showing the amount and source of any other income.

B. ~~As a part of, and appended to the prescribed application form, the applicant shall present documentation for benefits from AHCCCS or SSI pursuant to R9-6-402(A)(1).~~

~~R9-6-404.~~R9-6-405. Eligibility Determination and Enrollment Process

- A.** ~~The Department shall review each completed application for completeness, for the certifications by both the applicant and the physician, and the application for benefits from either AHCCCS or SSI. The Department may seek to verify any and all information submitted in or in support of the application prior to or after a determination of eligibility. Applicants shall be required, upon request by the Department, to produce any reasonable documentation relating to eligibility. Failure to provide such documentation or provision of false or inaccurate information shall be grounds for denial of eligibility. If all portions are determined to be accurate, true and complete, if the certifications are present, and if the eligibility standards set forth in R9-6-402 are met, the applicant shall be declared eligible.~~ received and determine enrollment based on applicant eligibility, the date on which the application was completed, and the availability of funds.
- B.** ~~All applications shall be reviewed, and have an eligibility determination made, if all necessary documentation is included, at the time of receipt by the Department. If a slot is available for enrollment and support, the eligible person shall be enrolled. If none is available, the eligible person shall be placed on the waiting list. Enrollment or placement on the waiting list shall be in the order the applications are received, except that clinical trial study subjects shall be given priority over other eligible persons.~~ An applicant shall execute any consent forms or releases of information necessary for the Department to verify eligibility.
- C.** ~~The Department shall notify, in writing, both the applicant and the physician of the declaration of or denial of eligibility. The time-frames for approving or denying an application are described in R9-6-408.~~

~~R9-6-405.~~R9-6-406. Period of Eligibility Continuing Enrollment

- A.** ~~Eligibility shall continue for one year subject to a six-month review from the date of determination; The Department shall review eligibility every six months after enrollment unless one of the following events occur ending the occurs within the six-month period to end eligibility period immediately:~~
- 1. ~~Death of the eligible person~~ The enrolled individual dies;
 - 2. ~~Use of the therapeutic agent is halted~~ The enrolled individual stops using the drug or drugs on the advice of the physician a primary care provider;
 - 3. ~~Determination of eligibility and enrollment~~ The enrolled individual is determined eligible and enrolled to receive medical services through either AHCCCS or SSI another third-party payor other than Indian Health Services;
 - 4. ~~Increase in~~ The enrolled individual's annual family income increases to an amount above the allowable 300% of the poverty level; or
 - 5. ~~Establishment of residence~~ The enrolled individual establishes residency outside Arizona.
- B.** ~~The eligible person enrolled individual or the person's physician enrolled individual's primary care provider shall notify the Department within 30 days of after the occurrence of any of these the events listed in subsection (A).~~
- ~~B.C.~~** ~~The review at six months shall be based upon the submission of a follow-up application by the eligible person on a form prescribed by the Department. Failure to provide the follow-up application shall result in a denial of further eligibility by the Department. Before the expiration of each six-month period, the Department shall send each enrolled individual a letter requesting that the enrolled individual submit proof of annual family income and complete and submit a follow-up application form provided by the Department.~~
- 1. The enrolled individual shall submit to the Department proof of annual family income as described in R9-6-404(5) and a completed follow-up application form within 30 days after the date of the letter.
 - 2. The completed follow-up application form shall contain the following:
 - 1-a. Name The enrolled individual's name, address, and telephone number;
 - b. The enrolled individual's race and ethnicity, date of birth, sex, and social security number;
 - c. The enrolled individual's residency;
 - d. The number of individuals in the enrolled individual's family unit;
 - e. The enrolled individual's employment status;
 - 2- Status of the application made to SSI or to AHCCCS since the Department's determination of eligibility;
 - 3- f. Current The enrolled individual's annual family income;
 - g. Whether the enrolled individual is receiving benefits from SSI or AHCCCS;
 - h. Whether the enrolled individual is eligible to receive benefits from the Veterans' Administration;
 - i. Whether the enrolled individual has health insurance that would pay for drugs and, if so, to what extent;
 - j. The status of any application made to AHCCCS since the individual's enrollment in ADAP;

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4. k. Recertification utilizing the statement specified in R9-6-403(A)(3)(a) A statement by the enrolled individual or the parent or guardian of an enrolled minor individual that:
 - i. The information on the form is true and complete;
 - ii. The enrolled individual does not have health insurance coverage for the requested drugs or is an American Indian or Alaska Native who is eligible for but chooses not to use Indian Health Services;
 - iii. The enrolled individual, or the parent or guardian of an enrolled minor individual, understands that eligibility does not create an entitlement; and
 - iv. The enrolled individual, or the parent or guardian of an enrolled minor individual, grants permission to the Department to discuss the enrolled individual's follow-up application with AHCCCS for purposes of determining AHCCCS eligibility;
 - l. The signature of the enrolled individual or the parent or guardian of an enrolled minor individual and the date of signature; and
 - m. After every 24 months of continuous enrollment, a portion of the follow-up application completed by the enrolled individual's primary care provider including the following:
 - i. The primary care provider's name and business address, telephone number, and facsimile number;
 - ii. Physician's A statement by the primary care provider that treatment with the therapeutic agent drug or drugs is still appropriate; and
 - iii. The results and dates of the most recent HIV-related tests for the enrolled individual, if available;
 6. iv. A recertification by the physician with the statement specified in R9-6-403(A)(3)(b) A statement by the primary care provider that the information presented on the application is true and complete; and
 - v. The signature of the primary care provider and the date of signature.
- D.** The Department shall determine continuing enrollment based on the enrolled individual's eligibility and the availability of funds.
- E.** The time-frames for approving or denying continuing enrollment are described in R9-6-408.

R9-6-407. Appeal

- A.** ~~The provisions of this Section shall be applicable to applicants and eligible persons adversely affected by an action regarding eligibility.~~
- B.** ~~An applicant may seek review of any decision regarding eligibility by filing a written appeal with the assistant director of the Division of Disease Prevention no more than 20 days from the date of receipt of the eligibility decision.~~
- C.** ~~The assistant director shall review the eligibility decision and, within ten days of the filing of the appeal, shall mail the written determinations to the applicant. The determination shall include a statement regarding the right of the applicant to appeal to the Director, within 20 days of receipt of the assistant director's written determination, pursuant to A.A.C. R9-1-11 through R9-1-126.~~
- D.** ~~Any appeal made to the Director following the review by the assistant director shall constitute a waiver of the applicant's confidentiality, but solely for the purpose of the administrative proceeding.~~

R9-6-406; R9-6-407. Distribution Requirements

- A.** ~~The physician primary care provider shall submit to the Department an order on the physician's prescription form for one month's supply of the therapeutic agent for each enrolled person who is under the care of the physician. Each prescription shall be refillable a maximum of five times~~ write each drug prescription for an applicant or enrolled individual for the quantity of the drug packaged in the original container by the manufacturer.
- B.** ~~The Department shall purchase the therapeutic agent a prescribed drug and provide it the drug to the enrolled person's physician individual's pharmacy in quantities a quantity sufficient to meet the therapeutic regimen prescribed by the physician enrolled individual's primary care provider.~~
- C.** ~~The Department shall provide the therapeutic agent a drug in original, unopened containers as supplied packaged by its vendor the manufacturer.~~
- D.** ~~In the event the care of If an enrolled person is transferred to another physician individual changes primary care providers, the original physician primary care provider shall notify the Department in writing within five working seven days of after the transfer change. The following information original primary care provider shall be provided provide the following information in the written notice:~~
 1. ~~Name~~ The name and address of the enrolled ~~person individual~~;
 2. ~~Name~~ The name, and business address, and telephone number of ~~physician to whom care is transferred the new primary care provider~~;
 3. A release signed by the ~~patient enrolled individual~~ authorizing the Department to contact and exchange information with the ~~physician to whom care is transferred new primary care provider~~.
- E.** Failure to comply with subsection (D) may cause an interruption in or termination of support.

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R9-6-408. Time-frames

- A.** The overall time-frame described in A.R.S. § 41-1072 for each type of approval granted by the Department under this Article is provided in Table 1. The applicant or enrolled individual and the Department may agree in writing to extend the substantive review time-frame and the overall time-frame. An extension of the substantive review time-frame and the overall time-frame may not exceed 25% of the overall time-frame.
- B.** The administrative completeness review time-frame described in A.R.S. § 41-1072 for each type of approval granted by the Department under this Article is provided in Table 1 and begins on the date that the Department receives an application.
1. The Department shall send a notice of administrative completeness or deficiencies to the applicant or enrolled individual within the administrative completeness review time-frame.
 - a. A notice of deficiencies shall list each deficiency and the information and documentation needed to complete the application.
 - b. If the Department issues a notice of deficiencies within the administrative completeness review time-frame, the administrative completeness review time-frame and the overall time-frame are suspended from the date that the notice is issued until the date that the Department receives the missing information from the applicant or enrolled individual.
 - c. If the applicant or enrolled individual fails to submit to the Department all of the information and documents listed in the notice of deficiencies within 30 days from the date that the Department sent the notice of deficiencies, the Department shall consider the application or follow-up application withdrawn.
 2. If the Department issues an approval to the applicant or enrolled individual during the administrative completeness review time-frame, the Department shall not issue a separate written notice of administrative completeness.
- C.** The substantive review time-frame described in A.R.S. § 41-1072 for each type of approval granted by the Department under this Article is provided in Table 1 and begins as of the date on the notice of administrative completeness.
1. The Department shall send written notification of approval or denial of enrollment or continuing enrollment to the applicant or enrolled individual within the substantive review time-frame.
 2. During the substantive review time-frame, the Department may make one comprehensive written request for additional information, unless the Department and the applicant or enrolled individual have agreed in writing to allow the Department to submit supplemental requests for information.
 3. If the Department issues a comprehensive written request or a supplemental request for information, the substantive review time-frame and the overall time-frame are suspended from the date that the Department issues the request until the date that the Department receives all of the information requested.
 4. The Department shall issue an approval of enrollment or continuing enrollment unless:
 - a. The Department determines that the applicant or enrolled individual is ineligible.
 - b. The Department does not have funds available to enroll the applicant in or to continue the enrolled individual's enrollment in ADAP.
 - c. The Department determines that the applicant or enrolled individual submitted false or inaccurate information to the Department.
 - d. The Department determines that the applicant or enrolled individual failed to submit to the Department all of the information requested in a comprehensive or supplemental written request for information within 30 days after the request, or
 - e. The Department determines that the enrolled individual failed to submit to the Department proof of annual family income or a completed follow-up application as requested in the letter described in R9-6-406.
- D.** The Department shall send a written notice of appealable agency action that complies with A.R.S. Title 41, Chapter 6, Article 10 to each applicant or enrolled individual who is denied enrollment or continuing enrollment. The applicant or enrolled individual may file a notice of appeal with the Department within 30 days after receiving the notice of appealable agency action. The appeal shall be conducted in accordance with A.R.S. Title 41, Chapter 6, Article 10.
- E.** For the purpose of computing time-frames in this Section, the day of the act, event, or default from which the designated period of time begins to run is not included. Intermediate Saturdays, Sundays, and legal holidays are included in the computation. The last day of the period so computed is included unless it is a Saturday, a Sunday, or a legal holiday, in which event the period runs until the end of the next day that is not a Saturday, a Sunday, or a legal holiday.

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Table 1. Time-frames (in days)

<u>Type of Approval</u>	<u>Statutory Authority</u>	<u>Overall Time-frame</u>	<u>Administrative Completeness Review Time-frame</u>	<u>Substantive Review Time-frame</u>
<u>Application for ADAP Enrollment</u>	<u>A.R.S. § 36-136</u>	<u>52</u>	<u>10</u>	<u>42</u>
<u>Follow-up Application for ADAP Continuing Enrollment</u>	<u>A.R.S. § 36-136</u>	<u>30</u>	<u>10</u>	<u>20</u>

~~R9-6-408~~R9-6-409. Confidentiality

The Department considers ADAP application materials and all information received or maintained by the Department in connection with ADAP application for support and subsequent actions shall to be considered as confidential medical information, as defined in 9 A.A.C. 1, Article 3. The provisions of A.A.C. R9-1-311 et seq. shall govern the Department Department shall comply with 9 A.A.C. 1, Article 3 with regard to disclosing these materials and this information.

Exhibit A. Consent for HIV Testing Renumbered

Consent for HIV Testing

Information on HIV

The Human Immunodeficiency Virus (HIV) is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). HIV is spread through the exchange of blood (including transfusion), sexual fluids (semen and vaginal secretions) and sometimes through breast milk. HIV can be transmitted from mother to baby during pregnancy or childbirth.

HIV Testing

There are several laboratory tests for HIV. The most common is the antibody test, which is a blood test that detects antibodies produced by the body in response to infection with HIV.

A positive antibody test consists of a repeatedly reactive (the same specimen testing positive twice) enzyme immunoassay (EIA) and a reactive Western blot (supplementary test). A positive antibody test means that an individual is infected with HIV; however, this does not always mean that the individual has AIDS. Research indicates that early and regular medical care is important to the health of a person with HIV. Certain treatments are now available to delay HIV-associated illnesses.

A negative antibody test indicates that no detectable antibodies are present in the blood. An individual may not have antibodies because the individual is not infected with HIV or because detectable antibodies have not yet been made in response to infection. The production of these antibodies could take 3 months or longer. Therefore, in certain cases, an individual may be infected with HIV and yet test negative. Individuals with a history of HIV risk behaviors within the past 3 to 6 months should consider retesting.

Like any test, HIV testing is not 100% reliable and may occasionally produce both false positive and false negative results.

Means to Reduce Risk for Contracting or Spreading HIV

Risk of contracting or spreading HIV can be reduced by avoiding or decreasing contact with blood and sexual fluids (semen and vaginal secretions). Some methods of decreasing the risk of contracting or spreading HIV include abstaining from sexual intercourse, using methods that limit exposure to body fluids during intercourse (such as the proper use of condoms), not engaging in injecting drug use, not sharing needles, or using bleach and water to clean needles and syringes. The use of certain medications by a HIV-infected woman during pregnancy may reduce the chances of HIV transmission from mother to child.

Disclosure of Test Results

I understand that if the HIV test results are positive, the physician or facility representative conducting the test will make reasonable efforts to notify me of the results at the address or phone number I have provided, and will provide or arrange for counseling as required by Arizona state laws and regulations regarding (1) the HIV (2) AIDS and (3) appropriate precautions to reduce the likelihood of transmission of the virus to others. I agree to assume all risks that may result if I cannot be contacted.

I understand that Arizona law and regulations require that if my test results are positive, they will be submitted to local and state health departments. Information received by these health departments may only be released (1) if there is written authorization from the person being tested; (2) for statistical purposes without individual identifying information; or as otherwise required or allowed by law.

I also understand that the physician or facility may report to the Arizona Department of Health Services identifiable 3rd parties such as a spouse or sex partner who may be at risk of contracting the virus if I do not release this information. Finally, I understand that the test results may be placed in a medical record kept by the facility or person administering the test and that persons involved in providing or paying for my health care may have access to that information.

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Identifying Information

Additional Sources of Information on HIV

Additional information regarding testing for HIV is available through your county health department and, in the Phoenix metropolitan area, (602) 234-2752, the Tucson metropolitan area, (520) 326-2437, or outside the Phoenix area, 1-800-334-1540. National Hotline: English, 1-800-342-2437; Spanish, 1-800-344-7432; TTY/TDD, 1-800-243-7012.

Consent

I have been given the opportunity to ask questions regarding this information and have had my questions answered to my satisfaction. I understand that this test can be performed anonymously at a public health agency. I also understand that I may withdraw my consent at any time before a blood sample is taken in order to conduct a test, and that I may be asked to put my decision to withdraw my consent in writing if I have signed this consent. I also understand that this is a voluntary test and that I have a right to refuse to be tested.

My signature below indicates that I have received and understand the information I have been given and I voluntarily consent to and request HIV testing.

Patient/Subject Name (Printed)

Patient/Subject or Legal Representative Signature

Date

Witness

NOTICE

The Arizona Department of Health Services does not discriminate on the basis of disability in the administration of its programs and services as prescribed by Title II of the Americans with Disabilities Act of 1990 and Section 504 of the Rehabilitation Act of 1973. If you need this publication in an alternative format, please contact the ADHS Office of HIV/STD Services at (602) 230-5819 or 1-800-367-8939 (state TDD/TTY Relay).

Exhibit B. Consentimiento Para la Prueba de VIH Renumbered

Consentimiento Para la Prueba de VIH

Información sobre el VIH

El virus de Inmunodeficiencia Humana (VIH) es el virus que causa el Síndrome de Inmunodeficiencia Adquirida (SIDA). VIH se transmite a través del contacto con sangre (incluyendo la transfusión), fluidos sexuales (semen y secreciones vaginales) y en algunas ocasiones a través de la leche materna. VIH puede ser transmitido de la madre al bebé durante el embarazo o al momento del parto.

La prueba del VIH

Existen pruebas de laboratorio para saber si una persona está infectada con el VIH. La más común es la prueba de anticuerpos. Esta es un exámen de sangre que detecta los anticuerpos producidos por el cuerpo al reaccionar contra la infección por VIH.

Un examen de anticuerpos positivo consiste de una prueba por inmunoenálisis enzimático (EIA) (realizada dos veces en cada espécimen) y una prueba reactiva por Western Blot u otras pruebas confirmatorias. El resultado positivo a la prueba de anticuerpos quiere decir que el individuo está infectado con el VIH; sin embargo, esto no siempre quiere decir que el individuo tenga el SIDA. Investigaciones médicas señalan que atención médica temprana y continua es importante para la salud de una persona con el VIH. Hoy en día se dispone de tratamientos para retardar las enfermedades asociadas con el SIDA.

Un exámen de anticuerpos negativo indica que no se han detectado anticuerpos en la sangre. Un individuo puede no tener anticuerpos porque el individuo no está infectado(a) o porque aún no se han producido suficientes anticuerpos contra la infección. Estos anticuerpos pueden tardar tres meses o más para ser producidos. De tal manera, en ciertos casos, un individuo puede estar infectado con el VIH y su prueba resultar negativa. Los individuos que han tenido comportamiento de alto riesgo en los últimos tres a seis meses deberían pensar en repetir la prueba.

Como cualquier prueba, la prueba del VIH no es 100% segura y en alguna ocasión puede producir resultados falsos ya sea positivos o negativos.

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Maneras de reducir el riesgo de infección o transmisión del VIH

El riesgo de contraer o transmitir el VIH se puede reducir al evitar contacto con la sangre y fluidos sexuales (semen y secreciones vaginales). Algunos métodos para disminuir el riesgo de infección o transmisión del VIH incluyen: abstinencia sexual, usar métodos que limitan el contacto de fluidos corporales durante la relaciones sexuales (como el uso correcto de condones), no usar drogas intravenosas, no compartir agujas, y usar “cloro” (blanqueador) y agua para limpiar las jeringas y las agujas. En mujeres infectadas con VIH, el uso de ciertos medicamentos durante el embarazo, puede reducir el riesgo de transmisión del VIH de madre a hijo.

El resultado de la prueba

Entiendo que si el resultado de la prueba del VIH es positivo, el doctor o el representante de la institución que hizo el examen va a hacer esfuerzos suficientes para notificarme del resultado a la dirección (domicilio) o al teléfono que he proporcionado y que me dará información, cumpliendo con los requisitos de la ley estatal de Arizona, sobre (1) el VIH, (2) el SIDA, y (3) las precauciones necesarias para reducir la posibilidad de transmisión del virus a otras personas. Estoy de acuerdo en asumir todos los riesgos que resultarán de no poder contactarme.

Entiendo que la ley estatal de Arizona exige que si el resultado de mi prueba es positivo, éste se reportará a los departamentos de salud local y estatal. La información que estos departamentos reciben solamente puede ser revelada a otras personas: (1) si hay una

Identifying Information/Datos de Identidad

autorización por escrito de la persona que se ha hecho la prueba; (2) por razones de estudios estadísticos sin revelar la identidad del individuo, o por cualquier otra razón que la ley permita.

También entiendo que el doctor o la institución puede reportar al Departamento de Salud del Estado de Arizona, la identidad de terceras personas como: los esposos(as) o los compañeros(as) sexuales que pueden estar en riesgo de contraer con el virus si decido no darles esta información. Por último, entiendo que el resultado de la prueba puede guardarse con el resto de mi información médica en la agencia o por la persona que hizo el examen; y que las personas encargadas de proveer o pagar por el cuidado de mi salud pueden tener acceso a esta información.

Otras fuentes de información sobre el VIH

Información adicional sobre el examen del VIH está disponible a través del departamento de salud de su condado. En el área metropolitana de Phoenix llame al (602) 234-2752, en el área metropolitana de Tucson (520) 326-2437, y en el resto de Arizona 1-800-334-1540. Líneas telefónicas a nivel nacional son: en inglés 1-800-342-2437; en español 1-800-344-7432. (TTY/TDD) Transmisión de voz 1-800-243-7012.

Consentimiento

Se me ha dado la oportunidad de hacer preguntas respecto a esta información y me han sido contestadas satisfactoriamente. Entiendo que este examen se puede hacer de forma anónima en una agencia de salud pública. También entiendo que puedo retirar mi consentimiento en cualquier momento antes de que me saquen la sangre para hacer la prueba y que me pueden pedir que ponga por escrito mi decisión de retirar mi consentimiento si ya había firmado este permiso. Entiendo también que este examen es voluntario y que tengo el derecho a negarme a que se me haga la prueba.

Mi firma indica que he recibido y he entendido la información que se me ha proporcionado y que voluntariamente autorizo y solicito la prueba del VIH.

Nombre del paciente (letra imprenta)

Firma del paciente o de su representante legal

Fecha

Testigo

AVISO

El Departamento de Salud del Estado de Arizona no discrimina basado en los impedimentos de las personas en la administración de los programas y servicios ordenado por la ley de 1990: Americanos con Impedimentos, Título II y la Sección 504 de la ley de Rehabilitación de 1973. Si usted necesita esta publicación por otros medios de comunicación, favor ponerse en contacto con el Departamento de Salud del Estado de Arizona, Oficina de Servicios de VIH/ETS al 1-800-842-4681 (transmisión de voz estatal) or 1-800-367-8939 (transmisión TDD/FYY estatal).

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R9-6-410. Human Immunodeficiency Virus Testing Renumbered

A blood test performed pursuant to A.R.S. § 13-1415 for antibodies to HIV shall use an enzyme immunoassay test and shall be licensed by the Food and Drug Administration (FDA). Blood that is reactive according to the manufacturer's recommendations shall be retested in duplicate, diluting from the original specimen. Repeatedly reactive blood shall be tested with an FDA-licensed Western blot test. Western blot band patterns shall be interpreted according to the recommendations, "Interpretation and Use of the Western Blot Assay for Serodiagnosis of Human Immunodeficiency Virus Type 1 Infections", Morbidity and Mortality Weekly Report, July 21, 1989, vol. 38, No. S-7, Centers for Disease Control, 1600 Clifton Road, N.E., Atlanta, GA 30333, incorporated herein by reference and no other amendments and on file with the Office of the Secretary of State. Test results shall be reported directly to the Department.

ARTICLE 9. HIV-RELATED TESTING

R9-6-901. Definitions

In this Article, unless otherwise specified:

1. "Health professional" has the same meaning as "health care provider" in A.R.S. § 36-661.
2. "Hospital" means a health care institution licensed by the Department as a general hospital, a rural general hospital, or a special hospital under 9 A.A.C. 10.
3. "Informed consent" means permission to conduct an HIV-related test obtained from a subject who has capacity to consent or an individual authorized by law to consent for a subject without capacity to consent after an explanation that complies with A.R.S. § 36-663(B).

R9-6-409-R9-6-902. Consent for HIV-related Testing

- A. ~~A person~~ An individual ordering a ~~an~~ HIV-related test shall obtain consent for the test, unless the test has been ordered by the ~~a~~ court under A.R.S. §§ ~~8-341, 13-1210, or 13-1415(B)~~ or falls under A.R.S. § 36-663(D).
1. If the test is ordered in a hospital, the individual ordering the test shall obtain ~~specific~~ written informed consent ~~is required as specified in subsection (B).~~
 2. If the test is ordered outside a hospital by a physician licensed pursuant to A.R.S. Title 32, Chapter 13, 17, or 29, a ~~registered nurse practitioner certified pursuant to A.R.S. Title 32, Chapter 15,~~ or a physician's assistant certified pursuant to A.R.S. Title 32, Chapter 25, the individual ordering the test shall obtain ~~consent shall be~~ either written informed consent as specified in subsection (B) or oral informed consent.
 3. If the test is ordered outside a hospital by a health professional licensed under A.R.S. Title 32, but not listed in subsection (A)(2), who is authorized to provide HIV-related tests within the health professional's scope of practice, the individual ordering the test shall obtain written informed consent as specified in subsection (B).
 4. If the HIV-related test is performed anonymously, ~~then~~ the individual ordering the test shall obtain oral consent ~~is required and no record shall be made with~~ not make a record containing personal identifying information ~~on~~ about the patient ~~subject~~.
- B. ~~Written consent shall be on~~ An individual obtaining written, informed consent for an HIV-related test shall use the form shown in Exhibit A (English) or Exhibit B (Spanish).
1. ~~Individuals and facilities~~ Except as described in subsection (A)(4), an individual using the consent form may add ~~or~~ affix the following ~~additional~~ information in the Identifying Information section of the form:
 - a. ~~patient/subject's~~ The subject's name and identifying number,
 - b. ~~facility~~ Facility identifying information,
 - c. ~~facility~~ Facility processing codes, and
 - d. ~~patient/subject's~~ The subject's date of birth and sex.
 2. This form may be reproduced to accommodate a multiple copy or carbonless form.

Exhibit A. Exhibit A. Consent for HIV-related Testing

Consent for HIV-related Testing

Information on HIV

The Human Immunodeficiency Virus (HIV) is the virus that causes Acquired ~~Immune Deficiency~~ Immunodeficiency Syndrome (AIDS). HIV is spread through the exchange of blood (including transfusion); ~~or~~ sexual fluids (semen and vaginal secretions) and sometimes through breast milk. HIV can be transmitted from mother to baby during pregnancy or childbirth.

HIV-related Testing

There are several laboratory tests for HIV. The most common is the antibody test, which is a blood test that detects antibodies produced by the body in response to infection with HIV.

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A positive antibody test consists of a repeatedly reactive (the same specimen testing positive twice) enzyme immunoassay (EIA) and a reactive Western blot (or other supplementary confirmatory test). A positive antibody test means that an individual is infected with HIV; however, this does not always mean that the individual has AIDS. Research indicates that early and regular medical care is important to the health of ~~a person~~ an individual with HIV. Certain treatments are now available to ~~delay~~ treat HIV-associated illnesses.

A negative antibody test indicates that no detectable antibodies are present in the blood. An individual may not have antibodies because the individual is not infected with HIV or because detectable antibodies have not yet been made in response to infection. The production of these antibodies could take 3 months or longer. Therefore, in certain cases, an individual may be infected with HIV and yet test negative. Individuals with a history of HIV risk behaviors within the past 3 to 6 months should consider retesting.

Like any test, HIV-related testing is not accurate 100% reliable of the time and may occasionally produce both false positive and false negative results.

Means to Reduce Risk for Contracting or Spreading HIV

Risk of contracting or spreading HIV can be reduced by avoiding or decreasing contact with blood and sexual fluids (semen and vaginal secretions). Some methods of decreasing the risk of contracting or spreading HIV include abstaining from sexual intercourse, using methods that limit exposure to body fluids during intercourse (such as the proper use of condoms), not engaging in injecting drug use, not sharing needles, or using bleach and water to clean needles and syringes. The use of certain medications by ~~a~~ an HIV--infected woman during pregnancy may reduce the chances of HIV transmission from mother to child.

Disclosure of Test Results

I understand that if the HIV test results are positive, the physician or facility representative conducting the test will make reasonable efforts to notify me of the results at the address or phone number I have provided, and will provide or arrange for counseling as required by Arizona state laws and regulations regarding (1) ~~the~~ HIV, (2) AIDS, and (3) appropriate precautions to reduce the likelihood of transmission of the virus to others. I agree to assume all risks that may result if I cannot be contacted.

I understand that Arizona law and regulations require that if my test results are positive, they will be submitted to local and state health departments. Information received by these health departments may only be released: (1) if there is written authorization from the ~~person~~ individual being tested; (2) for statistical purposes without individual identifying information, or (3) as otherwise required or allowed by law.

Identifying Information

I also understand that the physician or facility may report to the Arizona Department of Health Services identifiable 3rd parties such as a spouse or sex partner who may be at risk of contracting the virus if I do not release this information. Finally, I understand that the test results may be placed in a medical record kept by the facility or person administering the test and that persons involved in providing or paying for my health care may have access to that information.

Additional Sources of Information on HIV

Additional information regarding testing for HIV is available through your county health department and, in the Phoenix metropolitan area, (602) 234-2752, the Tucson metropolitan area, (520) ~~326-2437~~ 791-7676, or outside the Phoenix area, 1-800-334-1540. National Hotline: English, 1-800-342-2437; Spanish, 1-800-344-7432; TTY/TDD, 1-800-243-7012.

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Consent

I have been given the opportunity to ask questions regarding this information and have had my questions answered to my satisfaction. I understand that this test can be performed anonymously at a public health agency. I also understand that I may withdraw my consent at any time before a blood sample is taken in order to conduct a test, and that I may be asked to put my decision to withdraw my consent in writing if I have signed this consent. I also understand that this is a voluntary test and that I have a right to refuse to be tested.

My signature below indicates that I have received and understand the information I have been given and I voluntarily consent to and request HIV-related testing.

Patient/Subject Name (Printed)

Patient/Subject or Legal Representative Signature

Date

Witness

NOTICE

The Arizona Department of Health Services does not discriminate on the basis of disability in the administration of its programs and services as prescribed by Title II of the Americans with Disabilities Act of 1990 and Section 504 of the Rehabilitation Act of 1973. If you need this publication in an alternative format, please contact the ADHS Office of HIV/STD Services at (602) 230-5819 or 1-800-367-8939 (state TDD/TTY Relay).

~~Exhibit B~~ Exhibit B. Consentimiento Para La Prueba de VIH

Consentimiento Para la Prueba de VIH

Información sobre el VIH

El virus de Inmunodeficiencia Humana (VIH) es el virus que causa el Síndrome de Inmunodeficiencia Adquirida (SIDA). VIH se transmite a través del contacto con sangre (incluyendo la transfusión); o fluidos sexuales (semen y secreciones vaginales) y en algunas ocasiones a través de la leche materna. VIH puede ser transmitido de la madre al bebé durante el embarazo o al momento del parto.

La prueba del VIH

Existen pruebas de laboratorio para saber si una persona está infectada con el VIH. La más común es la prueba de anticuerpos. Esta es un exámen de sangre que detecta los anticuerpos producidos por el cuerpo al reaccionar contra la infección por VIH.

Un examen de anticuerpos positivo consiste de una prueba por inmunoanálisis enzimático (EIA) (realizada dos veces en cada espécimen) y una prueba reactiva por Western Blot u otras pruebas confirmatorias. El resultado positivo a la prueba de anticuerpos quiere decir que el individuo está infectado con el VIH; sin embargo, esto no siempre quiere decir que el individuo tenga el SIDA. Investigaciones médicas señalan que atención médica temprana y continúa es importante para la salud de una persona con el VIH. Hoy en día se dispone de tratamientos para retardar las enfermedades asociadas con el SIDA.

Un exámen de anticuerpos negativo indica que no se han detectado anticuerpos en la sangre. Un individuo puede no tener anticuerpos por que el individuo no está infectado(a) o porque aún no se han producido suficientes anticuerpos contra la infección. Estos anticuerpos pueden tardar tres meses o más para ser producidos. De tal manera, en ciertos casos, un individuo puede estar infectado con el VIH y su prueba resultar negativa. Los individuos que han tenido comportamiento de alto riesgo en los últimos tres a seis meses deberían pensar en repetir la prueba.

Como cualquier prueba, la prueba del VIH no es 100% segura y en alguna ocasión puede producir resultados falsos ya sea positivos o negativos.

Maneras de reducir el riesgo de infección o transmisión del VIH

El riesgo de contraer o transmitir el VIH se puede reducir al evitar contacto con la sangre y fluidos sexuales (semen y secreciones vaginales). Algunos métodos para disminuir el riesgo de infección o transmisión del VIH incluyen: abstinencia sexual, usar métodos que limitan el contacto de fluidos corporales durante la relaciones sexuales (como el uso correcto de condones), no usar drogas intravenosas, no compartir agujas, y usar “cloro” (blanqueador) y agua para limpiar las jeringas y las agujas. En mujeres infectadas con VIH, el uso de ciertos medicamentos durante el embarazo, puede reducir el riesgo del transmisión del VIH de madre a hijo.

El resultado de la prueba

Entiendo que si el resultado de la prueba del VIH es positivo, el doctor o el representante de la institución que hizo el exámen va a hacer esfuerzos suficientes para notificarme del resultado a la dirección (domicilio) o al teléfono que he proporcionado y que me dará información, cumpliendo con los requisitos de la ley estatal de Arizona, sobre (1) el VIH, (2) el SIDA, y (3) las precauciones necesarias para reducir la posibilidad de transmisión del virus a otras personas. Estoy de acuerdo en asumir todos los riesgos que resultarán de no poder contactarme.

Entiendo que la ley estatal de Arizona exige que si el resultado de mi prueba es positivo, éste se reportará a los departamentos de salud local y estatal. La información que estos departamentos reciben solamente puede ser revelada a otras personas: (1) si hay una

Identifying Information/Datos de Identidad

autorización por escrito de la persona que se ha hecho la prueba; (2) por razones de estudios estadísticos sin revelar la identidad del individuo, o (3) por cualquier otra razón que la ley permita.

También entiendo que el doctor o la institución puede reportar al Departamento de Salud del Estado de Arizona, la identidad de terceras personas como: los esposos(as) o los compañeros(as) sexuales que pueden estar en riesgo de contraer con el virus si decido no darles esta información. Por último, entiendo que el resultado de la prueba puede guardarse con el resto de mi información médica en la agencia o por la persona que hizo el examen; y que las personas encargadas de proveer o pagar por el cuidado de mi salud pueden tener acceso a esta información.

Otras fuentes de información sobre el VIH

Información adicional sobre el examen del VIH está disponible a través del departamento de salud de su condado. En el área metropolitana de Phoenix llame al (602) 234-2752, en el área metropolitana de Tucson (520) ~~326-2437~~ 791-7676, y en el resto de Arizona 1-800-334-1540. Líneas telefónicas a nivel nacional son: en inglés 1-800-342-2437; en español 1-800-344-7432. (TTY/TDD) Transmisión de voz 1-800-243-7012.

Consentimiento

Se me ha dado la oportunidad de hacer preguntas respecto a esta información y me han sido contestadas satisfactoriamente. Entiendo que este exámen se puede hacer de forma anónima en una agencia de salud pública. También entiendo que puedo retirar mi consentimiento en cualquier momento antes de que me saquen la sangre para hacer la prueba y que me pueden pedir que ponga por escrito mi decisión de retirar mi consentimiento si ya había firmado este permiso. Entiendo también que este exámen es voluntario y que tengo el derecho a negarme a que se me haga la prueba.

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Mi firma indica que he recibido y he entendido la información que se me ha proporcionado y que voluntariamente autorizo y solicito la prueba del VIH.

Nombre del paciente (letra imprenta)

Firma del paciente o de su representante legal

Fecha

Testigo

AVISO

El ~~Departamento~~ Departamento de Salud del Estado de Arizona no discrimina basado en los impedimentos de las personas en la administración de los programas y servicios ordenado por la ley de 1990: Americanos con Impedimentos, Título II y la Sección 504 de la ley de Rehabilitación de 1973. Si usted necesita esta publicación por otros medios de comunicación, favor ponerse en contacto con el Departamento de Salud del Estado de Arizona, Oficina de Servicios de VIH/ETS al 1-800-842-4681 (transmisión de voz estatal) or 1-800-367-8939 (transmisión TDD/TYY estatal).

R9-6-410, R9-6-903, Human Immunodeficiency Virus Court-ordered HIV-related Testing

A. ~~A An individual who tests a specimen of blood or another body fluid to detect HIV antibody test performed pursuant to under court order issued under A.R.S. §§ 8-341 or 13-1415 for antibodies to HIV shall use an enzyme immunoassay a test and shall be licensed by the United States Food and Drug Administration (FDA) for use in HIV screening. Blood that If a specimen is reactive two or more times according to the test manufacturer's recommendations, the individual shall be retested in duplicate, diluting from the original specimen retest the specimen using a licensed supplemental or confirmatory assay or as recommended by the original test manufacturer's package insert. Repeatedly reactive blood shall be tested with an FDA-licensed Western blot test. Western blot band patterns shall be interpreted according to the recommendations, "Interpretation and Use of the Western Blot Assay for Serodiagnosis of Human Immunodeficiency Virus Type 1 Infections", Morbidity and Mortality Weekly Report, July 21, 1989, vol. 38, No. S-7, Centers for Disease Control, 1600 Clifton Road, N.E., Atlanta, GA 30333, incorporated herein by reference and no other amendments and on file with the Office of the Secretary of State.~~

B. ~~Test results The individual shall be reported report each test result for each subject directly to the Department.~~

NOTICE OF PROPOSED RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 16. DEPARTMENT OF HEALTH SERVICES

OCCUPATIONAL LICENSING

PREAMBLE

1. Sections Affected

R9-16-401
R9-16-401
R9-16-402
R9-16-402
R9-16-403
R9-16-404
R9-16-405
R9-16-405
R9-16-406
R9-16-406
R9-16-407
R9-16-407
R9-16-408
R9-16-409

Rulemaking Action

Repeal
New Section
Repeal
New Section
New Section
New Section
Repeal
New Section
Repeal
New Section
Repeal
New Section
Repeal
Repeal

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R9-16-410	Repeal
R9-16-411	Repeal
R9-16-412	Repeal
R9-16-413	Repeal
R9-16-414	Repeal

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. § 36-136(F)

Implementing statute: A.R.S. § 36-136.01

3. A list of all previous notices appearing in the Register addressing the proposed rules

Notice of Rulemaking Docket Opening: 7 A.A.R. 3120, July 20, 2001

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

Name: Kathleen Phillips, Rules Administrator

Address: Department of Health Services
1740 W. Adams, Suite 102
Phoenix, AZ 85007

Phone: (602) 542-1264

Fax: (602) 364-1150

E-mail: kphillips@hs.state.az.us

or

Name: Will Humble, Office Chief

Address: Department of Health Services
3815 N. Black Canyon Highway
Phoenix, AZ 85015

Phone: (602) 230-5941

Fax: (602) 230-5933

E-mail: whumble@hs.state.az.us

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

The current rules, adopted September 29, 1976, set forth requirements for the registration of sanitarians with the Sanitarians' Council (Council). The last Five-Year Review Report (Report) was approved by the Governor's Regulatory Review Council (G.R.R.C.) on January 9, 1996. Proposed rules were drafted and published in the Arizona Administrative Register on September 20, 2000, oral proceedings were held, and a final rulemaking package was submitted to G.R.R.C. In the process of reviewing the final rulemaking package, substantive and statutory issues were identified and the rulemaking was terminated. The proposed rules address issues in the Report, reflect current industry standards and Council policy, incorporate current statutory requirements, and resolve the issues identified during the G.R.R.C. review.

R9-16-401 is being repealed and replaced with new definitions. R9-16-402 provides an individual with procedures for applying to take the sanitarian examination and be registered as a sanitarian. R9-16-403 details how a registered sanitarian renews registration and provides procedures when registration has lapsed. R9-16-404 requires registered sanitarians to notify the Council when there is a change in the registered sanitarian's name or address. R9-16-405 is being repealed and replaced with licensing time-frame rules. R9-16-406 sets forth the authority of a registered sanitarian and requirements for a sanitarian aide and R9-16-407 provides criteria and procedures for suspending the registration of a registered sanitarian. The remaining Sections, R9-16-408 through R9-16-414, are being repealed because the rules exceed the Council's statutory authority or contain material that is not appropriate for rulemaking.

6. Reference to any study that the agency proposes to rely on and its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material:

Not applicable

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7. 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

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

The Department will benefit from increasing the sanitarian examination fee for individuals to the actual cost of the sanitarian examination under A.R.S. § 36-136.01. The Department will also incur costs for promulgating the rules and implementing licensing time-frames.

An applicant for sanitarian registration will benefit from the elimination of the prohibition against the applicant's taking the sanitarian examination more than three times within five years. An applicant will have minimally increased costs due to the increase in the sanitarian examination fee. In addition, the proposed rules require individuals previously registered through reciprocity to take the sanitarian examination which will minimally increase those individuals' costs.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Kathleen Phillips, Rules Administrator

Address: Department of Health Services
1740 W. Adams, Suite 102
Phoenix, AZ 85007

Phone number: (602) 542-1264

Fax number: (602) 364-1150

E-mail: kphillips@hs.state.az.us

or

Name: Will Humble, Office Chief

Address: Department of Health Services
3815 N. Black Canyon Highway
Phoenix, AZ 85015

Phone number: (602) 230-5941

Fax number: (602) 230-5933

E-mail: whumble@hs.state.az.us

10. The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

Date: January 29, 2002

Time: 9:00 a.m.

Location: Department of Health Services, Conference Room 411
1740 W. Adams
Phoenix, AZ 85007

Nature: Public hearing on the proposed rule

Written comments on the proposed rules may be submitted to the individuals listed in questions # 4 and #9 no later than the close of record 5:00 p.m., January 29, 2002.

(Please call (602) 364-2580 for special accommodations pursuant to the Americans with Disabilities Act.)

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

Not applicable

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

Not applicable

13. The full text of the rules follow:

TITLE 9. HEALTH SERVICES

**CHAPTER 16. DEPARTMENT OF HEALTH SERVICES
OCCUPATIONAL LICENSING**

ARTICLE 4. REGISTRATION OF SANITARIANS

Section

R9-16-401.	<u>Legal Authority Definitions</u>
R9-16-402.	<u>Definitions Sanitarian Examination and Registration</u>
R9-16-403.	<u>Reserved Annual Registration Renewal</u>
R9-16-404.	<u>Reserved Change of Name or Address</u>
R9-16-405.	<u>Reciprocity Time-frames</u>
R9-16-406.	<u>Application for registration Authority of a Registered Sanitarian</u>
R9-16-407.	<u>Fees Denial, Suspension, or Revocation</u>
R9-16-408.	<u>Examination Repealed</u>
R9-16-409.	<u>Registered sanitarian; examples of duties Repealed</u>
R9-16-410.	<u>Denial or application for registration Repealed</u>
R9-16-411.	<u>Suspension and revocation of registration Repealed</u>
R9-16-412.	<u>Re-registration Repealed</u>
R9-16-413.	<u>Continuing education Repealed</u>
R9-16-414.	<u>Violations Repealed</u>

ARTICLE 4. REGISTRATION OF SANITARIANS

R9-16-401. Legal Authority Definitions

The Sanitarians' Council, a component of the Arizona Department of Health Services, pursuant to the authority granted in A.R.S. § 36-136.01, hereby adopts the following regulations for the registration of sanitarians:

In this Article, unless otherwise specified:

1. "Applicant" means an individual requesting from the Council:
 - a. Approval to take the sanitarian examination;
 - b. Registration as a sanitarian; or
 - c. Renewal of registration as a sanitarian.
2. "Application packet" means a Council-approved application form and the documentation necessary to establish an individual's qualifications for registration as a sanitarian.
3. "Billet" means an individual's military job position and job description.
4. "Council" means the Sanitarians' Council established under A.R.S. § 36-136.01(A).
5. "Course" means a program of instruction for which credit toward graduation or certification is given.
6. "Day" means calendar day.
7. "Environmental health" means the well-being of a human as affected or influenced by external conditions such as: bacteria and viruses; transmitted diseases; hygiene; housing; and contamination of food, air, water, or soil.
8. "Full-time military duty" means active duty in any branch of the United States military service.
9. "Natural science" means anatomy, bacteriology, biochemistry, biology, botany, biophysics, biostatistics, cell physiology, chemical engineering, chemistry, ecology, embryology, endocrinology, entomology, environmental health, epidemiology, food bacteriology, dairy sciences, genetics, geophysics, geology, herpetology, histology, hydro geology, hydrology, ichthyology, limnology, microbiology, molecular biology, ornithology, parasitology, pathology, pharmacy, physics, physiology, plant taxonomy, radiological health, sanitary engineering, sewage sanitation, soil science, toxicology, vector control, veterinary science, virology, or zoology or the study of air pollution, community health, environmental diseases, hazardous waste, industrial hygiene, infectious diseases, occupational safety, or public health.
10. "Person" has the same meaning as in A.R.S. § 1-215.
11. "Practice of a registered sanitarian" means acting under the authority of R9-16-406(A).
12. "Registration" means the approval issued by the Council to an applicant who meets the requirements in A.R.S. § 36-136.01 and this Article.
13. "Regulatory authority" has the same meaning as in A.A.C. R9-8-107(B)(11).
14. "Supervise" means oversee and provide guidance for the accomplishment of a function or activity.

R9-16-402. Definitions Sanitarian Examination and Registration

In Article 4, unless the context otherwise requires:

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1. ~~“Continuing education unit” means 10 contact hours of participation in an organized continuing education experience under responsible sponsorship, capable direction and qualified instruction. One contact hour is the equivalent of 50 minutes of classroom study.~~
2. ~~“Council” means the Sanitarians’ Council established by the Director.~~
3. ~~“Department” means the Department of Health Services.~~
4. ~~“Director” means Director of the Department.~~
5. ~~“Registered sanitarian” means a sanitarian registered in accordance with the provisions of A.R.S. § 36-136.01.~~
6. ~~“Sanitarian aide” means a person who performs specific environmental sanitation activities under the supervision of a registered sanitarian pursuant to R9-16-409(B)(6) and R9-16-409(C). A high school education or its equivalent shall be the minimum educational qualifications for the sanitarian aide.~~
7. ~~“Sanitarian in training” means a person who:~~
 - a. ~~Possesses the necessary education or experience required to become eligible for registration as a sanitarian in Arizona; and~~
 - b. ~~Has submitted evidence that he has been accepted to work in the field of environmental health by a health department, school, government agency or by private industry; and~~
 - e. ~~Has filed an application with the Council for registration as a sanitarian.~~
8. ~~“Training agency” means an institution, governmental agency, private business enterprise, or association which conducts a course or program of instruction which will qualify for continuing education credit pursuant to R9-16-413(E).~~

A. The Council shall provide the sanitarian examination at least four times per calendar year.

B. An applicant meeting any one of the requirements in A.R.S. § 36-136.01(F) may sit for the sanitarian examination.

C. At least seven days before a Council meeting, an applicant shall:

1. Submit an application form to the Council that contains:
 - a. The applicant’s full name and all former names;
 - b. The applicant’s current address and telephone number;
 - c. The applicant’s social security number;
 - d. If applying under A.R.S. § 36-136.01(F)(1) on the basis of the applicant’s employment by a public health agency or private industry in a position directly related to environmental health:
 - i. The name of each of the applicant’s employers.
 - ii. The applicant’s position for each employer.
 - iii. The months and years of employment in each position, and
 - iv. The name and telephone number of each individual who supervised the applicant during five years of employment in environmental health;
 - e. If applying under A.R.S. § 36-136.01(F)(2) on the basis of military duty:
 - i. Each of the applicant’s billets in environmental health.
 - ii. The months and years in each billet, and
 - iii. The name and telephone number of each individual who supervised the applicant during five years of full-time military duty in environmental health;
 - f. If applying under A.R.S. § 36-136.01(F)(3) on the basis of education in natural science:
 - i. The name and address of each college or university attended.
 - ii. The months and years of attendance.
 - iii. Any degree obtained, and
 - iv. A listing of courses in natural science completed with a grade of C or better;
 - g. Whether the applicant has had an application for a registration, license, or certificate related to the practice of a registered sanitarian denied or rejected by any state or jurisdiction including the:
 - i. Reason for denial or rejection.
 - ii. Date of the denial or rejection, and
 - iii. Name and address of the state or jurisdiction that denied or rejected the application;
 - h. Whether the applicant has had a registration, license, or certificate related to the practice of a registered sanitarian suspended or revoked by any state or jurisdiction or entered into a consent agreement with a state or jurisdiction including the:
 - i. Reason for the suspension, revocation, or consent agreement;
 - ii. Date of the suspension, revocation, or consent agreement; and
 - iii. Name and address of the state or jurisdiction that suspended or revoked the registration, license, or certificate or issued the consent agreement;
 - i. Whether the applicant has pled guilty to, been convicted of, or entered a plea of no contest to a felony or misdemeanor related to the applicant’s employment as a sanitarian including the:
 - i. Felony or misdemeanor charged;
 - ii. Date of conviction or plea; and
 - iii. Court having jurisdiction over the felony or misdemeanor;

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B. A registered sanitarian shall send written notice of a change in the registered sanitarian's mailing address to the Council within 30 days from the date of the change.

R9-16-405. Reciprocity Time-frames

A. ~~The Council will issue a registration certificate without examination to an applicant who holds a current and valid certificate issued under laws or a voluntary certification program of any other state, territory or the District of Columbia, provided:~~

- ~~1. The out-of-state certificate was issued as the result of successfully passing an examination developed by an examination service used by the Council for sue by state or other governmental sanitarian registration agencies within the 10 year period next preceding the date of application for current Arizona registration, and~~
- ~~2. The applicant meets the requirements of A.R.S. § 36-136.01(G).~~

B. ~~The Council may also issue a registration certificate without examination to an applicant who meets the requirements of A.R.S. § 36-136.01(G), if the examination which was successfully passed was substantially equivalent to the examination describe in R9-16-408(B), but was taken prior to the 10 year period preceding application, if proof of completion of 10 contact hours of continuing education courses per year for the previous 3 years, is provided with the application. The continuing education courses used as the basis for registration through reciprocity must be substantially related to the field of environmental health.~~

A. The overall time-frame described in A.R.S. § 41-1072(2) for each type of approval granted by the Council is set forth in Table 1. The applicant and the Department may agree in writing to extend the substantive review time-frame and the overall time-frame. The substantive review time-frame and the overall time-frame may not be extended by more than 25% of the overall time-frame.

B. The administrative completeness review time-frame described in A.R.S. § 41-1072(1) for each type of approval granted by the Council is specified in Table 1.

1. The administrative completeness review time-frame begins:

- a. For an applicant applying to take the sanitarian examination, when the Council receives the application packet required in R9-16-402;
- b. For an applicant who has been approved to take the sanitarian examination, when the applicant takes the sanitarian examination; or
- c. For an applicant applying to renew the applicant's registration as a sanitarian, when the Council receives the application packet required in R9-16-403.

2. If an application packet in subsection (B)(1)(a) or (B)(1)(c) is:

- a. Incomplete, the Council shall provide a deficiency notice to the applicant describing the missing documentation or incomplete information. The administrative completeness review time-frame and the overall time-frame are suspended from the date of the notice until the date the Council receives the documentation or information listed in the deficiency notice. An applicant shall submit to the Council the documentation or information listed in the deficiency notice within the time period specified in Table 1 for responding to a deficiency notice.
 - i. If the applicant submits the documentation or information listed in the deficiency notice within the time period specified in Table 1 the Council shall provide a written notice of administrative completeness to the applicant.
 - ii. If the applicant does not submit the documentation or information listed in the deficiency notice within the time period in Table 1, the Council considers the application withdrawn and shall return the application packet to the applicant; or
- b. Complete, the Council shall provide a notice of administrative completeness to the applicant.

3. If an applicant takes and submits the sanitarian examination in subsection (B)(1)(b) and the examination is:

- a. Incomplete, the Council shall provide a deficiency notice to the applicant stating that the applicant's sanitarian examination is incomplete and identifying the date of the next scheduled sanitarian examination. The administrative completeness review time-frame and the overall time-frame are suspended from the date of the notice until the Council receives a completed sanitarian examination; or
- b. Complete, the Council shall provide a written notice of administrative completeness to the applicant.

C. The substantive review time-frame described in A.R.S. § 41-1072(3) is specified in Table 1 and begins to run on the date of the notice of administrative completeness.

1. If an application for approval to take the sanitarian examination in subsection (B)(1)(a):

- a. Does not comply with the requirements in this Article and A.R.S. § 36-136.01, the Council shall provide a comprehensive request for additional information to the applicant.
 - i. If the applicant does not submit the additional information within the time specified in Table 1 or the additional information submitted by the applicant does not demonstrate compliance with this Article and A.R.S. § 36-136.01, the Council shall provide the applicant a written notice of denial that complies with A.R.S. § 41-1092.03(A); or

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- ii. If the applicant submits the additional information within the time specified in Table 1 and the additional information submitted by the applicant demonstrates compliance with this Article and A.R.S. § 36-136.01, the Council shall provide a written notice of approval to take the sanitarian examination to the applicant; or
- b. Complies with the requirements in this Article and A.R.S. § 36-136.01, the Council shall provide a written notice of approval to take the sanitarian examination to the applicant.
- 2. If the Council determines that an applicant:
 - a. Failed to sit for the sanitarian examination within the time-frame in subsection (E), the Council shall provide a written notice to the applicant requiring the applicant to submit a new application for approval to take the sanitarian examination;
 - b. Failed the sanitarian examination, the Council shall provide a written notice of appealable agency action that complies with A. R. S. Title 41, Chapter 6, Article 10 to the applicant; or
 - c. Passed the sanitarian examination, the Council shall issue a certificate of registration as a sanitarian to the applicant.
- 3. If an application for renewal of registration as a sanitarian in (B)(1)(c):
 - a. Does not comply with the requirements in this Article and A.R.S. § 36-136.01, the Council shall provide a comprehensive request for additional information to the applicant:
 - i. If the applicant does not submit the additional information within the time specified in Table 1 or the additional information submitted does not demonstrate compliance with the requirements in this Article and A.R.S. § 36-136.01, the Council shall provide a written notice of appealable agency action that complies with A.R.S. Title 41, Chapter 6, Article 10 to the applicant; or
 - ii. If the applicant submits the additional information within the time specified in Table 1 and the additional information submitted demonstrates compliance with the requirements in this Article and A.R.S. § 36-136.01, the Council shall issue a renewal certificate of registration as a sanitarian to the applicant; or
 - b. Complies with the requirements in this Article and A.R.S. § 36-136.01, the Council shall issue a renewal certificate of registration as a sanitarian to the applicant.
- D.** If an applicant receives a written order of appealable agency action in subsections (C)(1)(a)(i) or (C)(2)(b), the applicant may file a notice of appeal with the Department within 30 days after receiving the notice of appealable agency action. The appeal shall be conducted according to A.R.S. Title 41, Chapter 6, Article 10.
- E.** If the Council grants approval to take the sanitarian examination or renews a certificate of registration as a sanitarian during the administrative completeness review time-frame, the Council shall not issue a separate written notice of administrative completeness.
- F.** If an applicant does not sit for the sanitarian examination within 12 months of the Council’s approval to take the sanitarian examination, the applicant shall, before taking the sanitarian examination:
 - 1. Submit a new application for Council approval and the application fee required in R9-16-402(C);
 - 2. Receive Council approval to take the sanitarian examination; and
 - 3. Submit the nonrefundable examination fee required in R9-16-402(D).
- G.** If a time-frame’s last day falls on a Saturday, Sunday, or a legal holiday, the Council considers the next business day as the time-frame’s last day.

Table 1. Time-frames

<u>Type of Approval</u>	<u>Statutory Authority</u>	<u>Overall Time-frame</u>	<u>Administrative Completeness Review Time-frame</u>	<u>Time to Respond to Deficiency Notice</u>	<u>Substantive Review Time-frame</u>	<u>Time to Respond to Comprehensive Written Request</u>
<u>Sanitarian Examination (R9-16-402)</u>	<u>A.R.S. § 36-136.01(B)</u>	<u>290 days</u>	<u>200 days</u>	<u>60 days</u>	<u>90 days</u>	<u>60 days</u>
<u>Registration (R9-16-402)</u>	<u>A.R.S. § 36-136.01(B)</u>	<u>90 days</u>	<u>30 days</u>		<u>60 days</u>	<u>30 days</u>
<u>Annual Registration Renewal (R9-16-403)</u>	<u>A.R.S. § 36-136.01(C)</u>	<u>180 days</u>	<u>90 days</u>	<u>15 days</u>	<u>90 days</u>	<u>15 days</u>

R9-16-406. Application for Registration Authority of a Registered Sanitarian

A. Application forms for registration as a registered sanitarian can be obtained from the Department.

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- ~~B.~~ The application fee and the completed application forms must be received by the Department at least 30 days before the date fixed for the examination or for consideration by the Council when registration without examination is involved.
- ~~C.~~ An affirmative vote by at least 3 members of the Council will be required to approve any registration.
- ~~A.~~ A registered sanitarian may:
 - 1. Act as an authorized representative of a regulatory authority under 9 A.A.C. 8; and
 - 2. Sign inspection reports under 9 A.A.C. 8 and 9 A.A.C. 17.
- ~~B.~~ A individual who is not a registered sanitarian shall:
 - 1. Not approve or disapprove operation of a food establishment under 9 A.A.C. 8; or
 - 2. Submit inspection reports to a registered sanitarian under 9 A.A.C. 8 and 9 A.A.C. 17.

R9-16-407. Fees Denial, Suspension, or Revocation

- ~~A.~~ All fees shall be made payable to the State of Arizona sanitarians Fund.
- ~~B.~~ A fee of \$40.00 shall accompany each application for initial registration as a sanitarian by examination or reciprocity. Where examination is required, this fee is non-returnable.
- ~~C.~~ A fee of \$10.00 shall be submitted with a completed application form for the annual renewal of a registration certificate. Annual renewal fees are due and payable on December 1. A published list of registered sanitarians will be issued on February 15. The names of those who have not paid the renewal fee prior to January 1 will be omitted from the published list. Reinstatement after a period of delinquency of 12 months or more shall be subject to the filing of a new application for registration, to the passing of a written examination, and to the payment of the \$40.00 application fee.
- ~~A.~~ The Council may deny, suspend, or revoke a sanitarian's registration if the Council determines that an applicant or a registered sanitarian:
 - 1. Intentionally provided false information on an application or cheated during the sanitarian examination;
 - 2. Pled guilty to, been convicted of, or entered into a plea of no contest to a felony or misdemeanor resulting from employment as a registered sanitarian;
 - 3. Assisted an unregistered person to circumvent the requirements in this Article;
 - 4. Allowed an unregistered individual to use the registered sanitarian's registration; or
 - 5. Failed to comply with any of the requirements in A.R.S. § 36-136.01 or this Article.
- ~~B.~~ In determining whether to deny an applicant's registration or suspend or revoke a sanitarian's registration, the Council shall consider the threat to public health based on:
 - 1. Whether there is repeated non-compliance with statutes or rules,
 - 2. Whether there is a pattern of violations or non-compliance,
 - 3. Type of violation,
 - 4. Severity of violation, and
 - 5. Number of violations.
- ~~C.~~ The Council's notice of denial, suspension, or revocation to the applicant or registered sanitarian, notice of hearing, and all hearing procedures shall comply with A.R.S. Title 41, Article 10.
- ~~D.~~ The Council shall provide written notice of a registered sanitarian's denial, suspension, or revocation containing a description of the sanitarian's noncompliance with applicable statutes and rules, by certified mail, to each local health department and each public health service district.

R9-16-408. Examination Repealed

- ~~A.~~ Only persons who meet the requirements set forth in A.R.S. § 36-136.01, Subsection G, shall be eligible for admission to examination for registration as a sanitarian.
- ~~B.~~ Examinations for registration as a sanitarian will be administered not less than twice each calendar year, at such times and places in this State as may be specified by the Council. Such examinations will be written and will include such applicable subjects pertinent to the qualifications of a registered sanitarian as the Council may prescribe. The examination papers will not disclose the name of any applicant but will be identified by a number assigned by the Department. The preparation of the examination will be the responsibility of the Council, provided that the Council may at its discretion use material prepared by recognized examination agencies.
- ~~C.~~ A person will not be registered if he fails to meet the minimum grade requirements for examination specified by the Council. If an applicant fails to meet such minimum grade requirements in his 1st examination, he may be re-examined at a regularly scheduled examination upon resubmitting his application accompanied by the prescribed fees, provided that no more than 2 re-examinations may be administered to any person in any 4-year period.
- ~~D.~~ The examination papers, and records pertaining thereto, will be filed with the Department and retained for at least 4 years.

R9--16-409. Registered sanitarian; examples of duties Repealed

- ~~A.~~ There is 1 class of sanitarian for registration purposes. This shall not be construed to prevent further classification by an employer of registered sanitarians for personnel administration purposes. A registered sanitarian may plan, organize, manage, implement and evaluate 1 or more program areas comprising the field of environmental health. Environmental program areas include, but are not limited to: food, beverage, and lodging sanitation; housing, water supply sanitation; land

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use; solid, liquid and hazardous waste disposal; insect, rodent and vermin control; epidemiology; accident prevention; swimming pool and public bathing facility sanitation; radiation safety; air and water quality; noise pollution; and institutional and industrial hygiene. In performing these activities, a registered sanitarian is involved in sanitation related community education, investigation, consultation, review of construction plans, collecting of samples, interpreting laboratory data, enforcement actions and development of regulations.

1. All registered sanitarians must be proficient in the following general duties:
 - a. Development and execution of 1 or more phases, or 1 or more activities, of an environmental health program.
 - b. Performance of responsible environmental health work in a health department, school, government agency or in private industry.
 - c. Conduct of investigations of potential environmental health problems and the preparation of suitable recommendations for their solutions.
 - d. Submission of reports of duties performed including evaluations and recommendations for improvement of program.
2. A registered sanitarian may also:
 - a. Prepare and present environmental health information for teaching public health concepts.
 - b. Promote improvement in environmental health practice and enforcement of State laws and local ordinances through skillful presentation of facts to the public.
 - c. Supervise other registered sanitarians or sanitarian aides.

B. The requirement of A. R. S. § 36-136.01 for registration do not apply to:

1. Any person teaching lecturing or engaging in research in environmental health but only insofar as such activities are performed for academic purposes.
2. Any person who is a sanitary engineer, public health engineer, public health engineer assistant or registered professional engineer except when they are working as a sanitarian.
3. Any public health officer or public health department director pursuant to A. R. S. §§ 36-163 or 36-184.
4. Any person who holds an Arizona license to practice medicine and surgery or veterinary medicine.
5. Laboratory personnel when performing or supervising the performance of sanitation related laboratory functions.
6. Any person employed in environmental sanitation by a State or local governmental agency whose duties are restricted to inspection of 1 of the following:
 - a. Air pollution control
 - b. Barber shops
 - c. Bedding
 - d. Bees and honey
 - e. Cosmetology shops
 - f. Eggs
 - g. Foster homes
 - h. Grading, sampling and labeling of dairy products
 - i. Grain warehouses
 - j. Meat
 - k. Pesticide applications
 - l. Plumbing
 - m. Public and semi-public bathing places
 - n. Produce
 - o. Septic tank installations
7. A sanitarian in training for a period not to exceed 1 year.
8. This exception does not apply to persons whose duties include a combination of those listed in R9-16-409(B)(6) or 1 of those listed in R9-16-409(B)(6) in combination with other duties related to environmental sanitation.

C. Sanitarian aides and sanitarians in training shall be directly supervised by a registered sanitarian in accordance with the following provisions:

1. No approval or disapproval for operation of a permitted establishment or regulated facility shall be granted.
2. All inspection reports shall be reviewed and co-signed by a registered sanitarian.
3. Permission to operate a regulated establishment shall be decided by the registered sanitarian reviewing the inspection reports.

R9-16-410. Denial of application for registration Repealed

A. The Council may deny an application for registration if the applicant has:

1. Made a false statement of fact in the application; or
2. Been convicted of a crime relating to the qualifications or activities as a registered sanitarian, unless clear and convincing evidence of completion of a rehabilitative course of therapy is presented; or

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3. Committed an act of fraud or negligence resulting in a revocation or denial of an application for registration, within the past 3 years, unless clear and convincing evidence of retraining or other appropriate rehabilitation such as community service work is presented; or
 4. Omitted the required information; or
 5. Failed the examination or failed to qualify for the examination; or
 6. Failed to obtain continuing education as required by R9—16-405(B) or R9—16-413.
- B.** Upon denial of an application for registration under this rule, the Council shall notify the applicant that the application is denied, stating:
1. The reason(s) for denial; and
 2. That the applicant has the right to a hearing if written request for hearing is filed with Director within the 15 days after service of the notice of denial. Service of notice of denial shall be made by certified mail, return receipt requested, addressed to the applicant at the latest address filed by the applicant in writing with the Council.
- C.** The Administrative Procedures Act (A. R. S. § 41-1001 et seq.) and the Department rules of practice and procedures (R9—1-111 et seq.) will govern all hearings required by this Article.

R9-16-411. Suspension and revocation of registration Repealed

- A.** The Council may recommend to the Director that disciplinary action be taken against the holder of a certificate or registration who commits any of the following acts:
1. Fraud or misrepresentation in obtaining a certificate, whether in the application or qualification examination;
 2. Gross negligence, bribery or incompetence in the practice of the profession;
 3. Aiding, abetting or knowingly conspiring with an unregistered person to evade provisions of this Article.
 4. Allowing one's registration to be used by an unregistered person or acting as agent, partner, or associate of an unregistered person with intent to evade provisions of this Article.
 5. Violating rules of this Article.
 6. Committing a crime related to activities as a registered sanitarian.
- B.** If a majority of the quorum of the Council find the holder of a certificate or registration has violated any of the provisions of R9—16-411(A), The Council may recommend to the Director, in writing, that the sanitarian be placed on probation, or the certificate be suspended or revoked.
- C.** The Council will notify the sanitarian of any such disciplinary recommendation by certified mail, return receipt requested, addressed to the sanitarian at the latest address filed by the sanitarian in writing with the Council.
- D.** If the Director decides to take disciplinary action against any sanitarian in accordance with the provisions of R9—16-411(B), there shall be a hearing conducted according to the provisions set forth in rule R9—1-101 et seq., unless waived in writing by the sanitarian.
- E.** Any orders for probation, suspension, or revocation imposed by the Director shall stipulate all requirements necessary to restore the sanitarian to regular status.
- F.** The Director shall immediately notify each county or city health department in the State of the suspension or revocation of a certificate or of the reissuance of a suspended or revoked certificate.
- G.** Decisions of the Director shall be subject to judicial review pursuant to A. R. S. Title 12, Chapter 7, Article 6.

R9-16-412. Re-registration Repealed

- A.** A sanitarian whose registration has been suspended for a period of time shall automatically be re-registered at termination of the period of suspension if all stipulations in the order of suspension have been met. If the period of suspension extends from 1 calendar year into the next, then the procedure for renewal as described in R9—16-407(C) shall be followed.
- B.** A sanitarian who has had his or her registration revoked may apply to the Council for re-registration as a sanitarian. The application shall include substantial evidence that the sanitarian has completed a rehabilitative training course or therapy, or that the basis for revocation has been otherwise removed.

R9-16-413. Continuing education Repealed

- A.** Each registered sanitarian must complete at least 1 continuing education unit per calendar year to be eligible to apply for renewal of registration as a sanitarian. A maximum of 1 continuing education unit may be accrued during any 1 calendar year for carryover use during the following calendar year.
- B.** The continuing education unit must meet the following minimum criteria in order for credit to be given by the Council:
1. It is a course of study directly related to the responsibilities of a sanitarian in carrying out administrative, educational, investigational or technical duties in the field of environmental health;
 2. It must have a specific, written objective(s) which describes expected outcomes for the participant.
 3. It must be presented by a college or university accredited by an agency approved by the Council on Post-Secondary Accreditation or by a knowledgeable person(s) who has specialized training and experience in the subject being covered in the program.
 4. It must last at least 1 contact hour.

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5. ~~It must utilize a mechanism to validate participation. This may include, but is not limited to, earned credits or verification of attendance.~~
6. ~~It incorporates course evaluation procedures for measuring the effectiveness of the program.~~
- C.** ~~The Council may defer the continuing education requirement to allow certificate holders to practice if the applicant is able to show good cause why the continuing education requirements could not be timely met. The request for deferral must be enclosed with the application for renewal. The deferred contact hours must be completed during the year for which the license is issued. No more than 1 consecutive year of deferred continuing education shall be granted by the Council.~~
- D.** ~~Certificates or other documentation of attendance or completion of continuing education activity must be submitted with each renewal application unless a deferral is requested.~~
 1. ~~A copy of a certificate or other documentation must have the subject or subject matter covered, the date or dates of attendance, the location of the activity, the number of contact hours completed while in attendance and signature of the registrant.~~
 2. ~~It is the responsibility of the registered sanitarian to assure that required evidence of compliance with the continuing education requirements is submitted to the Council on forms provided by the Council.~~
 3. ~~If a registered sanitarian attends a continuing education course which has not been approved by the Council, the registered sanitarian may request, at the time of registration renewal or before, that the course be approved for continuing education credit. For the Council to consider a request from a registered sanitarian to received continuing education credit, the registered sanitarian must submit documentation to the Council which indicates that the course meets the requirements of this rule.~~
 4. ~~The Council shall act on all requests for renewal of registration or approval of continuing education courses received from registered sanitarians under this rule within 60 days of receipt.~~
- E.** ~~A training agency may apply to the Council for recognition of its courses as continuing education for registered sanitarians. Eligibility for specific continuing education units or fractions thereof will be determined by the Council in accordance with the criteria set forth in subsection (B).~~

R9-16-414. Violations Repealed

Any person or agency who violates any provision of this Article is subject to the penalties.

NOTICE OF PROPOSED RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

PREAMBLE

<u>1. Sections Affected</u>	<u>Rulemaking Action</u>
R12-1-201	Amend
R12-1-202	Amend
R12-1-203	Amend
R12-1-205	Amend
R12-1-206	Amend
R12-1-207	Amend
R12-1-208	Amend
R12-1-209	Repeal
R12-1-209	New Section
Appendix A	Amend
R12-1-602	Amend
R12-1-603	Amend
R12-1-604	Amend
R12-1-605	Amend
R12-1-606	Amend
R12-1-607	Amend
R12-1-608	Amend
R12-1-609	Amend
R12-1-610	Amend
R12-1-611	Amend
R12-1-613	Amend

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R12-1-614	Amend
R12-1-615	Repeal
Appendix A	Amend
Appendix B	Repeal
R12-1-901	Amend
R12-1-902	New Section
R12-1-903	Amend
R12-1-904	Amend
R12-1-905	Amend
R12-1-906	Amend
R12-1-907	Amend
R12-1-908	Amend
R12-1-909	Amend
R12-1-910	Amend
R12-1-911	Amend
R12-1-912	Repeal
R12-1-1201	Amend
R12-1-1202	Amend
R12-1-1205	Amend
R12-1-1206	Repeal
R12-1-1207	Amend
R12-1-1208	Repeal
R12-1-1209	Amend
R12-1-1210	Amend
R12-1-1213	Amend
R12-1-1214	Amend
R12-1-1215	Amend
R12-1-1216	Amend
R12-1-1217	Amend
R12-1-1218	Amend
R12-1-1219	Amend
R12-1-1220	Amend
R12-1-1223	Amend
R12-1-1401	New Section
R12-1-1402	Amend
R12-1-1403	Amend
R12-1-1404	Amend
R12-1-1405	Amend
R12-2-1406	Amend
R12-1-1407	Amend
R12-1-1408	Amend
R12-1-1409	Amend
R12-1-1410	Amend
R12-1-1411	Repeal
R12-1-1412	Amend
R12-1-1413	Amend
R12-1-1414	Amend
R12-1-1415	Amend
R12-1-1416	Amend
R12-1-1417	Repeal
R12-1-1417	New Section
R12-1-1418	New Section
R12-1-1421	Amend
R12-1-1422	Amend
R12-1-1423	Amend
R12-1-1425	Amend
R12-1-1426	Amend
R12-1-1427	Amend
R12-1-1429	Amend

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R12-1-1433	Amend
R12-1-1434	Amend
R12-1-1435	Amend
R12-1-1436	Amend
R12-1-1437	Amend
R12-1-1439	Amend
R12-1-1440	Amend
R12-1-1441	Amend
R12-1-1443	Amend
R12-1-1444	Amend
Appendix A	Repeal
Appendix A	New Section
Appendix B	New Section
R12-1-1702	Amend
R12-1-1703	Amend
R12-1-1712	Amend
R12-1-1714	Amend
R12-1-1715	Amend
R12-1-1716	Amend
R12-1-1717	Amend
R12-1-1718	Amend
R12-1-1719	Amend
R12-1-1720	Amend
R12-1-1721	Amend
R12-1-1722	Amend
R12-1-1723	Amend
R12-1-1731	Amend
R12-1-1733	Amend
R12-1-1734	Amend
R12-1-1741	Amend
R12-1-1742	Amend
R12-1-1743	Amend
R12-1-1751	Amend

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

General: A.R.S. § 30-654(B)

Specific: A.R.S. §§ 30-657, 30-671(B), 30-672(H) and (J), 30-673, 30-686, 30-687, 30-688, 32-2842, and 32-2843

3. A list of all previous notices appearing in the Register addressing the proposed rules:

Notice of Rulemaking Docket Opening: 6 A.A.R. 4834, December 29, 2000

Notice of Rulemaking Docket Opening: 7 A.A.R. 4097, September 14, 2001

4. The name and address of Agency personnel with whom persons may communicate regarding the rules:

Name: Daniel H. Kuhl
Address: Arizona Radiation Regulatory Agency
4814 South 40th Street
Phoenix, AZ 85040
Telephone: (602) 255-4845, ext. 233
Fax: (602) 437-0705
E-mail: dkuhl@arra.state.az.us

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

Introductory Statement. The vast majority of the changes are the result of a Five-Year Review of the rules contained in the following Articles: Article 2, completed in February 2000; Article 17, completed in June 2000; Articles 6 and 9, completed in September 2000; and Articles 12 and 14, completed in October 2000. The reviews have resulted in some significant rule changes.

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Article 2: Licensing requirements for devices or equipment that produce nonionizing radiation are being moved to Article 14, where the devices are regulated. Article 2 returns to its original format which was the registration of devices or equipment that produce ionizing radiation. Additionally, the notification requirements in this Article are being combined into a single rule, R12-1-209, for clarification purposes.

Article 4: R12-1-419 is amended to list all of the rules requiring the use of personnel monitoring. Hopefully, this amendment will alleviate the need to search through all of the rules to determine if a particular group of radiation workers will need personnel monitoring.

Article 6: A number of definitions are added and deleted to assist the reader to understand the requirements in this Article. Fluoroscopic treatment simulators will be exempted from the requirements effecting other fluoroscopic systems regulated in R12-1-606. Unclear language concerning the holding of animals during veterinary x-rays is amended. Persons holding animals during x-ray procedures will be required to meet all of the safety requirements in R12-1-613. The mammography rules in Article 6 are updated to include the latest federal standards. Physicist training requirements in R12-1-615, and procedures and tests for mammography systems in Appendix B are deleted because the most current training standards are listed in incorporated federal reference.

Article 9: Article 9 is amended to include a list of definitions needed to understand the updates that were added during the previous rulemaking. R12-1-904 is amended to require applicants to provide a staff list to the Agency so that safety concerns associated with inadequate staffing will be addressed before the registration is issued. R12-1-905 is amended to allow the use of accelerator produced photon radiation to produce x-ray images when performing electron therapy. Training requirements for operators of particle accelerators in R12-1-906 is delineated according to medical or industrial use. The requirement to perform a periodic smear survey in R12-1-911 and maintain an adequate ventilation system in R12-1-912 are deleted because contamination concerns are already addressed in Article 4.

Article 12: Article 12 is amended to repeal the "hearing procedures" conflict with those of the Office of Administrative Hearings. There are new Divisions added to the list under R12-1-1215. Included are laser demonstrations, class II medical devices, TENORM, and other nonionizing radiation producing machines. Corresponding additions are being made to the associated administrative time-frames listed in R12-1-1223. The new rules supporting the TENORM category will be offered for review in the next rule proposal, RMP-054.

Article 14: The new registration requirements in R12-1-1401 are moved from Article 2, in an attempt to consolidate all of the nonionizing requirements in a single Article and to separate nonionizing regulations from ionizing regulations. With the separation it is believed that the use of "registration" better describes the regulatory process that is used to record the possession of nonionizing devices.

The definitions in R12-1-1402 are updated to correspond with current federal standards. A number of new requirements are added R12-1-1413, R12-1-1414, and R12-1-1415 to keep Arizona abreast of the most current tanning standards. Because of the potential hazard associated with photothermolysis devices, a Class II medical device used to remove body hair, the Agency is proposing new rules for their use in R12-1-1417. The rules regulating the use of high intensity mercury lamps are moved to R12-1-1418 as a result of the new rules located in R12-1-1417. R12-1-1433 is rewritten to include the latest laser standards. Also, the rule is reorganized to more easily access this rule's requirements. Training standards for medical laser users are added to R12-1-1439, and Class IIIa laser lighting and entertainment products used for commercial purposes are moved to R12-1-1440 because of the public hazard associated with their misuse. The outdated laser classification measurements that are currently listed in R12-1444 will be replaced with an incorporated reference to the current federal standards. Many of the rules contained in Article 14 are being amended so that they will contain current language and format. Application information needed to license a nonionizing radiation producing machine will be listed in a new Appendix B.

Article 17: The regulation of particle accelerators listed in R12-1-1734 is deleted because rules regulating their use are located in Article 9. A new rule is added regulating the use of well logging sources in uncased wells. In the past well logging in uncased holes has been regulated through the use of conditions in the radioactive material license.

6. A reference to any study that the Agency relies on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, analysis of the study, and other supporting material:

None

7. 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

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

The changes proposed for Article 2 should not pose a financial burden on radiation-producing machine users. The changes are made in an attempt to reorganize and at the same time clarify the requirements associated with registration of ionizing radiation producing machines.

The changes proposed for Article 6 should do little to impact the financial status of users of x-ray producing machines in the practice of medicine. The changes to the mammography rules are extensive, however, all of the users should be impacted very little by the proposed changes because Agency inspectors are already insuring that mammographers are meeting the most current FDA standards. The federal FDA requires that Agency inspectors, who inspect these facilities for the federal government, inspect registrants according to the most current federal standards, even if the standards have not been amended to the Arizona rules.

The changes proposed for Article 9 are made to improve the clarity and understandability of the rules it contains. In many cases unclear language is removed or modified. These changes should have little economic impact on the affected registrants.

The changes proposed for Article 12 will have little economic impact on the licensees and registrants regulated by the Agency. Most of the changes are made to conform to the hearing procedures of the Office of Administrative Hearings. Obviously, the additional workload that may be transferred to their personnel may impact them while decreasing

Agency administrative costs. The cost of the hearings has not been determined. Also, there is a potential civil penalty cost associated with each category, should a licensee fail to meet the rules for use of radiation sources. The monetary values of the civil penalties are thoroughly defined in the existing Article 12.

Article 14 is undergoing the most extensive review and associated proposed changes. Many laser and tanning facility requirements are being incorporated from the most current federal standards. These changes may present some increase in operating cost, if a user has not made an effort to stay abreast of industry safety. The actual cost associated with staying abreast of the new standards is unknown, however, it is believed to be minimal when compared to the cost of the machines that produce the nonionizing radiation. As stated above, new requirements for photothermolysis systems are newly proposed at this time. The annual cost to license a system will be \$44. It is estimated that there are less than 25 users of photothermolysis systems in the state at this time affected by the new rules. With the addition of Class IIIa laser lighting and entertainment products used for commercial purposes to R12-1-1440, a \$350 registration fee will be assessed because of the public hazard associated with their misuse.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Daniel H. Kuhl, State Health Physicist II
Address: Arizona Radiation Regulatory Agency
4814 South 40th Street
Phoenix, AZ 85040
Telephone: (602) 255-4845, ext. 233
Fax: (602) 437-0705
E-mail: dkuhl@arra.state.az.us

10. The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

An oral proceeding at the Agency is scheduled for Wednesday February 27, 2002, at 9:00 a.m. A person may submit written comments concerning the proposed rules by submitting them no later than 5:00 p.m., on February 27, 2002, to the following person:

Name: Aubrey V. Godwin, Director
Location: Arizona Radiation Regulatory Agency
Address: 4814 South 40th Street
Phoenix, AZ 85040
Telephone: (602) 255-4845
Fax: (602) 437-0705

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

Not applicable

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

<u>Rule</u>	<u>Incorporation</u>
R12-1-603(C)	NCRP Report No. 49
R12-1-614(A)(5)	American Associates of Physicists in Medicine Report 29 (Table 3.3)
R12-1-614(A)(15)	<i>Mammology Quality Control</i> published by the American College of Radiology
R12-1-614(B)(2)	21 CFR 900
R12-1-614(C)(1)(a)	21 CFR 900
R12-1-614(C)(1)(b)	21 CFR 900
R12-1-614(C)(1)(c)	21 CFR 900
R12-1-904(H)	<i>Radiation Oncology in Integrated Cancer Management</i> , published by the Inter-Society Council for Radiation Therapy
R12-1-1402(B)	21 CFR 1040(10), there are 5 listings in this rule
R12-1-1402(B)	ANSI Z136-1, <i>American Standard for the Safe Use of Lasers</i>
R12-1-1402(C)	21 CFR 1040(30)(d)
R12-1-1404(A)	IEEE C95.1-1999, Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields
R12-1-1405(A)	IEEE C95.1-1999, Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields
R12-1-1407(F)	21 CFR 1040(30)
R12-1-1413(A)	21 CFR 1040(20)
R12-1-1413(D)	21 CFR 1040(10)
R12-1-1422(C)	21 CFR 1040(10)
R12-1-1425(A)	21 CFR 1040(10)
R12-1-1425(B)	21 CFR 1040(10)
R12-1-1426(A)	ANSI Z136.1, <i>American Standard for the Safe Use of Lasers</i>
R12-1-1426(A)	21 CFR 1040(10)
R12-1-1426(B)	ANSI Z136.1, <i>American Standard for the Safe Use of Lasers</i>
R12-1-1426(C)	ANSI Z136.1, <i>American Standard for the Safe Use of Lasers</i>
R12-1-1426(D)	ANSI Z136.1, <i>American Standard for the Safe Use of Lasers</i>
R12-1-1426(E)	21 CFR 1040(10)
R12-1-1427(A)	ANSI Z136.1, <i>American Standard for the Safe Use of Lasers</i>
R12-1-1429	ANSI Z136.1, <i>American Standard for the Safe Use of Lasers</i>
R12-1-1440(A)	21 CFR 1040(10)
R12-1-1440(R)	21 CFR 1040(10)
R12-1-1441	ANSI Z136.1, <i>American Standard for the Safe Use of Lasers</i>
R12-1-1444(B)	21 CFR 1040(10)

13. The full text of the rules follows:

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

ARTICLE 2. REGISTRATION, INSTALLATION, AND SERVICE OF IONIZING RADIATION PRODUCING MACHINES; AND CERTIFICATION OF MAMMOGRAPHY FACILITIES
~~**RADIATION MACHINE FACILITY REGISTRATION OR LICENSING, INSTALLATION AND SERVICE-REGISTRATION, AND MAMMOGRAPHIC FACILITY CERTIFICATION**~~

Section

- R12-1-201. Exemptions
- R12-1-202. Application Requirements for Registration ~~or Certification of Ionizing and Nonionizing Radiation Machine Facilities of Ionizing Radiation Producing Machines~~ Notification
- R12-1-203. Application for Registration of Servicing and Installation
- R12-1-205. Expiration of Notice of Registration
- R12-1-206. ~~Assembler and/or Transfer Obligation~~ Assembly, Installation, Removal from Service, and Transfer
- R12-1-207. Reciprocal Recognition of Out-of-State Radiation Machines
- R12-1-208. ~~Mammographic Certification Requirements~~ Mammographic Certification Requirements Certification of Mammography Facilities
- R12-1-209. ~~Licensing Requirements for Nonionizing Radiation Machine Facilities~~ Notifications
- Appendix A. Application Information

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

Section

- R12-1-419. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose

ARTICLE 6. USE OF X-RAYS IN THE HEALING ARTS

Section

- R12-1-602. Definitions
- R12-1-603. ~~General Safety Provisions~~ Operational Standards, Shielding, and Darkroom Requirements
- R12-1-604. General Procedures ~~Procedural Requirements~~
- R12-1-605. ~~General Equipment Requirements~~ X-ray Machine Standards
- R12-1-606. Fluoroscopic and Fluoroscopic Treatment Simulator Systems
- R12-1-607. Additional X-ray Machine Standards, Shielding Requirements, and Procedures, Except Diagnostic Radiographic Systems Other Than Fluoroscopic ~~or and~~ Dental Intraoral Systems
- R12-1-608. Special Requirements for Mobile Diagnostic Radiographic Systems ~~Equipment~~, Except Dental Intraoral
- R12-1-609. Special Requirements for Chest Photofluorographic Systems
- R12-1-610. Dental Intraoral Radiographic Systems
- R12-1-611. Therapeutic X-ray Systems of Less Than 1 ~~One~~ MeV
- R12-1-613. Veterinary Medicine Radiographic Systems
- R12-1-614. Mammography ~~Mammographic Systems~~
- R12-1-615. Radiologic Physicist Training Repealed
- Appendix A. Information to be Submitted by Persons Proposing to Conduct Healing Arts Screening Other Than Mammography
- Appendix B. Procedures and Tests for Mammography systems Repealed

ARTICLE 9. ~~RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS~~

Section

- R12-1-901. Purpose and Scope
- R12-1-902. Reserved Definitions
- R12-1-903. General Requirements for the Issuance of a Registration for Particle Accelerators
- R12-1-904. Special Registration of Particle Accelerators Used in the Practice of Medicine ~~Requirements for Medical Use of Particle Accelerators~~
- R12-1-905. Medical Particle Accelerator Equipment, Facility and Shielding, and Spot Checks
- R12-1-906. Limitations
- R12-1-907. Shielding and Safety Design Requirements

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- R12-1-908. Particle Accelerator Controls and Interlock Systems
- R12-1-909. Warning ~~Systems~~ Devices
- R12-1-910. Operating ~~Procedures~~ procedures
- R12-1-911. Radiation ~~Surveys~~ Survey Requirements
- R12-1-912. ~~Ventilation Systems~~ Repealed

ARTICLE 12. ADMINISTRATIVE PROVISIONS

Section

- R12-1-1201. ~~Criteria for Determining~~ Timeliness
- R12-1-1202. Administrative ~~Hearings~~ Hearing Procedures
- R12-1-1205. Intervention in Administrative Hearings; Director as a Party
- R12-1-1206. ~~Decisions of the Hearing Officer and the Board in Administrative Hearings~~ Repealed
- R12-1-1207. Rehearings and Reviews of Decisions in Administrative Hearings
- R12-1-1208. ~~Judicial Review~~ Repealed
- R12-1-1209. Notice of Violation
- R12-1-1210. Response to Notice of Violation
- R12-1-1213. Severity Levels of Violations
- R12-1-1214. Mitigating Factors
- R12-1-1215. License and Registration Divisions
- R12-1-1216. Civil Penalties
- R12-1-1217. Augmentation of Civil Penalties
- R12-1-1218. Payment of Civil Penalties
- R12-1-1219. Additional Sanctions-Show Cause
- R12-1-1220. Escalated Enforcement
- R12-1-1223. Registration and Licensing Time-frames

**ARTICLE 14. REGISTRATION OF NONIONIZING RADIATION SOURCES
AND STANDARDS FOR PROTECTION AGAINST NONIONIZING RADIATION
RULES FOR THE CONTROL OF NONIONIZING RADIATION**

Section

- R12-1-1401. ~~Repealed~~ Registration of Nonionizing Radiation Sources and Service Providers
- R12-1-1402. Definitions
- R12-1-1403. General Safety Provisions and Exemptions
- R12-1-1404. Radio Frequency Equipment ~~Requirements~~
- R12-1-1405. Radio Frequency Exposure Limits
- R12-2-1406. Radio Frequency Hazard Caution Signs, Symbols, Labeling and Posting
- R12-1-1407. ~~Special Requirements for~~ Microwave Ovens
- R12-1-1408. Reporting of Radio Frequency Radiation Incidents
- R12-1-1409. Medical Surveillance for Radio Frequency Occupational Workers
- R12-1-1410. Radio Frequency Compliance Measurements ~~Criteria~~
- R12-1-1411. ~~Licensing of Tanning Facilities~~ Repealed
- R12-1-1412. ~~Tanning Operations~~ General Safety Requirements for the Operation of Tanning Facilities
- R12-1-1413. Tanning Equipment Standards
- R12-1-1414. ~~Operation and Use of~~ Tanning Equipment Operators
- R12-1-1415. ~~Tanning Facility~~ Warning Signs and Statements for Tanning Facilities
- R12-1-1416. Reporting of ~~Tanning Injuries~~ of Injuries In Tanning Facilities
- R12-1-1417. ~~High Intensity Mercury Vapor Discharge (HID) Lamps~~ Photothermolysis
- R12-1-1418. ~~Reserved~~ High Intensity Mercury Vapor Discharge (HID) Lamps
- R12-1-1421. Laser Safety ~~Requirements, Surveys and Records~~
- R12-1-1422. ~~General Requirements for All~~ Laser Facilities
- R12-1-1423. Laser Prohibitions
- R12-1-1425. Laser Product Classification
- R12-1-1426. ~~Laser and Collateral Radiation Exposure Limits~~ Maximum Permissible Exposure Limits to Laser and Col-
lateral Radiations
- R12-1-1427. ~~Requirements for~~ Laser Caution Signs, Symbols and Labels
- R12-1-1429. Posting of Laser Facilities
- R12-1-1433. Laser-controlled Areas
- R12-1-1434. Laser Safety Officer ~~Duties~~

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- R12-1-1435. Laser Protective Eye Wear for Use in Laser Facilities
R12-1-1436. Reporting of Laser Incidents
R12-1-1437. Special Lasers Additional Requirements for Special Lasers and Applications
R12-1-1439. Medical Lasers Additional Requirements for Medical Laser Applications
R12-1-1440. Laser Light Shows and Demonstrations
R12-1-1441. Measurements and Calculations to Determine MPE Limits for Lasers
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Appendix A. Radiofrequency Radio Frequency Devices
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**ARTICLE 17. RADIATION SAFETY REQUIREMENTS FOR
WIRELINE SERVICE OPERATIONS AND SUBSURFACE
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Section

- R12-1-1702. Required Written Agreement
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R12-1-1714. Radiation Survey Instruments
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R12-1-1719. Labeling
R12-1-1720. Inspection and Maintenance
R12-1-1721. Training Requirements
R12-1-1722. Operating and Emergency Procedures
R12-1-1723. Personnel Monitoring
R12-1-1731. Security
R12-1-1733. Subsurface Tracer Studies
R12-1-1734. Use of a Sealed Source in a Well Without a Surface Casing and Particle Accelerators
R12-1-1741. Radiation Surveys
R12-1-1742. Documents and Records Required at Field Stations
R12-1-1743. Documents and Records Required at Temporary Job Sites
R12-1-1751. Notification of Incidents, Abandonment and Lost Sources

**ARTICLE 2. REGISTRATION, INSTALLATION, AND SERVICE OF IONIZING RADIATION PRODUCING
MACHINES; AND CERTIFICATION OF MAMMOGRAPHY FACILITIES ~~RADIATION MACHINE FACILITY
REGISTRATION OR LICENSING, INSTALLATION AND SERVICE REGISTRATION, AND MAMMOGRAPHIC
FACILITY CERTIFICATION~~**

R12-1-201. Exemptions

- A. Electronic equipment that produces X-radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this Article, providing an exposure rate, from any accessible surface, averaged over an area of 10 square centimeters (1.55 in.²) does not exceed ~~129 nC/kg~~ 129µC/kg per hour (0.5 milliroentgen per hour) at 5 cm (2.0 in.) ~~from any accessible surface of such equipment~~. The production, testing, or factory servicing of electronic equipment that produces X-radiation incident to its operation is not such equipment shall not be exempt.
- B. Radiation machines in storage or in transit to or from storage ~~while in transit or storage incident thereto~~ are exempt from the requirements of this Article.
- C. No change
- ~~D. The following nonionizing radiation machines are exempt from the registration requirement prescribed in this Article:~~
- ~~1. Radiofrequency emitting devices which are designed and marketed as consumer products, including but not limited to, microwave ovens, citizen band and amateur radio transmitters, and remote control transmitters used in toys and garage door openers;~~
 - ~~2. Radiofrequency devices where the radiofrequency power input to the radiating element does not exceed 7 watts, provided the emission frequency of such devices does not exceed 1 Gigahertz;~~

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3. All certified Class I, Class II, Class IIa, and Class IIIa laser products, except for those that allow access to Class IIIb or Class IV laser radiation during servicing, are exempted from these rules, provided that the laser product is maintained as a certified Class I, Class II, Class IIa, or Class IIIa laser product throughout its useful life;
4. Lasers in storage, during shipment or sale, provided the such lasers are inoperable or not operated.

R12-1-202. Application Requirements for Registration or Certification of Ionizing and Nonionizing Radiation Machine Facilities of Ionizing Radiation Producing Machines - Notification

- A. No change
- B. No change
- ~~C.~~ The registrant shall notify the Agency within 30 days of any change to the information contained in the notice of registration and, when appropriate, certification issued pursuant to R12-1-208.
- ~~C.D.~~ In addition to the application form or forms, the applicant shall remit the appropriate registration or licensing fee in R12-1-1306 and such other information as may be required to comply with R12-1-208.
- ~~D.E.~~ With the application form for registration of radiation machines, except Each applicant applying for registration of a stationary x-ray system, with the exception of bone densitometry, cabinet radiography, podiatry, dental, and mammography facilities, the applicant shall provide a scale drawing of the room in which a stationary the x-ray system is located. The drawing shall denote the type of materials and the thickness (or lead equivalence) of each barrier of the room (walls, ceilings, floors, doors, windows). The drawing shall also denote the type and frequency of occupancy in adjacent areas including those above and below the x-ray room of concern (e.g., hallways, offices, parking lots, and lavatories). Estimates of workload shall also be provided with the drawing.
- ~~E.F.~~ Each registrants moving an existing radiation machine to a new locations in an existing facility or to a new facility shall provide to the Agency the information required by this subsection.
- ~~E.G.~~ An applicant proposing to use a particle accelerator for medical purposes shall not use the particle accelerator until the Agency inspection required in R12-1-914 has been completed.

R12-1-203. Application for Registration of Servicing and Installation

- A. Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this state shall apply for registration of radiation machine service or installation, such services with the Agency within 30 days following the effective date of this Article. Subsequent applications shall be submitted prior to furnishing or offering to furnish any radiation machine service or installation such services.
- B. Application for registration shall be completed on forms furnished by the Agency and shall contain all information required by A.R.S. § 30-672.01.

R12-1-205. Expiration of Notice of Registration

A Notice of Registration, or certification issued according pursuant to R12-1-208, shall expire at the end of the day on the date stated in the Notice of Registration or certification therein unless a registrant or certificate holder, not less than 30 days prior to the expiration of the registrant's or certificate holder's existing Notice of Registration or certification, has filed an application in proper form for renewal. If a timely application for renewal has been filed, the existing Notice of Registration or certification shall not expire until the application status has been finally determined by the Agency.

R12-1-206. Assembly, Installation, Removal from Service, and Transfer

- A. ~~A~~ Any person who assembles, or installs ionizing radiation machines in this state shall notify the Agency within 15 days of:
 1. No change
 2. No change
 3. No change
- B. No change
- C. No change
- D. No change

R12-1-207. Reciprocal Recognition of Out-of-State Radiation Machines

- A. When any radiation machine is to be brought into the state, for temporary use, the person proposing to bring a radiation such machine into the state shall give written notice to the Agency at least three working days before a radiation such machine is to be used in the State. The notice shall include the type of radiation machine; the nature, duration, and scope of use; and the exact location where the radiation machine is to be used. If for a specific case the three working-day period would impose an undue hardship, the person may upon application to the Agency, obtain permission to proceed sooner.
- B. In addition, the owner of the radiation machine and the person possessing the machine while in the state shall:
 1. No change
 2. Supply the Agency with a copy of the machine's registration and such other information necessary to ensure safe operation while in the state; and

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3. No change

- C. ~~A~~ No radiation machine shall not be operated within the state on a temporary basis in excess of 180 calendar days per year.

R12-1-208. Certification of Mammography Facilities ~~Mammographic Certification Requirements~~

Facilities required to be certified ~~according to~~ pursuant to A.R.S. ~~30-672.J~~ 30-672(J) shall:

1. No change
2. Provide evidence with the application that physicians reading mammographic images have the with the application evidence that all physicians reading the mammographic images have the training and experience required in A.R.S. § 32-2842(A) 32-2842.A; and,
3. Provide evidence with the application that physicians reading mammographic images have met the minimum criteria established by their respective licensing boards, as required in A.R.S. § 32-2842(C). Require that all physicians reading mammographic images provide evidence that they meet the requirements of A.R.S. § 32-2842.C.

R12-1-209. Licensing Requirements for Nonionizing Radiation Machine Facilities ~~Notifications~~

- ~~A. A person shall not receive, possess, use, or transfer a nonexempt nonionizing radiation producing machine except as authorized according to this Article.~~
- ~~B. An application to license a nonionizing radiation machine shall be submitted within 30 days after acquisition of a nonexempt nonionizing radiation producing machine. The application shall be on forms provided by the Agency. The application forms will request information from the applicant concerning the subject matter identified in Appendix A of this Article.~~
- ~~C. The licensee shall notify the Agency within 30 days of any change to the information contained in the license application.~~
- ~~D. In addition to the application form, the applicant shall remit the appropriate license fee, according to R12-1-1303.~~
- A. A registrant shall notify the Agency within 30 days of any change to the information contained in the notice of registration and, when appropriate, certification issued pursuant to R12-1-208.
- B. A person that possesses a radiation machine registered by the Agency shall notify the Agency within 15 days when a machine is disposed of or transferred. The notification shall contain the name and address of the person receiving the machine, if it is sold, leased, or transferred to another person; the manufacturer, model, and serial number of the machine; and the date the machine was taken out of service.

Appendix A. Application Information

An application shall contain the following information as required in R12-1-202 (B), before a registration ~~or license~~ will be issued. The Agency shall provide an application form to an applicant with a guide, if available, or shall assist the applicant to ensure only correct information is provided in the application.

Name and mailing address of applicant	Use location
Person responsible for radiation safety program	Telephone number
Type of facility	Facility subtype
Legal structure and ownership	Signature of certifying agent
Radiation machine information	Equipment identifiers
Shielding information	Scale drawing, <u>if applicable</u>
Equipment operator instructions and restrictions	Physicist name and training, if applicable
Classification of professional in charge	
Record of calibration for therapy units	Type of request: amendment, new, or renewal
Protection survey results, if applicable	
Type of industrial radiography program, if applicable	Contact person
Radiation Safety Officer name, if applicable	
Laser class and type, if applicable	Appropriate fee listed in Article 13 schedule
Other licensing and registration requirements listed in Articles 2, 6, 8, 9, and 14 <u>and 9</u>	

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

R12-1-419. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose

- A. No change
- B. No change
1. No change
 2. No change
 3. No change

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4. ~~Individuals working with open beam fluoroscopic systems capable of exposing the individuals to 10% of the limits in R12-1-408(A). The individual monitoring device shall be located on the person according to the following requirements:~~
 - ~~a. An individual monitoring device used for the dose to an embryo or fetus of a declared pregnant woman, according to R12-1-415(A), shall be located under the protective apron at the waist. A qualified expert shall be consulted to determine the dose to the embryo/fetus for the rare occasion in which this individual monitoring device has a monthly reported dose equivalent value in excess of 0.5 mSv (50 mrem). For purposes of these rules, the value to be used for determining the dose to an embryo or fetus according to R12-1-415(C)(1), for occupational exposure to radiation from medical fluoroscopic equipment is the value reported by the individual monitoring device worn at the waist underneath the protective apron which has been corrected for the particular individual and her work environment by a qualified expert;~~
 - ~~b. An individual monitoring device used for eye dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron;~~
 - ~~e. When only 1 individual monitoring device is used to determine the effective dose equivalent for external radiation according to R12-1-408(C)(2), it shall be located at the neck outside the protective apron. When a 2nd individual monitoring device is used for the same purpose, it shall be located under the protective apron at the waist. (Note: The 2nd individual monitoring device is required for a declared pregnant woman.)~~
4. Personnel monitoring shall be worn by the following:
 - a. Individuals operating mobile x-ray equipment; except dental intraoral systems, as described in R12-1-608;
 - b. Individuals operating chest photofluoroscopic systems, as described in R12-1-609;
 - c. Individuals holding animals receiving diagnostic x-ray procedures, as described in R12-1-613;
 - d. Individuals servicing enclosed beam x-ray systems with bypassed interlocks, as described in R12-1-803;
 - e. Individuals operating open beam fluoroscopic systems and ancillary personnel working in the room when the fluoroscopic system is in use;
 - f. Individuals on their extremities when operating x-ray machines with no safety devices, or if service is performed in the primary beam, as described in R12-1-806.
 - g. Individuals performing industrial radiography or operating an uncertified enclosed x-ray machine, as described in Article 5;
 - h. Individuals performing well logging, as described in Article 17; and
5. Personnel monitoring devices shall be located on the person according to the following requirements:
 - a. An individual monitoring device used for the dose to an embryo or fetus of a declared pregnant woman, according to R12-1-415(A), shall be located under the protective apron at the waist. A qualified expert shall be consulted to determine the dose to the embryo/fetus for the rare occasion in which this individual monitoring device has a monthly reported dose equivalent value in excess of 0.5 mSv (50 mrem). For purposes of these rules, the value to be used for determining the dose to an embryo or fetus according to R12-1-415(C)(1), for occupational exposure to radiation from medical fluoroscopic equipment is the value reported by the individual monitoring device worn at the waist underneath the protective apron which has been corrected for the particular individual and her work environment by a qualified expert;
 - b. An individual monitoring device used for lens dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron;
 - c. When only 1 individual monitoring device is used to determine the effective dose equivalent for external radiation according to R12-1-408(C)(2), it shall be located at the neck outside the protective apron. When a 2nd individual monitoring device is used for the same purpose, it shall be located under the protective apron at the waist. (Note: The 2nd individual monitoring device is required for a declared pregnant woman.)

C. No change

1. No change
2. No change

D. No change

1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
2. No change
3. No change
4. No change
5. No change

ARTICLE 6. USE OF X-RAYS IN THE HEALING ARTS

R12-1-602. Definitions

1. "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.
2. "Added filter" means the filtration added to the inherent filtration.
3. "Aluminum equivalent" means the thickness of aluminum (type 1100 alloy) affording the same attenuation, under specified conditions, as the material in question. (The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper).
4. "Assembler" means any person engaged in the business of assembling, replacing, or installing ~~1 one~~ or more components into an x-ray system or subsystem.
5. "Attenuation block" means a block or stack, having dimensions 20 cm by 20 cm by 3.8 cm (7.9 inches by 7.9 inches by 1.5 inches) of type 1100 aluminum alloy or other materials having equivalent attenuation.
6. "Automatic exposure control" means a device which automatically controls ~~1 one~~ or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (See "Phototimer").
7. "Barrier" (See "Protective barrier")
8. "Beam Axis" means a line from the source through the centers of the x-ray fields.
9. "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.
"C-arm x-ray system" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.
10. "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical or physical process.
"Cinefluorography" means fluorography that uses a movie camera to record images on film for later playback.
11. "Coefficient of variation" means the ratio of the standard deviation to the mean value of a population of observations.
"Collimator" means an adjustable device, generally of lead, fixed to an x-ray tube housing to intercept or collimate the useful beam and which has a lead equivalency not less than that of the tube housing assembly.
12. "Contact therapy system" means that the x-ray tube port is put in contact with or within 5 centimeters (2 inches) of the surface being treated.
"Compression device" means a device used to bring object structures closer to the image plane of a radiograph and used to make a part of the human body a more uniform thickness so the optical density of the radiograph will be more uniform.
"Computed tomography" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data. For purposes of these rules this term has the same meaning as "CT".
13. "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, push-buttons, and other hardware necessary for manually setting the technique factors.
"Cooling curves" means the graphical relationship between heat units stored and cooling time.
"CT gantry" means tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers which hold and/or enclose these components.
14. "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.
15. "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.
16. ~~"Diagnostic type protective tube housing" means an x-ray tube housing so constructed that the leakage radiation measured at the distance of 1 meter from the source cannot exceed 25.8 μ C/kg (100 mR) in 1 hour when the tube is operated at its maximum continuous rated current for the maximum rated tube potential.~~
"Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.
17. "Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").
18. "Entrance exposure rate" means the roentgens per unit time at the point where the center of the useful beam enters the patient.
19. "Equipment" (See "X-ray equipment")
20. "Filter" means material placed in the useful beam to absorb preferentially selected radiations.
21. "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.
"Fluoroscopic system" means a radiographic x-ray system used to directly visualize the motion of internal structures and fluids to aid in the diagnosis of disease.

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22. "Focal spot" means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.
23. ~~"Full beam detector" means a radiation detector of such size that the total cross section of the maximum size useful beam is intercepted.~~
24. "General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of a specific anatomical region.
25. "Gonadal shield" means a protective barrier for the testes or ovaries.
"Grid" means a device used to improve the image detail in a radiographs by reducing the intensity of x-ray scatter radiation exiting the film side of the patient
26. "Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate intensity is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.
27. "Healing Arts Radiography" means the practice of applying x-radiation to human patients for diagnostic or therapeutic purposes at the direction of a licensed practitioner. Healing arts radiography includes any or all of the following acts:
a. Positioning the x-ray beam with respect to the patient;
b. Anatomical positioning of the patient;
c. Selecting exposure factors; or
d. Initiating the exposure.
"Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when the tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe x-ray tests for the purpose of diagnosis and treatment.
"Image intensifier" means an electronic device, installed in a x-ray system housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher intensity.
28. "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformation.
29. "Inherent filtration" means the filtration of ~~permanently in~~ the useful beam provided by the permanently installed components of the tube housing assembly; ~~it includes the window of the x-ray tube and any permanent tube or source enclosure.~~
30. ~~"Interlock" means a device for precluding access to a high radiation area by automatically reducing the exposure rate upon entry by personnel.~~
31. "Kilovolts peak (kVp)" (See "Peak tube potential")
32. "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.
33. "Leakage radiation" means all radiation emanating from coming from within the tube housing except the useful beam and radiation produced when the exposure switch or timer is not activated.
34. "Leakage technique factors" means the technique factors associated with the diagnostic source tube housing assembly which are used in measuring leakage radiation. They are defined as follows:
a. For capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (mAs) or the minimum obtainable from the unit, whichever is larger.
b. For field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential.
c. For all other source assemblies equipment, the maximum-rated peak tube potential and maximum rated continuous tube current for the maximum rated peak tube potential.
35. "mA" means milliamperes.
"Mammographic x-ray system" means an x-ray system used to image human breasts.
36. "mAs" means milliamperes second.
37. "Mobile equipment" (See "X-ray equipment")
38. "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.
39. "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. (i.e. "Breast phantom" means an artificial test object which simulates the average composition of, and various structures in the breast.)
40. ~~"Phototimer" (See automatic exposure control) means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s) that is/are part of an electronic circuit which controls the duration of the time the tube is activated.~~
41. "Portable equipment" (See "X-ray equipment")

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42. "Primary protective barrier" (See "Protective barrier")
43. "Protective apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.
44. "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure.
- a. "Primary protective barrier" means the material, excluding filters, placed in the useful beam, ~~for protective purposes, to reduce the radiation exposure.~~
- b. "Secondary protective barrier" means the material which attenuates stray radiation ~~means a barrier sufficient to attenuate the stray radiation to the required degree.~~
45. "Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.
46. "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction. (See also "Direct scattered radiation")
- "Screen" means a device that converts the energy of the x-ray beam into visible light that interacts with the radiographic film, forming the latent image. More commonly called an "intensifying screen".
47. "Secondary protective barrier" (See "Protective barrier")
48. "Shutter" (See collimator) ~~means an adjustable device, generally of lead, fixed to an x-ray tube housing to intercept or collimate the useful beam and which has a lead equivalency not less than that of the tube housing assembly.~~
49. "Source" means the focal spot of the x-ray tube.
50. "Source-image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.
51. "Spot check" means an abbreviated calibration procedure which is performed to assure that a previous calibration continues to be valid.
- "Spot film" means a radiograph which is made during fluoroscopic examination to permanently record medical conditions which exist during the examination.
52. "Stationary equipment" (See "X-ray equipment")
53. "Stray radiation" means the sum of leakage and scattered radiation.
- "System" (See x-ray system)
54. "Therapeutic type protective tube housing" means:
- a. ~~For x-ray therapy equipment not capable of operating at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the source does not exceed 258 μ C/kg (one roentgen) in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential.~~
- b. ~~For x-ray therapy equipment capable of operating at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the source does not exceed 0.1 percent of the useful beam dose rate at one meter from the source for any of its operating conditions.~~
- "Technique chart" means a tabulation of technique factors.
- "Technique factors" means the following conditions of operation:
- For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
- For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of x-ray pulses;
- For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;
- For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and
- For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.
- "Treatment simulator" means a diagnostic x-ray system that duplicates a medical particle accelerator or other teletherapy in terms of its geometrical, mechanical, and optical qualities; the main function of which, is to display radiation treatment fields so that the target volume may be accurately encompassed without delivering excess irradiation to surrounding normal tissue.
- "Tube" means x-ray tube unless otherwise specified.
- "Tube housing assembly" means the tube housing with the tube installed. It includes high-voltage and/or filament transformers and other appropriate elements contained within the tube housing.
- "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.
55. "Useful beam" means the radiation ~~emanating from the which passes through the tube housing port or the radiation head and passing through and~~ the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation ~~switch or timer is activated.~~
56. "Virtual source" means a point from which radiation appears to originate.

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“Visible area” means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

- 57- “X-ray equipment” means an x-ray system, subsystem, or component described further by the following terms:
- a- Mobile means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.
 - b- Portable means x-ray equipment designed to be hand-carried.
 - e- Stationary means x-ray equipment which is installed in a fixed location.
 - d- Transportable mobile means x-ray equipment installed in a vehicle or trailer.

“X-ray system” means an assemblage of components for the controlled production of x-rays. It includes, as a minimum, an x-ray high voltage generator, an x-ray control, a tube housing assembly, a beam limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

“X-ray tube” means any electron tube which is designed for the conversion of electrical energy into x-ray energy. For purposes of these rules this term is synonymous with “tube”.

R12-1-603. General Safety provisions Operational Standards, Shielding, and Darkroom Requirements

- A. ~~A~~ No person shall not make, sell, lease, transfer, lend or install x-ray equipment or the supplies used in connection with the such equipment unless the such supplies and equipment, when properly placed in operation and properly used, will meet the requirements of these rules. This includes responsibility for the delivery of cones or collimators, filters, adequate timers, and fluoroscopic shutter (where applicable).
- B. No change
- 1. No change
 - 2. The registrant shall maintain records documenting compliance with subsection (B)(1) Paragraph B.1- above for each individual using equipment under the registrant’s registrants’ control practicing “Healing Arts Radiography”.
 - 3. The registrant shall provide safety rules to each individual operating x-ray equipment under the registrant’s his control, including any restrictions in operating procedures necessary for the safe use of the equipment and require that the operator demonstrate familiarity with these rules.
- C. No change
- 1. No change
 - 2. The required attenuation of protective barriers shall be as determined in accordance with the National Council on Radiation Protection Report No. 49, “Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies Up To 10 MeV”, September 15, 1976 Edition, published by the National council on Radiation Protection and Measurement, Inc., which is incorporated herein by reference and on file with the Agency and the Office of Secretary of State. This incorporation contains no future editions or amendments.
 - 3. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - 4. The registrant shall also meet the structural shielding requirements in R12-1-607(C), if the x-ray system in question is not fluoroscopic or intraoral.
- D. No change
- 1. No change
 - 2. No change

R12-1-604. General Procedures Procedural Requirements

- A. ~~A~~ The registrant shall ensure the following procedural requirements are met in the operation of x-ray equipment:
- 1. No change
 - 2. No change
 - a. All individuals shall be positioned so such that no part of the body including the extremities not protected by 0.5 mm lead equivalent, will be struck by the useful beam.
 - b. No change
 - c. No change
 - d. When a portion of the body of any staff or ancillary personnel is potentially subjected to stray radiation which could result in that individual receiving 10% one-quarter of the maximum permissible dose as defined in Article 4 of this Chapter, additional protective devices may be required by the Agency.
 - 3. Persons shall not be exposed to the useful beam except for a healing arts purpose authorized by a licensed practitioner of the healing arts. Specifically prohibited are:

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- a. Exposure of an individual without meeting the required healing art requirements and proper ~~prescription~~ directive;
- b. No change
- c. Exposure of an individual for the purpose of healing arts screening except as authorized by the Agency after submitting to the Agency the information listed in Appendix A of this Section ~~pursuant to Appendix A of this Article~~. If any information submitted to the Agency becomes invalid or outdated, the Agency shall be immediately notified.

4. No change

B. No change

1. No change
2. No change
3. No change
4. No change
5. No change

R12-1-605. X-ray Machine Standards General Equipment Requirements

A. No change

B. No change

C. No change

1. No change
2. No change
3. No change
4. No change
5. No change

D. Multiple tubes. Where 2 ~~two~~ or more radiographic tubes are controlled by 1 ~~one~~ exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

E. No change

F. Exposure reproducibility. The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if the value of the average exposure (E) is greater than or equal to 5 ~~five~~ times the difference between the maximum exposure (E_{max}) and minimum exposure (E_{min}) when 4 ~~four~~ exposures are made at identical technique factors, $[E \geq 5(E_{max} - E_{min})]$.

~~**G.** Film processing equipment shall be utilized in accordance with the manufacturer's specifications and recommendations.~~

R12-1-606. Fluoroscopic and Fluoroscopic treatment Simulator Systems

A. No change

1. No change
2. No change
3. No change
4. No change

5. The x-ray field size produced by fluoroscopic systems with image intensification and manual shutter control, where the fluoroscopic tube is above the table top, shall not exceed the diameter of the image receptor with the shutters open to the fullest extent, and at the maximum SID ~~"SID"~~ which the fluoroscopic tube is capable of producing radiation.

B. Fluoroscopic primary protective barrier

1. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which always intercepts the entire cross-section of the useful beam at any SID.
2. The fluoroscopic tube shall not be capable of producing radiation unless the primary protective barrier is in a position to intercept the entire cross-section of the useful beam.
3. Fluoroscopic radiation production shall automatically terminate when the primary protective barrier is removed from the useful beam.
4. The fluoroscopic primary protective barrier shall meet the following requirements for attenuation of the useful beam.
 - a. For equipment installed before November 15, 1967, the required lead equivalent of the barrier shall not be less than 1.5 millimeters for up to 100 kVp, 1.8 millimeters for greater than 100 kVp and less than 125 kVp, and 2.0 millimeters for 125 kVp or greater. (For conventional fluoroscopes, these requirements may be assumed to have been met if the exposure rate measured at the viewing surface of the fluorescent screen does not exceed 12.9 uC/kg (50 milliroentgens) per hour with the screen in the primary beam of the fluoroscope without a patient, under normal operating conditions.) For equipment installed or reinstalled thereafter, the required lead equivalent of the barrier shall not be less than 2.0 millimeters for up to 125 kVp or shall not be less than 2.7 millimeters for 125 kVp or greater.

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- b. For fluoroscopic systems utilizing image intensification, the exposure rate, due to transmission through the primary protective barrier, shall not exceed 516 nC/kg (2 milliroentgens) per hour at 10 centimeters (4 inches) from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each 258 UC/kg (1 roentgen) per minute of entrance exposure rate.
 - c. Compliance with subsection (B)(4)(a) and (b) shall be determined with the image receptor positioned 35.5 centimeters (14 inches) from the panel or table top, at normal operating technical factors and with the attenuation block in the useful beam for systems with image intensification.
- C. No change**
- 1. The exposure rate measured at the point where the center of the useful beam enters the patient shall not exceed 2.6 ~~µ~~ mC/kg (10 roentgens) per minute at any combination of tube potential and current, except during recording of fluoroscopic images or when provided with optional high-level control.
 - 2. When provided with optional high-level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 ~~µ~~ mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, unless the high-level control is activated, in which case 5.2 ~~µ~~ mC/kg (20 roentgens) shall not be exceeded.
 - a. No change
 - b. No change
 - 3. Compliance with subsection (C)(1) and (C)(2) ~~Paragraph (C)(1) and (C)(2)~~ above shall be determined as follows:
 - a. No change
 - b. No change
 - c. No change
 - d. In fluoroscopy involving a mobile C-arm x-ray system ~~a mobile C-arm type of fluoroscope~~, the exposure rate shall be measured at 30 centimeters (11.8 inches) from the input surface of the fluoroscopic imaging assembly.
 - e. In fluoroscopy involving a C-arm x-ray system ~~a C-arm type fluoroscope~~, the exposure rate shall be measured 30 centimeters (~~11.8 5-9~~ inches) from the input surface of the fluoroscope imaging assembly, with the x-ray source positioned at any available SID, provided that the end of the beam-limiting device or spacer is not closer than 30 centimeters (~~11.8 5-9~~ inches) from the input surface of the fluoroscopic image assembly.
 - f. No change
- D. No change**
- 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
- E. Each fluoroscopic system installation shall be subject to all of the following requirements for the control of stray radiation:**
- 1. No change
 - 2. Except for fluoroscopy performed using portable or mobile C-arm x-ray systems or during surgical procedures, protective drapes, or hinged or sliding panels of at least 0.25 millimeters lead equivalent, shall be provided between the patient and fluoroscopist to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the machine, but drapes and panels shall not be substituted for a protective apron; and
 - 3. No change
- F. No change**
- 1. Activation of the fluoroscopic tube shall be controlled by a “dead-man” switch(s) ~~“deadman type” exposure switch(s)~~.
 - 2. No change
 - 3. No change
 - 4. No change
- G. No change**
- H. Fluoroscopic treatment simulators**
- 1. Simulators are exempt from subsections (A) through (G).
 - 2. A beam limiting device restricting the beam to the area of clinical interest shall be used.
 - 3. The control panel shall include devices labeled for settings or physical factors, such as kVp, mA, or exposure time.
 - 4. The fluoroscopic exposure switch or switches shall be of the “deadman” type.
 - 5. Only persons whose presence is necessary shall be in the simulator room during exposure and shall be protected with lead aprons of at least 0.5 mm lead equivalent or portable shields, and lead gloves.
 - 6. The operator shall stand behind a barrier and shall be able to observe the patient during simulator exposures.

R12-1-607. Additional X-ray Machine Standards, Shielding Requirements, and Procedures, Except Diagnostic

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Radiographic Systems Other Than Fluoroscopic or Dental Intraoral Systems

- A.** No change
1. No change
 2. No change
 - a. No change
 - b. No change
 - c. Beam limiting devices not incorporating light beams to define the projected radiation field shall be clearly labeled indicating the SID and image receptor size at which each such device complies with the applicable requirements of subsection (A)(2)(a) or (b) subparagraph (a) or (b) above;
 - d. No change
 - e. All beam limiting devices installed after ~~August 8, 1986, the effective date of this Section~~, on general purpose fixed and mobile radiographic x-ray systems, shall provide a step less means of continuous adjustment of the projected radiation field size.
 3. No change
- B.** No change
1. No change
 2. The exposure switch shall meet the requirements of a “dead-man” switch ~~“deadman type switch”~~, and except for those used in with “spot-film” devices in fluoroscopy, shall be so arranged that it cannot be conveniently operated outside a shielded area.
 3. X-ray systems ~~Systems~~ provided with automatic exposure control shall indicate at the control panel when this mode is selected, and a visual and/or audible signal shall indicate termination of the exposure.
 4. No change
 - a. No change
 - b. Control setting indicators ~~Indicators labeled control settings~~ or meters indicating the appropriate technical factors: kVp, mAs mA, or exposure time, ~~or~~ mass, and any special mode selected for the exposure.
- C.** No change
1. All wall, floor and ceiling areas struck by the useful beam shall have primary protective barriers. Primary protective barriers in walls shall extend from the finished floor to a minimum height of 2.13 meters (7 feet) ~~seven feet~~.
 2. Secondary protective barriers shall be provided in all wall, floor, and ceiling areas not having primary protective barriers or where the primary protective barrier requirements are lower than the secondary barrier requirements.
 3. No change
 4. No change
- D.** No change
1. No change
 2. No change
 3. The useful beam shall be restricted to the clinical area of interest.
 4. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 5. A log containing a record of patient identification, the x-ray procedure performed, the date it was performed, number of views, and initials of the individual performing the procedure shall be maintained for Agency review. The log shall be maintained for 3 years from the date the procedure is performed.

R12-1-608. ~~Special Requirements for Mobile Diagnostic Radiographic Systems Equipment~~, Except Dental Intraoral

- A.** No change
1. No change
 2. A ~~dead-man type of exposure~~ “dead-man” switch shall be provided, together with an electrical cord of sufficient length so that the operator can stand out of the useful beam and at least 1.82 meters (6 feet) from the patient during all x-ray exposures.
 3. No change
- B.** Structural shielding. When a mobile unit is used routinely in 1 one location, it shall be considered a fixed installation subject to the shielding requirements specified in R12-1-603(C), and R12-1-607(C).
- C.** Operating procedures
1. All provisions of R12-1-607(D) shall apply.

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2. Personnel monitoring shall be worn by persons operating mobile x-ray systems and in accordance with R12-1-419(B), required for all individuals operating mobile x-ray equipment.

R12-1-609. ~~Special Requirements for~~ Chest Photofluorographic Systems

- A. No change
 1. All provisions of R12-1-607(A) and (B) shall apply.
 2. No change
- B. No change
- C. No change
 1. No change
 2. No change
 3. Personnel monitoring shall be worn by persons operating photofluoroscopic systems and in accordance with R12-1-419(B), required for all individuals operating the equipment.

R12-1-610. Dental Intraoral Radiographic Systems

- A. No change
 1. No change
 2. No change
 3. No change
 4. A timer shall be provided to terminate the exposure at a preset time interval, ~~preset~~ present product of current and time, and preset number of pulses, or a preset radiation exposure to the image receptor.
 5. No change
 6. No change
 7. No change
 8. The control panel shall include:
 - a. A device (~~usually a milliammeter~~) which will give positive indication during radiation production; and
 - b. Indicators labeled control settings or meters indicating the appropriate technical factors: kVp, mA, or exposure time, ~~or mass~~, and any special mode selected for the exposure.
- B. No change
 1. No change
 2. Primary protective ~~When dental x-ray units are installed in adjacent rooms or areas, protective barriers shall be provided~~ installed between the rooms or areas when dental x-ray units are used in adjacent rooms or areas.
 3. No change
 4. No change
 5. No change
- C. No change
 1. ~~Neither the dentist nor assistants~~ The dentist or other persons shall not hold patients or films during exposure. ~~nor shall any individual be regularly used for this service. Only persons required for the radiographic procedure shall be in the radiographic room during exposures.~~
 2. The ~~During each exposure, the~~ operator shall stand at least 1.82 meters (6 feet) from the patient or behind a protective barrier during each exposure.
 3. No change
 4. ~~The~~ Neither the tube housing or ~~nor~~ the cone shall not be hand-held during the exposure.
 5. Dental fluoroscopy shall not be performed without an image intensifier. ~~Fluoroscopy without image intensification shall not be used in dental examinations.~~

R12-1-611. Therapeutic x-ray Systems of Less Than ~~1~~ One MeV

- A. No change
 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 2. No change
 3. No change
 - a. No change
 - b. No change
 4. No change
 - a. No change
 - b. No change

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- c. No change
 - 5. No change
 - 6. No change
 - 7. No change
 - 8. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - 9. Multiple tubes. When a control panel may energize more than ~~1 one~~ x-ray tube:
 - a. It shall be possible to activate only ~~1 one~~ x-ray tube during any time interval;
 - b. No change
 - c. No change
 - 10. No change
 - 11. No change
 - a. No change
 - b. No change
 - 12. Low filtration x-ray tubes. Each x-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled ~~on as such upon~~ the tube housing assembly and at the control panel.
- B.** No change
- 1. Warning lights. Treatment rooms to which access is possible through more than ~~1 one~~ entrance shall be provided with a warning lights, in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "on".
 - 2. No change
 - 3. No change
 - 4. No change
 - a. No change
 - b. No change
 - c. No change
 - d. Opening of any door of the treatment room during exposure shall result in automatic termination of x-ray production or reduction of radiation levels to an average of no more than 516 nC/kg (2 milliroentgens) per hour and a maximum of 2.6 μ C/kg (10 milliroentgens) per hour at a distance of ~~1 one~~ meter (3.3 feet) from the target in any direction. After such shut-off or reduction, it shall be possible to restore the machine to full operation only from the control panel.
- C.** No change
- 1. No change
 - 2. No change
 - 3. The installation shall be operated in compliance with any limitations indicated by the protection survey required by ~~subsection paragraph~~ (C)(1) above.
- D.** No change
- 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. Records of calibration performed pursuant to ~~subsection (D)(3) paragraph (3)~~ above shall be maintained by the registrant for at least 2 years after completion of the calibration and shall be made available for inspection by the Agency.
 - 6. No change
- E.** Spot checks. Spot checks shall be performed on x-ray systems capable of operation at greater than 150 kVp. ~~The Such~~ spot checks shall meet the following requirements:
- 1. No change
 - 2. No change
 - 3. The written spot check procedure shall specify the frequency ~~of the at which such~~ tests or measurements, ~~made at intervals~~ not to exceed monthly;

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4. The spot check procedure shall note conditions which shall require recalibration of the system in accordance with ~~subsection paragraph~~ (D)(1); and
5. Records of spot-check measurements performed as required by ~~subsection paragraph~~ (E)(3) above shall be maintained, available for inspection by the Agency, for ~~3~~ three years following ~~the~~ such measurements.

F. No change

1. Therapeutic x-ray systems shall not be left unattended unless the system is secured according to subsection ~~in accordance with subparagraph~~ (A)(8)(e) above.
2. No change
3. No change
4. At 150 kVp or greater the patient shall be the only person ~~No individual other than the patient shall be~~ in the treatment room during production of radiation. At less than 150 kVp an unless such individual may be in the room with patient provided the person is protected by a barrier sufficient to meet the requirements of Article 4 of this Chapter. ~~No individual other than the patient, shall be in the treatment room while radiation is being produced when the kVp exceeds 150.~~

R12-1-613. Veterinary Medicine Radiographic Systems

A. No change

1. No change
2. No change
3. ~~A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least 6 feet from the animal during all x-ray exposures. Each radiographic system shall have a "dead-man" exposure switch with an electrical cord of sufficient length to allow the operator to stand out of the useful beam at least 6 feet during x-ray exposures.~~

B. ~~Appropriate shielding shall be employed such as protective gloves and apron, and the animal positioned so that no part of the occupationally exposed person's body will not be struck by the useful beam. Persons exposed to ionizing radiation for this purpose shall be monitored.~~

B. Procedures:

1. Unless required to restrain an animal, the operator shall stand at least 1.82 meters (6 feet) away from the useful beam and the animal during radiographic exposures.
2.
3. Persons other than the operator shall not be in the x-ray room or area while an exposure is being made unless the persons' assistance is required.
4. When an animal must be held in position during an x-ray exposure, mechanical supporting or restraining devices shall be used when techniques permit.
5. A person holding an animal during an x-ray exposure shall:
 - a. Wear protective gloves and apron of not less than 0.5 millimeter lead equivalent or whole body protective barriers;
 - b. Wear personnel monitoring; and
 - c. Be positioned so that no part of the person's body, except hands and arms, will be struck by the useful beam.
6. If a person holds or supports an animal or a film during an x-ray exposure, the name of the person shall be recorded in an x-ray log containing the animal's name, the type of x-ray procedure, and the date of the procedure.
7. As a condition of employment a person shall not be required to routinely hold or support animals, or hold film during radiation exposures.

C. Operating procedures:

1. ~~The operator shall stand well away from the tube housing and the animal during radiographic exposures. Provisions shall be made so that the operator will not be required to stand in the useful beam. Hand-held fluoroscopic screens shall not be used. The tube housing shall not be held by the operator. No individual other than the operator shall be in the x-ray room while exposures are being made unless such individual's assistance is required.~~
2. ~~In any application in which the operator or other assisting individual is not located behind a protective barrier, clothing consisting of a protective apron and gloves having a lead equivalent of not less than 0.5 millimeters shall be worn by the operator and any other individual in the room during exposures.~~
3. ~~No individual shall be regularly employed to hold or support animals or hold film during radiation exposures. Occupationally exposed individuals shall not perform this service except in where cases in which no other method is available and that person shall be provided with a personnel monitoring device.~~
4. ~~If an individual must support an animal or a film during an x-ray exposure, the name of the individual holding the animal shall be recorded in an x-ray log containing the animal's name, the type of examination, and the date the examination was performed.~~

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R12-1-614. Mammography Mammographic Systems

- A. No change
1. No change
 2. No change
 3. No change
 4. No change
 5. The combination of focal spot size, source-to-image distance and magnification shall produce a radiograph with a resolution of at least 12 line pairs per millimeter at an object-to-image receptor distance of 4.5 five centimeters; or the standards in Table 3-3 of the American Associates of Physicists in Medicine, Report No. 29, August 1990 Edition, published by the American Institute of Physics, Inc., incorporated ~~herein~~ by reference and on file with the Agency and the Office of Secretary of State, are followed This incorporation by reference contains no future editions or amendments.
 6. The compression device used with the mammographic unit shall be parallel to the imaging plane, not varying at any spot by more than 1 centimeter, to adequately immobilize and compress the breast.
 7. The mammographic x-ray system with automatic pressure units shall: ~~shall be capable of:~~
 - a. Have available, compression paddles compatible with each size image receptor being utilized;
 - ~~b.a. Be capable of compressing~~ For automatic pressure units only, compressing the breast with a force of at least 25 pounds, and not more than ~~47~~ 40 pounds, and maintaining the compression for at least 3 seconds; and
 - ~~c.b. Be used in such a manner that the~~ The chest wall edge of the compression device paddle is shall be aligned just beyond the chest wall edge of the image receptor so such that the chest wall edge of the compression device paddle does not appear on the image receptor, in the mammogram:
 8. No change
 - a. The availability of at least 2 different sizes of moving anti-scatter grids including one for each size image receptor utilized; ~~capability of using anti-scatter grids which are specifically designed for mammography, integral to the x-ray system, and are available for all image receptor sizes; and~~
 - b. No change
 9. No change
 10. The collimation ~~Collimation shall be provided which shall limit the useful beam to such that the x-ray field at the plane of the image receptor so that the beam does not extend beyond any edge of the image receptor at any designated source to image receptor distance by more than 1% of the source to image distance with the exception of the chest wall edge which shall not extend beyond the image receptor by more than 2% of the source to image distance, except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the source to image receptor distance;~~
 11. No change
 12. Mammographic x-ray systems operating with automatic exposure control shall be capable of maintaining a constant film density to within +/-0.30 optical density units over the clinical range of kVp used clinically used kVps, for a breast having an equivalent phantom thicknesses from 2 of 2 centimeters to 6 centimeters. If, or if the film density cannot be maintained to within +/- 0.30 of the average kVp used of clinically used kVp settings and phantom thickness from 2 to 6 centimeters cannot be maintained by the automatic exposure control, a technique chart shall be developed that alters kVp and density control settings as a function of breast thickness and density. If a technique chart is used which maintains the film density shall be maintained within +/- 0.30 optical density units.;
 13. No change
 14. Cassettes shall not be used for mammography if 1 or more areas of greater than 1 cm 2 square centimeter or 2 or more area of less than 1 square centimeter of poor screen-film contact are seen when tested, using a 40 mesh screen test;
 15. No change
 - a. Meet the minimum mammography film standards for phantom performance standards of the in "Mammography Quality Control", 1992 Edition, published by the American College of Radiology, incorporated ~~herein~~ by reference and on file with the Agency and the at the Office of Secretary of State. This incorporation by reference contains no future editions or amendments. , for accreditation on the standard mammography film in use at the facility; or
 - b. Demonstrate in the image produced the presence of at least 4 fibers, 3 speck groups, and 3 masses which include the Shall be of a quality to observe the image of a 0.75 millimeter fiber, 0.32 millimeter speck group, and a 0.75 millimeter mass from an image made utilizing a Radiation Measurements Inc. (RMI), Model 156 phantom or equivalent.
 16. The mean glandular dose for 1 one craniocaudal view of a 4.2 centimeter (1.8 inch) compressed breast, composed of 50 percent adipose/50 percent glandular tissue, shall not exceed 300 millirads (3 milligray), for screen-film image receptor; and;

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17. A radiologic physicist meeting the requirements in R12-1-614(C)(1)(c) shall evaluate the operation of a mammographic x-ray system: Mammography units shall be calibrated when equipment is first installed, after any major changes or replacement of parts and at least annually and when quality assurance tests indicate calibration is needed.
 - a. When first installed and annually thereafter;
 - b. Following any major change in equipment or replacement of parts; and
 - c. When quality assurance tests indicate calibration is necessary.

B. Operating Procedures

1. Each mammography facility shall have a quality assurance program. The quality assurance program shall include performance and documentation of the following quality control tests, conducted at the required time intervals, with test results falling within the acceptable limits or corrective action taken when results fall outside of the acceptable limits. A radiologic physicist, as defined in R12-1-614(C)(1)(c), shall review the program and make any recommendations necessary for the facility to comply with these rules.
2. The quality assurance program shall meet the requirements contained in 21 CFR (900)(12)(d)(1); (e)(1)(i), (ii), and (iii); (e)(2)(i),(ii), and (iii); (e)(3)(i) and (ii); (e)(4)(i), (ii), (iii)(A) and (B); (e)(5)(i), (ii), (iii)(A), (iv), (v), (vi), (vii)(B) and (C), (viii), (ix), (x), and (xi); (e)(8)(ii); (e)(9)(ii); and (e)(10), 2001 Edition, published April 1, 2001, incorporated by reference and on file with the Agency and the Office of Secretary of State, and containing no future editions or amendments; or meet the following requirements:
 - a. Daily -sensitometric/densitometric evaluation of the image processing system shall demonstrate that Base + Fog < +0.03 optical density of operating level, Mid Density +/-0.15 optical density of operating level, and Density Difference +/-0.15 optical density of operating level;
 - b. Weekly-phantom image quality evaluations shall demonstrate the visualization of at least 4 fibers, 3 speck groups, and 3 masses with a background of >1.20 optical density, not varying by +/- 0.20 optical density;
 - c. Monthly-technique chart evaluations shall demonstrate updates for all equipment changes and that all examinations are being performed according to a physicist's density control recommendation;
 - d. Quarterly-fixer retention evaluations shall demonstrate an acceptable limit of <= 5.0 micrograms per square centimeter;
 - e. Quarterly-repeat analysis shall demonstrate an acceptable limit of < 2% increase in repeats.
 - f. Semiannually-darkroom fog evaluations shall meet the limit of <= 0.05 optical density of fog using the 2 minute exposed film method;
 - g. Semiannually-screen film contact evaluations shall meet the limit of < 1.0 centimeter squared area of poor contact using a 40 mesh screen on all clinically used screens;
 - h. Semiannual-compression force evaluations shall meet the limit of >= 25 pounds (111 Newtons) and < 47 pounds (209 Newtons);
 - i. Annually and whenever indicated by installation, major repairs, parts replacement or when other pertinent quality control test results indicate a calibration may be necessary, the following tests shall be performed: automatic exposure control performance and thickness response; kVp accuracy and reproducibility; system resolution; breast entrance air kerma and automatic exposure control reproducibility; average glandular dose; x-ray field/light field/image receptor alignment; compression paddle alignment; uniformity of screen speed; system artifacts; radiation output; decompression; and beam quality and half value layer.

C. Personnel

1. Each registrant shall require personnel performing mammography, which includes the production and interpretation of mammograms, and related quality assurance activities, to have met the following requirements:
 - a. The Interpreting physician shall meet the requirements of 21 CFR 900.12(a)(1)(i)(A) and (B)(1) and (2), (C), (D), and (ii)(A) and (B), 3001 Edition, published April 1, 2001, incorporated by reference and on file with the Agency and the Office of Secretary of State. This incorporation by reference contains no future editions or amendments, or:
 - i. Be licensed under Chapter 13 or 17 of A.R.S. § 32-1401 or § 32-1801;
 - ii. Have initially completed 40 hours of medical education credits in mammography;
 - iii. Be certified by the American Board of Radiology or the American Osteopathic Board of Radiology or be approved by the Arizona Board of Medical Examiners or the Arizona Board of Osteopathic Examiners as being qualified to read and interpret mammographic images;
 - iv. Have interpreted or reviewed an average of 300 mammograms per year during the preceding 2 years or have completed a radiology residency which included mammography interpretation; and
 - v. Have completed 15 hours of continuing medical education credits in mammography during the preceding 3 years.
 - b. The mammographic technologist shall meet the requirements of 21 CFR 900.12(a)(2)(i)(B), (ii)(A), (B), and (C)(iii), 2001 Edition, published April 1, 2001, incorporated by reference and on file with the Agency and the Office of Secretary of State. This incorporation by reference contains no future editions or amendments, or:

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- i. Possess a valid mammographic technologist certificate issued by the Medical Radiologic Technology Board of Examiners, as required in A.R.S. § 32-2841, or shall be pursuing mammographic certification by training under direct supervision of a technologist possessing a valid mammographic certificate, and
- ii. Have completed 15 hours of continuing medical education credits in mammography during the preceding 3 years.
- c. The radiologic physicist shall meet the requirements in 21 CFR 900.12(a)(3)(i) and (iii), and 21 CFR 900.12(a)(4), 2001 Edition, published April 1, 2001, incorporated by reference and on file with the Agency and the Office of Secretary of State. This incorporation by reference contains no future editions or amendments, or
 - i. Be certified by the American Board of Radiology, American Board of Medical Physics, or the American Board of Health Physics;
 - ii. Possess documentation of state approval;
 - iii. Hold a master's degree or higher in a physical science;
 - iv. Have initial experience of conducting, as a minimum, 1 mammographic facility survey and the evaluation of 10 mammographic units;
 - v. Have continuing experience of surveying, as a minimum, 2 mammography facilities and evaluation of 6 mammography units during the preceding 2 years; and
 - vi. Have completed 15 hours of continuing medical education credits in mammography during the preceding 3 years.
2. Records documenting the requirements in subsection (C)(1) shall be maintained for 3 years from the date the requirement is met and be available for Agency inspection.

D. Mammography films and reports shall be:

1. Maintained for a minimum of 5 years. In those cases where no subsequent mammography procedures are performed, the films and reports shall be maintained for 10 years; and
2. Available for comparison upon request for temporary or permanent transfer to other mammography facilities.
1. Each facility shall have a quality assurance testing program for the items listed in Appendix B. The procedures shall describe each test, the acceptable results, and corrective actions when required. Records of the quality assurance testing program shall be maintained for Agency inspection.
2. Each facility shall have an radiologic physicist as defined in R12-1-615 review all the test results for those tests specified in Paragraph 2 above. The radiologic physicist shall make recommendations as necessary for the facility to comply with these rules.

R12-1-615. Radiologic physicist training Repealed

The radiologic physicist utilized to provide the services required by R12-1-614(B)(2) shall:

A. Be certified by the American Board of Radiology or the American Board of Medical Physicists in:

1. Diagnostic Radiological Physics; or,
2. Radiological Physics; or,

B. Hold a Master's or Doctor's degree in physics, biophysics, radiological physics, health physics, or be certified by the American Board of Health Physics and have completed 1 year of full time training in diagnostic radiological physics and 2 years of full time work experience under the supervision of a diagnostic x-ray physicist in supporting a mammography facility.

Appendix A. Information to be Submitted by Persons Proposing to Conduct Healing Arts Screening Other Than Mammography

Healing Arts Screening Information
Submitted to the Agency According to R12-1-604(A)(3)(c)
(Other Than Mammography)
Information Submitted by Persons Proposing
to Conduct Healing Arts Screening, Other Than
Mammography

Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of the person(s) within agents within this state that are authorized to act on behalf of the applicant.
2. Disease or conditions to be diagnosed using the proposed for which the x-ray examinations are to be used in diagnoses.
3. A detailed description of the x-ray examination(s) that will be used in the diagnosis examinations are to be used in diagnoses.
4. A description ~~Description~~ of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

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5. An evaluation of any known alternative diagnostic modalities ~~alternate methods~~ not involving ionizing radiation which could achieve the same diagnosis as a goal for the screening program and why these modalities have not been chosen. ~~methods are not used instead of the x-ray examinations.~~
6. An evaluation of the x-ray equipment used in the screening program by a qualified expert ~~of the x-ray system(s) to be used in the screening program.~~ The evaluation by the qualified expert shall demonstrate that the x-ray equipment satisfies the ~~show that such system(s) do satisfy all~~ requirements of these rules.
7. A description of the diagnostic film quality control program.
8. A copy of the technique chart for the planned x-ray examination ~~procedures to be used.~~
9. The qualifications of each individual who will be operating the x-ray equipment ~~system(s).~~
10. The qualifications of the individual who will be supervising the operators of the x-ray equipment ~~system(s).~~
11. No change
12. A description of the planned procedures ~~for to be used in~~ advising a screened individual ~~the individuals and the screened individual's physician of the screening procedure results,~~ ~~screened and their private practitioners of the healing arts, of the results of the screening procedure and~~ the need for further medical care. ~~any further medical needs indicated.~~
13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examination ~~examinations.~~

Appendix B. Procedures and Tests for Mammography Systems Repealed

I. Procedures

- a. ~~Description of the x-ray examinations to be performed;~~
- b. ~~Description of the use of grids;~~
- e. ~~Description of the use of compression devices;~~
- d. ~~Description of any tests to be performed by the operator prior to the initial examinations;~~
- e. ~~Description of patient acceptance criteria (for self-referral screen only);~~
- f. ~~Description of image development procedures.~~

H. Quality Control

- a. ~~Daily tests on the film processor using sentitometry and densitometry procedures;~~
- b. ~~Monthly tests:~~
 1. ~~Availability of technique charts;~~
 2. ~~Image quality with a phantom;~~
- e. ~~Quarterly test: Retake analysis;~~
- d. ~~Annual tests:~~
 1. ~~Exposure timer accuracy;~~
 2. ~~Linearity of the mA stations;~~
 3. ~~Skin entrance exposure;~~
 4. ~~Exposure timer reproducibility;~~
 5. ~~Half Value Layer;~~
 6. ~~AEC, kVp, and thickness response;~~
 7. ~~AEC reproducibility;~~
 8. ~~Beam alignment, where appropriate;~~
 9. ~~Average glandular dose.~~

ARTICLE 9. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

R12-1-901. Purpose and Scope

- A. No change
- B. In addition to the requirements of this Article, all registrants are subject to the requirements of Articles 1, 2, 4, 6, and 10. ~~Registrants engaged in industrial radiographic operations are subject to the requirements of Article 5, and registrants engaged in the healing arts are subject to the requirements of Article 6 of these Rules.~~ Registrants engaged in the use of a particle accelerator for the ~~or~~ production of radioactive material are subject to the requirements of Article 3, and if the radioactive material is used for medical purposes, Article 7.

R12-1-902. Reserved Definitions

"Added filters" - (See Article 6)

"Arc therapy" means therapy that uses electrons to treat large superficial volumes which follow curved surfaces, as in postmastectomy patients.

"Beam limiting device" (See Article 6)

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“Beam monitoring system” means a system of devices that will monitor the useful beam during irradiation and will terminate irradiation when a preselected number of monitor units has been accumulated.

“Control panel” - (See Article 6)

“Full beam detector” means a radiation detector of such size that the total cross section of the maximum size useful beam is intercepted.

“Gantry” means that part of a linear accelerator that supports the radiation source so that it can rotate about a horizontal axis.

“Interlock” (See Article 1).

“Isocenter” means the point of intersection of the collimator axis and the axis of rotation of the gantry.

“Monitor unit” means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

“Moving beam therapy” means radiation therapy in which there is displacement of the useful beam relative to the patient. Moving beam therapy includes arc therapy, skip therapy, and rotational beam therapy.

“Rotational beam therapy” means radiation therapy that is administered to a patient from a radiation source that rotates around the patient’s body or the patient is rotated while the beam is held fixed.

“Skip therapy” means rotational beam therapy that is administered in such a way to maximize the dose to an area of interest and minimize the dose to surrounding healthy tissue.

“Spot checks”- (See Article 6)

“Stationary beam therapy” means radiation therapy involving a beam from a radiation source directed at the patient from different directions. The distance of the source from the isocenter remains constant irrespective of the beam direction.

“Virtual source” means a point from which radiation appears to originate.

R12-1-903. General Requirements for the Issuance of a Registration for Particle Accelerators

A. No change

B. No change

1. The applicant is qualified by training and experience to use the accelerator for the purpose in the application submitted to the Agency, as required in Article 2, and requested according to this Article, and Articles 4, and 10, of these rules to minimize danger to public health or property;
2. The applicant’s proposed equipment, facilities, operating and emergency procedures are adequate to protect health and minimize danger to public health and minimize danger to public health and safety or property;
3. The issuance of the registration will not be inimical to the health and safety of the public, and the applicant satisfies any other applicable special requirements requirement in this Section; and R12-1-904;
4. The applicant has appointed a radiation safety officer.
5. The applicant’s staff has substantial experience in the use of particle accelerators for the intended uses; and
6. The applicant has an adequate training program for particle accelerator operators.

R12-1-904. Special Registration of Particle Accelerators Used in the Practice of Medicine Requirements for Medical Use of Particle Accelerators

A. No change

B. No change

C. No change

1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
2. No change
 - a. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - b. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change

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- v. No change
- c. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
- D. No change
- E. Each registrant licensee shall establish and maintain a written quality management program to provide high confidence the radiation produced by the particle accelerator will be administered as directed by an authorized user. The quality management program shall include written policies and procedures to meet the specific patient safety objectives established by the Radiation Safety Officer or Radiation Safety Committee; if applicable, and as a minimum contain a quality control program that addresses the tests and checks listed in Appendix A.
- F. No change
- G. No change
- H. At the time of application for registration or when a therapy program is expanded to multiple sites, each applicant or registrant shall provide a description of the radiation therapy program. As a minimum the description shall describe the staffing of professional personnel at each facility, or expected ratio of patient workload to staff member for programs involving multiple therapy sites. If the staffing ratio exceeds the recommended levels in Radiation Oncology in Integrated Cancer Management, 1986 Edition, published in November 1986 by the Inter-Society Council for Radiation Therapy, incorporated by reference and on file with the Agency and the Secretary of State, the applicant shall provide to the Agency for approval the justification for the larger ratio and the safety considerations that have been addressed in establishing the program. This incorporation contains no future additions or amendments.

R12-1-905. Medical Particle Accelerator Equipment, Facility and Shielding, and Spot Checks

- A. No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - 2. No change
 - 3. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - 4. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - i. No change
 - ii. No change
 - iii. No change
 - f. No change
 - g. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
 - 5. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change

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- e. No change
- f. No change
 - i. No change
 - ii. No change
- 6. No change
 - a. No change
 - b. No change
 - c. An interlock system shall be provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted and irradiation with electrons when accessories specific for x-ray therapy are fitted; and
 - d. No change
- 7. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
- 8. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
- 9. No change
 - a. No change
 - b. No change
 - c. No change
- 10. No change
- B.** No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - 2. No change
 - 3. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
 - e. No change
 - f. No change
 - i. No change
 - ii. No change
 - iii. No change
- C.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change

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5. Records of spot checks shall be maintained available for inspection by the Agency for 2 years following the spot check measurements. Records of spot checks not performed by a qualified expert shall be signed off by a qualified expert within 15 days of the spot check being performed.

- D. No change
1. No change
 2. No change

R12-1-906. Limitations

- A. ~~A~~ ~~No~~ registrant shall not permit an individual: any person to act as a particle accelerator operator until such person:
1. To act as:
 - a. A medical particle accelerator operator unless the individual is certified as required in § 32-2811 or is a qualified user meeting the requirements in R12-1-603(B); or
 - b. An industrial particle accelerator operator unless the individual has ~~Has~~ been instructed in radiation safety, and shall have demonstrated an understanding thereof;
 2. To act as a particle accelerator operator unless the individual has ~~Has~~ received copies of and instruction in this Article and the applicable requirements of Articles 4 and 10, pertinent registration conditions and the registrant's operating and emergency procedures, and shall have demonstrated an understanding of the material thereof; and
 3. Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed during the operation of the particle accelerator in his assignment.
- B. ~~Either~~ ~~Both~~ the Radiation Safety Committee ~~or~~ ~~and~~ the Radiation Safety Officer shall have the authority to terminate the operations at a particle accelerator facility if ~~such action is deemed necessary to protect health and/or minimize danger to public health and safety or property.~~
- C. Equipment capable of both stationary and moving beam therapy shall meet the following requirements:
1. Irradiation shall not be possible unless either stationary or moving beam therapy has been selected at the control panel.
 2. An interlock shall be provided to ensure that the machine will operate only in the mode that has been selected.
 3. An interlock shall be provided to terminate irradiation if the gantry fails to move properly during moving beam therapy.
 4. Means shall be provided to prevent movement during stationary therapy.
 5. The mode of operation shall be displayed at the control panel.

R12-1-907. Shielding and Safety Design Requirements

- A. A person experienced in the principles of radiation protection and installation design shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation. A copy of the installation radiation survey shall be provided to the Agency prior to the Agency inspection conducted according to R12-1-904(G).
- B. The registrant shall ~~shield~~ provide each particle accelerator installation with the primary and secondary protective barriers ~~that are necessary to comply assure compliance with R12-1-408 and R12-1-416.~~

R12-1-908. Particle Accelerator Controls and Interlock Systems

- A. Instrumentation, readouts and controls on the particle accelerator control panel console shall be clearly identified and easily discernible.
- B. All entrances into ~~the area a target room containing the particle accelerator room or target room,~~ or other high radiation area, shall be provided with interlocks that shut down the machine if an entrance door is opened under conditions of barrier penetration.
- C. When an interlock system has been tripped, it shall only be possible to resume operation of the particle accelerator by manually resetting the interlock switch at the entrance where it had been tripped, controls at the position where the interlock has been tripped, and lastly at the main control console.
- D. No change
- E. All safety interlocks shall be fail safe in design, i.e., designed so that any defect or component failure in the interlock system prevents operation of the particle accelerator.
- F. A scram button or other emergency power cutoff switch shall be located and easily identifiable in the area containing the particle accelerator all high radiation areas. The scram button shall ~~Such a cutoff switch prevent the particle accelerator being restarted shall include a manual reset so that the accelerator cannot be restarted from the accelerator control panel console without resetting the scram button cutoff switch.~~

R12-1-909. Warning Systems Devices

- A. High radiation areas and entrances to the high radiation areas in medical facilities shall be equipped with a continuously operating warning light system that operates when, and only when radiation is being produced. All areas, except those in medical facilities, designated as high radiation areas, and entrances to the areas shall be equipped with easily observable

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flashing or rotating warning light system that operates when, and only when, radiation is being produced. Medical facilities shall be equipped with a continuously operating warning light system.

- B.** High radiation areas and entrances to the high radiation areas in nonmedical facilities shall be equipped with easily observable flashing or rotating warning light system that operates when, and only when, radiation is being produced.
- ~~**B-C.** High radiation areas associated with nonmedical particle accelerators except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the creation of the high radiation area. The warning device shall be clearly discernible in all high radiation areas and all radiation areas.~~
- ~~**C-D.** High radiation areas associated with all particle accelerators shall be posted according to Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with R12-1-428 and R12-1-429.~~

R12-1-910. Operating Procedures ~~procedures~~

- A.** A registrant shall secure from use a particle accelerator when it is not being used ~~Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.~~
- B.** Only the switch on the control panel ~~Only a switch on the accelerator control console shall be routinely used to turn the accelerator beam on and off during normal operations.~~ The safety interlock system may ~~shall not~~ be used to turn off the accelerator beam in emergencies ~~except in an emergency.~~
- C.** All safety and warning systems ~~devices~~, including interlocks, shall be tested ~~checked~~ for proper operation ~~operability~~ at intervals not to exceed 3 ~~three~~ months. Results of the ~~such~~ tests shall be maintained for Agency inspection for 3 years from the date of the test. ~~at the accelerator facility.~~
- D.** Electrical circuit diagrams of a particle ~~the~~ accelerator, and the associated interlock systems, shall be kept current and maintained for inspection by the Agency and available to the operator at the particle ~~each~~ accelerator facility.
- E.** By-passing an interlock(s), for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:
1. No change
 2. Recorded in a permanent log with a notice of the by-pass posted at the interlock(s) and at the control panel, ~~and a notice posted at the interlock(s) so bypassed and at the accelerator control console;~~ and
 3. No change
- F.** A copy of the current operating and emergency procedures shall be maintained at the particle accelerator control panel.

R12-1-911. Radiation ~~Surveys~~ Survey Requirements

- A.** ~~The registrant shall ensure that a portable survey instrument shall be~~ is available at all times in a particle accelerator facility.
- B.** No change
1. Check the operation of the portable survey instrument required in subsection (A) using a known radiation source prior to each ~~its~~ use;
 2. No change
 3. Perform surveys to determine the amount of airborne particulate radioactivity present in areas of airborne hazards in particle accelerator facilities of greater than 30 Mev; and
 4. Perform periodic smear surveys to determine the degree of contamination in target and adjoining areas when the conditions described in subsection (B)(3) exist;
 - ~~4.5.~~ Perform surveys and smear surveys as prescribed in the written procedures established by the Radiation Safety Officer of the particle accelerator facility and approved by the Agency at the time of application for registration.
- C.** No change
1. Radiation ~~Records of any radiation~~ protection surveys required in subsection (B), and an associated facility description, required in R12-1-202(E), until the registration is terminated.
 2. Records of particle ~~Particle~~ accelerator calibration, spot checks, personnel radiation safety system tests, and periodic radiation protection surveys until the registration is terminated.

R12-1-912. Ventilation Systems ~~Repealed~~

- ~~**A.** A registrant or licensee shall provide the means to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in Article 4, Appendix B, Table II of this Chapter.~~
- B.** A registrant or licensee shall not vent, release or otherwise discharge airborne radioactive material to an uncontrolled area which exceed the limits specified in Article 4, Appendix B, Table II of this Chapter, except as authorized pursuant to R12-1-435. For purposes of this Section, concentrations may be averaged over a period not greater than one year. Every reasonable effort should be made to maintain releases of radioactive material to uncontrolled areas as far below the limits in Appendix B, Table II of this Chapter, as practicable.

Appendix A. Quality Control Program

A. Mechanical Tests

1. Patient support assembly motions
2. Gantry angle indicators
3. Optical distance indicators
4. Alignment lights
5. Congruence of radiation beam and light field
6. Accuracy of field size indicators
7. Mechanical isocenter- gantry and collimator
8. Mechanical interlocks

B. Radiation Beam Tests

1. Machine operating parameters
2. Dose per monitor unit for x-ray and electron beams
3. Dose per degree for moving beam therapy
4. Radiation isocenter
5. Flatness and symmetry
6. Wedge transmission factors
7. Shadow tray transmission factors
8. Energy check on central axis
9. Radiation output versus field size.

C. Control Panel Checks

1. Radiation "ON" condition5. Digital displays
2. Indicator lamp check6. Analog display
3. Computer control of accelerator7. Status display
4. Interlock display8. Reset display

D. Facility Checks

1. Patient audio-visual communication
2. Entrance door interlock
3. Warning lights
4. Emergency off button

E. Dose Output Check

1. Each registrant shall use the services of a third party qualified expert or third party TLD system to verify the accelerator's radiation output every 2 years.
2. If the output check is not within +/- 5% of the calibrated output, the accelerator shall be recalibrated and the discrepancy investigated.
3. Records of output checks shall be maintained for 3 years.

F. Patient Dosimetry Calculation Checks

1. Calculation of patient treatment times
2. Computer calculation of patient treatment times

ARTICLE 12. ADMINISTRATIVE PROVISIONS

R12-1-1201. ~~Criteria for Determining~~ Timeliness

- A. No change
- B. No change

R12-1-1202. ~~Administrative Hearings~~ Hearing Procedures

- A. All hearings shall be governed by Title 41, Chapter 6, Article 10. Hearings on the appeal of notices of violation, orders of the Director, or the appeal of proposed licensing or registration actions by the Agency shall be held before the Radiation Regulatory Hearing Board or a hearing officer appointed by the Board.
 1. ~~If a hearing is held before the Board or if a hearing officer has not been appointed, the Chairperson of the Board or another person designated by the Chairperson shall act as the hearing officer.~~

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2. If the Chairperson determines that the hearing is to be held before an appointed hearing officer, the Chairperson shall confer with the hearing officer, the Agency's designated assistant Attorney General, and the licensee or registrant in establishing the time and place of the hearing. ~~The Chairperson shall also confer with the members of the Board before establishing the time and place of a hearing to be held before the Board itself.~~

~~B.~~ Except where statutes or provisions of this Chapter applicable to hearings before the Board specify otherwise, all hearings shall be governed by the Administrative Procedure Act, A.R.S. §§ 41-1061 through 41-1066. In the absence of other authority, the Arizona Rules of Civil Procedure shall be followed to the extent practicable.

~~C.~~ The hearing officer shall rule on all motions, hold prehearing or other conferences for purposes of clarifying procedural steps or legal or factual issues, conduct the hearing, grant continuances, and otherwise rule on procedural matters and regulate the course and manner of the hearing.

~~B.D.~~ All motions and rulings shall be in writing, except those made during the hearing may be oral. The results of all conferences shall be incorporated in the record. All hearings shall be recorded.

~~C.E.~~ If it is necessary that the hearing officer or Board visit the site of an alleged violation or activity to be licensed by the Agency in order to supplement testimonial or documentary evidence presented at the hearing, the purpose of the visit and all pertinent observations shall be entered into the record.

~~F.~~ A person may be represented by counsel at any proceeding.

~~G.~~ All testimony shall be under oath or affirmation.

R12-1-1205. Intervention in Administrative Hearings; Director as a Party

A. No change

B. No change

C. The motion shall be served upon the hearing officer or the Director at least 5 working days before the hearing. ~~An~~ An application for leave to intervene shall not be granted, if by doing so, the issues will be unduly broadened.

D. No change

E. No change

R12-1-1206. Decisions of the Hearing Officer and the Board in Administrative Hearings Repealed

~~A.~~ As soon as is practical after the conclusion of an administrative hearing, the hearing officer shall prepare and circulate written findings of fact and conclusions of law and a recommended decision. Each of the parties shall be given 15 calendar days within which to respond.

~~B.~~ The hearing officer may revise or supplement the original findings, conclusions, and recommended decision in light of responses made or may submit the findings, conclusions, recommended decisions, and a copy of all responses to the Board along with a legible or audible copy of the record and all documentary evidence admitted.

~~C.~~ A copy of any revised or supplemental findings, conclusions, or recommended decision shall be given to all parties.

~~D.~~ The Board shall render a decision as promptly as possible but not later than 90 calendar days following receipt of the hearing officer's submittal.

R12-1-1207. Rehearings and Reviews of Decisions in Administrative Hearings

~~A.~~ Any party who is aggrieved by a decision of the Board may file with the Board, not later than 15 working days after issuance of the decision, a written motion for rehearing or review of the decision specifying the particular grounds therefor. A motion for rehearing may be amended at any time before it is ruled upon by the Board.

~~B.~~ A response to a motion for rehearing may be filed by any other party within 10 working days after service of the motion or amended motion. The Board may require filing of written briefs upon the issues raised in the motion and may provide for oral argument.

~~A.C.~~ A rehearing or review of a ~~the~~ decision may be granted for any of the following reasons, ~~causes~~ materially affecting the moving party's rights:

1. Irregularity in the administrative proceedings of the Board or its hearing officer or the prevailing party, or any order or abuse of discretion, whereby the moving party was deprived of a fair hearing;
2. Misconduct of the Board or its hearing officer or the prevailing party;
3. Accident or surprise which could not have been prevented by ordinary prudence;
4. Newly discovered material evidence which could not with reasonable diligence have been discovered and produced at the original hearing;
5. Excessive or insufficient penalties;
6. Error in the admission or rejection of evidence or other errors of law occurring at the administrative hearing;
7. That the decision is not justified by the evidence or is contrary to law.

~~B.D.~~ The Board may affirm or modify a ~~the~~ decision or grant a rehearing to all or any of the parties and on all or part of the issues for any of the reasons listed in subsection (A) set forth above. An order granting a rehearing shall specify with particularity the ground or grounds on which a ~~the~~ rehearing is granted, and a ~~the~~ rehearing shall cover only the matters ~~so~~ specified.

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~~**C.E.**The Board may, on its own initiative, order a rehearing or review of its decision for any reason for which it might have granted a rehearing on motion of a party, no later than 15 working days after a decision is rendered. Not later than 15 working days after a decision is rendered the Board may on its own initiative order a rehearing or review of its decision for any reason for which it might have granted a rehearing on motion of a party. After giving the parties notice and an opportunity to be heard on the matter, the Board may grant a motion for rehearing for a reason not stated in the motion. In either case, the order granting the such a rehearing shall specify the grounds for the decision therefor.~~

~~**D.F.**When a motion for rehearing is based upon affidavits, they shall be served with the motion. An opposing party may, within 30 calendar days after the such service, serve opposing affidavits. This period of time, which period may be extended by the Board ~~for an additional period~~ if good cause is shown and a written stipulation is received from both parties. The Board may permit reply affidavits.~~

R12-1-1208. Judicial Review Repealed

Any application for judicial review shall be made within the time limit specified in A.R.S. § 12-904.

R12-1-1209. Notice of Violation

- A. No change
- B. ~~The notice shall specify the severity level and circumstances of the alleged violation, and the particular statute, rule or license condition violated. The notice shall also specify the category of the registration or license. The notice shall specify:~~
 - 1. The severity level and circumstances of the alleged violation;
 - 2. The particular statute, rule, or registration or license condition violated; and
 - 3. The division of the registration or license.
- C. ~~The notice shall also specify the License or Registration Division any proposed sanction and the amount of any proposed civil penalty, unless the civil penalty is waived authorized in R12-1-1216(C). The notice will specify a civil penalty if one is to be imposed by the Agency.~~

R12-1-1210. Response to Notice of Violation

- A. No change
 - 1. No change
 - 2. No change
 - 3. No change
- B. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
- C. If an adequate and timely response is not received to the notice, the Director shall issue an initial order conditionally imposing any or all sanctions and civil penalties proposed in the notice of violation. If no civil penalty was proposed, the initial order may impose the base civil penalty listed ~~scheduled~~ in R12-1-1216.
- D. No change

R12-1-1213. Severity Levels of Violations

- A. No change
 - 1. No change
 - a. Radiation exposure to a person ~~An individual exposure,~~
 - b. No change
 - c. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
 - 6. No change
- B. No change
 - 1. No change
 - a. Radiation exposure to a person ~~An individual exposure,~~
 - b. No change
 - c. No change
 - 2. No change
 - 3. No change
 - 4. No change

- C. No change
 - 1. No change
 - a. Radiation exposure to a person ~~An individual exposure,~~
 - b. No change
 - c. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
 - 6. No change
 - 7. No change
- D. No change
 - 1. No change
 - 2. No change
 - 3. Failure to maintain records of mammography quality control tests required in R12-1-614. ~~listed in Appendix B of 12 A.A.C.1, Article 6.~~
 - 4. No change
- E. No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - 2. No change

R12-1-1214. Mitigating Factors

- A. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - a. No change
 - b. No change
 - c. No change
- B. No change
 - 1. Reduce the scheduled civil penalty, including any augmentation, by 50% for the discovery, remedy, and voluntary reporting of a severity level I or II violation by the registrant or licensee; or
 - 2. Waive the scheduled civil penalty, including augmented civil penalties, for the discovery, remedy, and voluntary reporting of a severity level III, IV, or V violation by the registrant or licensee. For the purposes of this rule, "voluntary reporting" means that the registrant or licensee has notified the Agency of a violation, the reporting of which, may or may not be required under 12A.A.C.1

R12-1-1215. License and Registration Divisions

- A. No change
 - 1. Division I licenses and registrations:
 - Broad Academic Class A
 - Broad Academic Class B
 - Broad Academic Class C
 - Broad Industrial Class A
 - Broad Medical
 - Distribution
 - Class C Laser Facility
 - Fixed Gauge Class A
 - Industrial Radiography Class A
 - Well Logging
 - Low Level Radioactive Waste Disposal Site
 - NORM Commercial Disposal Site
 - Major Accelerator Facility
 - Medical Materials Class A
 - Medical Teletherapy

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Nuclear Laundry
Nuclear Pharmacy
Open Field Irradiator
Secondary Uranium Recovery
Waste Processor Class A
X-Ray Machine Class A

2. Division II licenses and registrations:
 - Broad Industrial Class B
 - Broad Industrial Class C
 - Class B Industrial Radiofrequency Facility
 - Class B Laser Facility
 - Class C Industrial Radiofrequency Facility
 - Fixed Gauge Class B
 - Class II Surgical Device
 - Health Physics Class A
 - Industrial Radiation Machine
 - Industrial Radiography Class B
 - NORM Commercial Disposal Site
 - X-Ray Machine Class B
 - Waste Processor Class B
 - Laser Light Show/Laser Demonstration
 - Limited Academic
 - ~~Medical Imaging Facility~~
 - Medical Laser
 - Medical Materials Class B
 - Medical Radiofrequency Device Facility
 - Research and Development
 - Self Shielded Irradiator
 - Tanning Facility
3. Division III licenses and registrations:
 - Class A Laser Facility
 - Class A Industrial Radiofrequency Facility
 - Depleted Uranium
 - Gas Chromatograph
 - General Depleted Uranium
 - General Industrial
 - General Medical
 - General Veterinary Medicine
 - Health Physics Class B
 - Laboratory
 - Radioactive waste transfer-for-disposal
 - TENORM
 - Leak Detector
 - Limited Industrial
 - Medical Materials Class C
 - Other Ionizing Radiation Machine
 - Portable Gauge
 - Possession Only
 - Unclassified
 - Veterinary Medicine
 - X-ray Machine Class C
 - Reciprocal
 - Other Nonionizing Radiation Machine

- B.** No change
C. No change
D. No change
1. No change
 2. No change
 3. No change

4. No change

R12-1-1216. Civil Penalties

- A.** No change
1. No change
 - a. No change
 - b. No change
 - c. No change
 2. No change
 - a. No change
 - b. No change
 - c. No change
 3. No change
 - a. No change
 - b. No change
 - c. No change
 4. No change
 - a. No change
 - b. No change
 - c. No change
 5. No change
 - a. No change
 - b. No change
 - c. No change
- B.** No change
1. No change
 2. No change
 3. No change
- C.** No change
1. No change
 2. The registrant or licensee submits a timely and adequate response to the notice, rectifies the conditions which appear to have caused the violation, and otherwise complies with the Act, 12 A.A.C. 1, registration, and license conditions.

R12-1-1217. Augmentation of Civil Penalties

- A.** A continuing violation ~~is~~, for the purposes of calculating the proposed civil penalty, is considered a separate violation for each day it continues. The second (or successive) day of a continuing violation is not considered a repeat violation of the violation occurring on the ~~first~~ first ~~4th~~ day.
- B.** If a second severity level I violation is committed within 5 years, the Agency shall increase the base ~~scheduled~~ civil penalty by 100%, provided the registration or license is not revoked under R12-1-1219.
- C.** If a ~~second~~ second severity level II violation is committed within a period of 5 years, the Agency shall increase the base ~~scheduled~~ civil penalty by 50%, provided the registration or license is not revoked under R12-1-1219.
- D.** If a severity level III violation is repeated within 5 years, the Agency shall increase the base ~~scheduled~~ civil penalty by 50%. If the same severity level III violation is repeated a ~~second~~ second time within 5 years, the base ~~scheduled~~ civil penalty shall be increased by 100%, provided the registration or license is not revoked under R12-1-1219.
- E.** If a severity level IV violation is repeated within 5 years, the Agency shall propose the base ~~scheduled~~ civil penalty.
1. If the same violation occurs 3 times within 5 years, the Agency shall increase the base ~~scheduled~~ civil penalty by 50%.
 2. If the same violation occurs 4 times within 5 years, the Agency shall increase the base ~~scheduled~~ civil penalty by 100%, provided the registration or license is not revoked under R12-1-1219.
- F.** If greater than 3 severity level V violations are observed during 2 consecutive inspections, the Agency shall impose a civil penalty for each violation. The base civil penalty for each violation is the base ~~scheduled~~ civil penalty assessed for a severity level V violation. If the inspection shows repetition of a violation the base civil penalty for each repeat violation is the base ~~scheduled~~ civil penalty assessed for a severity level IV violation. Subsection (E) does not apply to penalties under this subsection.
- G.** No change
- H.** No change
1. No change
 2. No change
 3. No change

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I. No change

R12-1-1218. Payment of Civil Penalties

- A. ~~Civil~~ A person shall pay civil penalties imposed under this Article ~~shall be paid~~ by certified check or money order payable to the Agency, and mailed or delivered to the Agency at the address shown on the notice of violation.
- B. No change

R12-1-1219. Additional Sanctions-Show Cause

- A. If a severity level I violation is repeated or if any ~~second 2nd~~ severity level I violation is committed within 10 years, the Agency shall require the registrant or licensee to show cause why the registration or license should not be suspended or revoked.
- B. If any ~~second 2nd~~ severity level II violation is committed within 5 years, or if a severity level II violation involving radioactive effluent releases, excessive radiation levels, or radiation overexposure to an individual is committed within 5 years of a similar severity level I violation, the Agency shall require the registrant or licensee to show cause why the registration or license should not be suspended or revoked.
- C. If repeated or different severity level III violations are committed on 3 separate occasions within any 5 year period, the Agency may require the registrant or licensee to show cause why the registration or license should not be suspended or revoked.

R12-1-1220. Escalated Enforcement

- A. No change
1. No change
 2. No change
 - a. No change
 - b. A different ~~second 2nd~~ severity level II violation, or
 - c. No change
- B. The Director may issue an order impounding the radiation source or ~~suspending, revoking,~~ or modifying the registration or license upon determining that conditions exist which cause a potential for a severity level I or severity level II violation.
- C. No change
- D. No change

R12-1-1223. Registration and Licensing Time-frames

The Agency shall perform an administrative completeness review and substantive review of an application for a new or renewal license or registration; or an amendment to a license or registration within the time-frames ~~provided~~ in Table A. The Agency shall review an application for an amendment to an existing license or registration which changes the license category listed in R12-1-1306, using the time-frames specified for the requested category.

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Table A. Registration and Licensing Time-frames

REGISTRATION AND LICENSING TIME-FRAMES			
License or Registration category in R12-1-1306	Administrative Completeness Review Time-frame, in days	Substantive Review Time-frame, in days	Overall Time-frame, in days
A1	90	30	120
A2	90	30	120
A3	90	30	120
A4	60	30	90
B1	90	30	120
B2	90	30	120
B3	90	30	120
B4	90	30	120
B5	90	30	120
B6	40	20	60
C1	60	30	90
C2	60	30	90
C3	60	30	90
C4	60	30	90
C5	60	30	90
C6	60	30	90
C7	60	30	90
C8	90	30	120
C9	60	30	90
C10	40	20	60
C11	90	30	120
C12	90	30	120
C13	90	30	120
C14	90	30	120
C15	90	30	120
C16	90	30	120
C17	90	30	120
D1	90	30	120
D2	90	30	120
D3	90	30	120
D4	40	20	60
D5	40	20	60
D6	90	30	120
D7	40	20	60
D8	60	30	90
D9	90	30	120
D10	90	30	120
D11	1095	365	1460
D12	730	180	910

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D13	365	90	455
D14	90	30	120
D15	40	20	60
D16	20	10	30
D17	40	20	60
D18	90	30	120
D19	365	120	485
<u>D20</u>	<u>60</u>	<u>30</u>	<u>120</u>
E1	40	20	60
E2	40	20	60
E3	40	20	60
E4	40	20	60
E5	90	30	120
<u>E6</u>	<u>90</u>	<u>30</u>	<u>120</u>
F1 E6	40	20	60
F2 E7	40	20	60
F3 E8	40	20	60
F4 E9	40	20	60
F5 E10	20	10	30
F6 E11	40	20	60
F7 E12	40	20	60
F8 E13	40	20	60
F9 E14	40	20	60
F10 E15	40	20	60
F11 E16	40	20	60
F12 E17	90	30	120

Footnote: “administrative completeness review time-frame”; “substantive review time-frame”, and “overall time-frame” are defined in A.R.S. § 41-1072.

ARTICLE 14. REGISTRATION OF NONIONIZING RADIATION SOURCES
AND STANDARDS FOR PROTECTION AGAINST NONIONIZING RADIATION
RULES FOR THE CONTROL OF NONIONIZING RADIATION

R12-1-1401. ~~Repealed~~ Registration of Nonionizing Radiation Sources and Service Providers

- A. A person shall not use a nonexempt nonionizing radiation source, defined in R12-1-1402, unless the source is registered by the Agency.**
- B. A person possessing a nonexempt nonionizing radiation source shall submit to the Agency an application for registration at least 30 days prior to its first use.**
 - 1. Nonexempt nonionizing sources requiring a registration are listed in R12-1-1302.**
 - 2. The person applying for the registration of a nonexempt nonionizing source shall use an application form provided by the Agency.**
 - 3. The applicant shall provide the information identified in Appendix B of this Article.**
- C. A registrant shall notify the Agency within 30 days of any change to the information contained in the registration, or sale of a source that results in termination of the activities conducted under the registration.**
- D. In addition to the application form, the applicant shall remit the appropriate registration fee specified in R12-1-1306.**
- E. Persons operating more than 1 facility, where nonionizing radiation producing sources are used, shall apply for a separate registration for each facility.**

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E. A person in the business of installing or servicing nonionizing radiation sources shall apply for registration of the business activities with the Agency 30 days prior to furnishing the service. Application for registration shall be on a form provided by the Agency and shall contain the information required in A.R.S. § 30-672(01).

R12-1-1402. Definitions

A. General definitions:

“Direct supervision” means supervising the use of a radiation source for medical purposes by a licensed practitioner while present inside the facility where it is being used.

“Licensed practitioner” means a person licensed or otherwise authorized by law to practice medicine, dentistry, osteopathy, podiatry, chiropractic or naturopathic medicine in this state.

“Nonexempt nonionizing radiation source” means any system or device containing a nonionizing radiation source listed in R12-1-1302(F).

~~**B.A. Radiofrequency and microwave radiation definitions:** The following terms have the meaning given when used in rules pertaining to radio frequency and microwave radiation:~~

- ~~1. “Accessible emission level” means the level of radio frequency radiation emitted from any source, expressed in terms of power density in milliwatts per square centimeter or electric and magnetic field strength as appropriate, and to which human access is normally possible.~~
- ~~2. “Far field region” means the region in which locally uniform distribution of electric and magnetic field strengths exists in planes transverse to the direction of propagation. The far field region shall be taken to exist at distances greater than $2D^2/M$ from the antenna, where M is the wavelength and D is the largest antenna aperture dimension.~~
- ~~3. “Near field region” means the region near an antenna in which the electric and magnetic field components vary considerably in strength from point to point. For most antennas the outer boundary of the region shall be taken to exist at a distance $M/2$ from the antenna surface, where M is the wavelength.~~
- ~~4. “Radio frequency controlled area” means any area to which access is controlled for the purpose of protection from radio frequency radiation.~~
- ~~5. “Radio frequency exposure limits” means the maximum permissible whole body exposure to humans, from any source of radio frequency radiation.~~
- ~~6. “Radio frequency ~~machine~~ source” means a radiation ~~machine~~ source or system which produces electromagnetic radiation in the frequency spectrum.~~
- ~~7. “Radio frequency radiation” means that electromagnetic radiation (including microwave radiation) with frequencies in the range of 0.3 megahertz to 100 gigahertz.~~
- ~~8. “Safety device” means any device incorporated into a radio frequency ~~source~~ ~~machine~~ which is designed to prevent human access to excessive levels of radio frequency radiation.~~

~~**C.B. Laser definitions:** The following terms have the meaning given when used in rules applicable to lasers:~~

- ~~1. “Accessible emission level (AEL)” means the maximum accessible emission level permitted within a particular class. For purposes of this Article this term is synonymous with “accessible emission limit”, ~~magnitude of emission of laser or collateral radiation to which human access is possible.~~~~
- ~~2. “Accessible emission limit” means the maximum accessible emission level of laser radiation permitted within a particular class.~~
~~“Accessible radiation” means radiation to which it is possible for the human eye or skin to be exposed in normal usage.~~
- ~~3. “Angular subtense” means the apparent visual angle, a, as calculated from the source size and distance from the eye.~~
- ~~4. “Aperture” means an opening through which radiation can pass ~~any opening in a protective housing through which radiation is emitted, thereby~~ allowing human access to the radiation.~~
- ~~5. “Aperture stop” means an opening serving to limit the size and to define the shape of the area over which radiation is measured.~~
- ~~6. “Certified laser product” means that the product is certified by a manufacturer pursuant to the requirements of 21 CFR 1040, 2001 Edition, Published April 1, 2001, Title 21, Code of Federal Regulations, Part 1040, 1993 Edition, Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated ~~herein~~ by reference and on file with the Agency and the Office of Secretary of State. ~~This incorporation by reference contains no future editions or amendments.~~
~~“CDRH” means the Center for Devices and Radiological Health.~~~~
- ~~7. “Class 1 laser” means a laser or laser system that may produce visible or invisible laser radiation. Under all normal conditions of operation, a Class 1 laser is considered to be incapable of causing injury from directly viewing the radiation beam. means any laser which permits human access during operation to laser radiation less than the accessible emission limits for any combination of emission duration and wavelength range.
~~a. “Class I dual limits” means, for classification purposes, laser or collateral radiation in the wavelength range of greater than 400 nanometers but less than or equal to 1400 nanometers exceeds the accessible emission limits of Class I if it exceeds both:~~~~

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- i. The Class I accessible emission limits for radiant energy within any range of emission duration; and
 - ii. The Class I accessible emission limits for integrated radiance within any range of emission duration.
8. “Class 2 laser ~~H~~Laser” means a laser or laser system that produces low-power visible laser radiation not exceeding 1 mW. Eye protection is normally afforded by the natural blink reflex time (0.25 s). Direct viewing of the radiation beam from a Class 2 laser is prohibited. ~~means any laser which permits human access during operation to laser radiation above the Class I accessible emission limits, up to the accessible emission limits of Class II accessible emission limits and does not permit human access to laser radiation in excess of the accessible emission limits of Class I for any other emission duration or wavelength range.~~
9. “Class 2a ~~Ha~~ laser products” means any laser product that permits human access during operation to levels of visible laser radiation in excess of the Class 2 ~~H~~ accessible emission limits, during its operation, but does not permit human access during operation to levels of laser radiation in excess of the accessible Class 2a ~~Ha~~ emission limits.
10. “Class 3a laser ~~III~~Laser” means a laser or laser system that produces moderate levels of visible or invisible laser radiation of 1 to 5 mW and requires more stringent control than a Class 2 laser. For those Class 3a lasers whose output is visible, the normal aversion response is generally sufficient to prevent eye injury. However, the use of collecting optics, e.g. binoculars, can produce retinal injury. Because the radiation beam is not observed in Class 3a laser that produces ultraviolet or infrared emissions the accessible emission level does not rely upon the normal aversion response, but rather on the fact that the eye of the exposed individual will not fixate on the radiation beam long enough to cause injury. ~~means any laser which permits human access during operation to laser radiation above the Class I accessible emission limits and, if applicable, Class II, but below the Class IIIa accessible emission limits. Class III lasers are separately designated as Class IIIa or Class IIIb.~~
- a. Class IIIa lasers are those lasers with an emission duration greater than 380 microseconds and in the wavelength range greater than 400 nanometers but less than or equal to 710 nanometers, with a radiant power of less than or equal to five milliwatts.
 - b. Class IIIb lasers are all other Class III lasers as defined above.
- “Class 3b Laser” means a laser or laser system that produces visible laser radiation of 5 to 500 mW of visible continuous wave output and 5 to 500 mW of invisible infrared laser radiation. A Class 3b laser is considered medium power laser and is capable of producing eye injury when viewed directly or with optics, even if viewed momentarily. The normal aversion response (0.25 s) to a Class 3b laser does not prevent injury. A Class 3b laser does not usually produce a hazardous diffuse reflection or fire hazard. At the upper end of the Class 3b power range skin burns may be possible.
11. “Class 4 ~~IV~~ laser” means a laser or laser system that produces visible or invisible laser radiation capable of causing injury to the eye and skin, and dangerous specular and diffuse reflections. Improper use may result in a fire hazard. ~~means any laser which permits human access during operation to laser radiation above the Class III accessible emission limits.~~
12. “Class 1, 2, 3, 4 ~~I, II, III, IV~~ facility” means a facility which has one or more Class 1, 2 ~~I, II~~ (including 2a ~~Ha~~), 3 ~~III~~ (including 3a ~~IIIa~~ and 3b ~~IIIb~~), or 4 ~~IV~~ lasers respectively. Facilities containing more than one class of laser shall be classified according to the highest laser class contained therein.
13. “Collateral radiation” means any electronic product radiation, except laser radiation, emitted by a laser as a result of the operation of the laser or any component of the laser product that is physically necessary for the operation of the laser. The accessible emission and maximum permissible exposure limits for collateral radiation are specified in 21 CFR 1040.10, 2001 Edition, published April 1, 2001, Title 21, Code of Federal Regulations, Section 1040.10, 1993 Edition, published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency and the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.
- “Continuous wave” (cw) means the output of a laser which is operated in a continuous rather than a pulsed mode. For purposes of these rules, a laser operating with a continuous output for a period 0.25 seconds, is regarded as a cw laser.
- “Controlled area” means an area where the occupancy and activity of those within is subject to control and supervision for the purpose of protection from radiation hazards.
14. “Demonstration laser” means any laser manufactured, designed, intended or used for purposes of demonstration, entertainment, advertising display, or artistic composition.
- “Embedded laser” means an enclosed laser with an assigned class number higher than the inherent capability for the laser system in which it is incorporated, where the systems lower classification is appropriate due to the engineering features limiting accessible emission.
- “Enclosed laser” means a laser that is contained within a protective housing of itself or of the laser system in which it is incorporated. Opening or removal of the protective housing provides additional access to laser radiation above the applicable MPE than possible with the protective housing in place. (An imbedded laser is an example of one type of enclosed laser.)

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15. "Federal performance standard for light-emitting products" means the regulations in 21 CFR 1040(10), 2001 Edition, published April 1, 2001 Title 21, Code of Federal Regulations, Section 1040.10, 1993 Edition, Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated ~~herein~~ by reference and on file with the Agency and the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.
16. "Human access" means access to laser or collateral radiation by any part of the human body.
17. "Incident" means an event or occurrence which results in a real or suspected accidental exposure to laser radiation which caused or is likely to cause biological damage.
18. "Integrated radiance" means radiant energy per unit area of a radiating surface per unit solid angle of emission, expressed in joules per square centimeter - steradian.
19. "Irradiance" means the radiant power incident on an element of a surface divided by the area of that element, expressed in watts per square centimeter.
"Laser." See the definition in Article 1.
20. "Laser controlled area" means any area into which human access is restricted for the purpose of radiation protection.
21. "Laser energy source" means any device intended for use in conjunction with a laser to supply energy for the operation of the laser. General energy sources such as electrical supply mains or batteries, shall not be considered to constitute laser energy sources.
22. "Laser product" means any manufactured product or assemblage of components which constitutes, incorporates, or is intended to incorporate a laser or laser system. A laser or laser system which is intended for use as a component of an electronic product shall itself be considered a laser product.
23. "Laser protective device" means any device used to reduce or prevent exposure of personnel to laser radiation. Included are: Such devices shall include protective eye wear, garments, engineering controls, and operational controls.
24. "Laser radiation" means all electromagnetic radiation emitted by a laser product, within the spectral range specified in the definition of "laser", in Article 1, which is produced as a result of controlled stimulated emission.
25. "Laser Safety Officer" (LSO) - means any individual, qualified by training and experience in the evaluation and control of laser hazards, who is designated by the ~~licensee registrant~~ and has the authority and responsibility to establish and administer the laser radiation protection program for a particular facility.
26. "Laser system" An assembly of electrical mechanical, and optical components which include a laser. means a laser in combination with an appropriate laser energy source, with or without additional incorporated components.
"Limited Exposure Duration (Tmax)" means an exposure duration which is specifically limited by the design or intended use(s).
"Maintenance" means performance of those adjustments or procedures specified in user information provided by the manufacturer with the laser or laser system, which are to be performed by the user to ensure the intended performance of the product. It does not include operation or service as defined in this Section.
27. "Maximum permissible exposure (MPE)" means the level of laser radiation to which a person may be exposed without hazardous effect or adverse biological changes in the eye or skin. "MPE" means the maximum permissible exposure limits for human exposure to laser or collateral radiation established by this Article. MPE limits for eye and skin exposure listed in ANSI Z136.1-2000 1993, American National Standard for Safe Use of Lasers, 2000 1993 Edition, Published by the Laser Institute of America, Incorporated herein by reference and on file with the Agency and the Office of Secretary of State, and for collateral radiation, in 21 CFR 1040(10), 2001 Edition, published April 1, 2001, Title 21, Code of Federal Regulations, Section 1040.10, 1993 Edition, Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency and the Office of Secretary of State. Both incorporation by references contain no future editions or amendments.
28. "Maintenance" means the performance of those adjustments or procedures by the user to keep equipment in its intended operating condition. Maintenance does not include operation or service.
"Operation" means the performance of the laser or laser system over the full range of its intended functions (normal operation). It does not include maintenance or service as defined in this Section.
29. "Protective housing" means any panel, partition, dividing wall, or similar device which prevents human access to laser or collateral radiation in excess of the prescribed accessible emission limit.
30. "Pulse duration" means the duration of a laser pulse; usually measured as the time interval between the half power points on the leading and trailing edges of the pulse. the time increment measured between the halfpeak power points at the leading and trailing edges of a pulse.
31. "Pulse interval" means the time duration between identical points on two successive pulses.
32. "Radiance" means the time-averaged radiant power per unit area of a radiating surface per unit solid angle of emission, expressed in watts per square centimeter per steradian.
33. "Radiant energy" means energy emitted, transferred or received in the form of radiation, expressed in joules.

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- 34. "Radiant exposure" means the radiant energy incident on an element of a surface divided by the area of that element, expressed in joules per square centimeter.
- 35. "Radiant power" means the time-averaged power emitted, transferred, or received in the form of radiation, expressed in watts.
- 36. "Safety interlock" means a device associated with the protective housing of a laser product, system or facility which prevents human access to laser and collateral radiation in excess of the prescribed accessible emission limit.
- 37. "Sampling interval" means the time interval during which the level of accessible laser or collateral radiation is sampled by a measurement process. The magnitude of the sampling interval in units of seconds is represented by the symbol "t".
- 38. "Secured enclosure" means an enclosure to which casual access is impeded by appropriate means, such as a door secured by lock, by latch, or by screws.
"Service" means the performance of those procedures or adjustments described in the manufacturer's instructions which may effect any aspect of the performance of the laser or laser system. It does not include maintenance or operation as defined in this Article.
"Tmax" See limiting exposure duration.
- 39. "Uncertified laser product" means any laser which has not been certified in accordance with the requirements of 21 CFR 1040(10), 2001 Edition, Published April 1, 2001, Title 21, Code of Federal Regulations, Part 1040, 1993 Edition, Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated ~~herein~~ by reference and on file with the Agency and the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.

D.C. Ultraviolet, high intensity light, and intense pulsed light source definitions: The following terms have the meaning given when used in rules on ultraviolet and high intensity light sources:

- "Consumer" means any member of the public who is provided access to a tanning device in exchange for a fee or other compensation, or any individual who, in exchange for a fee or other compensation, is afforded use of a tanning device as a condition or benefit of membership or access.
- "EPA" means the United States Environmental Protection Agency.
- "FDA" means the United States Food and Drug Administration.
- 1. "High intensity mercury vapor discharge (HID) lamp" means any mercury vapor or metal halide lamp incorporating a high-pressure arc discharge tube that has a fill consisting primarily of mercury and that is contained within an outer envelope but does not include the tungsten filament self-ballasted mercury vapor or metal halide lamp.
"Maximum exposure time" means the greatest continuous exposure time interval recommended by the manufacturer of a product.
"Photothermolysis" means the non-invasive aesthetic application of intense-pulsed light energy to selective superficial lesions such as unwanted body hair or veins.
- 2. "Protective sunlamp eye wear" means any device designed to be worn by a user of a product to reduce exposure of the eyes to radiation emitted by the product. ~~users of a sunlamp product to reduce radiation exposures to the eyes.~~
"Sanitize" means the effective bacterial treatment of surfaces of equipment and devices by an EPA or FDA registered product which provides a sufficient concentration of chemicals, and enough time to reduce the bacterial count, including pathogens, to a safe level. Chemical germicides that are registered with the EPA as hospital disinfectants when used at recommended dilutions and directions, may be approved for sanitizing of tanning devices.
- 3. "Self-extinguishing lamp" means any HID lamp which ceases operation in conformance with the requirements of the performance standard in 21 CFR 1040(30)(d), 2001 Edition published April 1, 2001, Title 21, Code of Federal Regulations, Paragraph 1040.30(d), 1993 Edition, Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated ~~herein~~ by reference and on file with the Agency and the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.
- 4. "Sunlamp product" means any electronic device which incorporates one or more ultraviolet lamps and is intended for use to induce skin tanning.
- 5. "Tanning device" means any equipment, that emits electronic radiation with wavelengths in the air between 200 and 400 nanometers including, but not limited to, a sunlamp, ultraviolet lamp, tanning booth, facial unit, UVA wand, or tanning bed. A tanning device also means any accompanying equipment, including, but not limited to, protective eye wear, timers, ballasts, starters, lamps, reflectors, cooling fans, acrylics, comfort pillows and hand rails, room, booth, cabinet, or other enclosure which houses sunlamp products for the purpose of irradiating any part of the human body for cosmetic or non-medical purposes. ~~means any room, booth, cabinet, tanning bed or other enclosure which houses sunlamp products for the purpose of irradiating any part of the human body for cosmetic or nonmedical purposes.~~
"Timer" means a device provided to terminate radiation exposure at a preset time.
- 6. "Ultraviolet lamp" means any light source that produces ultraviolet radiation and that is intended for use in any sunlamp product.
- 7. "Ultraviolet radiation" means electromagnetic radiation with a wavelength in air of between 200 and 400 nanometers.

R12-1-1403. General Safety Provisions and Exemptions

- A. No change
1. No change
 2. The licensee registrant provides sufficient information to enable the Agency to determine that alternative methods of achieving the same or a greater level of radiation protection will be used.
- B. The licensee registrant shall:
1. Ensure that nonionizing radiation sources are operated ~~only~~ by individuals who have been trained and have demonstrated competence in the safe use of the ~~sources equipment~~.
 2. Provide safety rules to individuals operating nonionizing radiation ~~machines~~ sources and ~~ensure the shall make these individuals are aware of any operating restrictions and procedures needed~~ restrictions in operating techniques required for the safe use of the ~~machines~~ sources.
 3. No change
 4. The following records shall be retained for 3 years for Agency review: Retain records, including but not limited to:
 - a. Results of all physical surveys and calibrations required by this Article for five years,
 - b. ~~The calibration of radiation survey instruments for five years,~~
 - b.e. Radiation source inventories; Inventories to account for sources of radiation for two years,
 - c.d. Maintenance, service, and modifications; and Records of maintenance, servicing or modifications which could affect the radiation emission characteristics of a machine for the life of the machine plus two years, and
 - d.e. Incidents involving known or suspected exposure to nonionizing radiation in excess of the limits permanent documentation of each incident involving known or suspected exposure to nonionizing radiation in excess of the maximum permissible exposure limits specified in this Article.
- C. A registrant ~~The licensee shall not operate, nor permit the operation of,~~ a nonionizing radiation ~~machine~~ source unless the ~~machine~~ source complies with all of the applicable requirements of this Article.

R12-1-1404. Radio Frequency Equipment Requirements

- A. A radiation source ~~Radiation machines~~ emitting accessible emission levels exceeding the maximum permissible radio frequency exposure levels for uncontrolled areas specified in IEEE C95.1-1991, Institute of Electrical and Electronics Engineers Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3kHz to 300 GHz, 1991 Edition, Published by the Institute of Electrical and Electronic Engineers, Inc., incorporated ~~herein~~ by reference, ~~and~~ on file with the Agency and the Office of Secretary of State, ~~and containing no future editions or amendments,~~ shall be operated only in a radio frequency controlled area, so arranged as to prevent human exposure in excess of the applicable values. Each point of access into a radio frequency controlled area shall be posted according to R12-1-1406, with warning signs meeting the specifications indicated in R12-1-1406, Figure 1.
- B. Radio frequency ~~machines~~ sources which are required to operate in a ~~be operated in a radio frequency~~ controlled area shall incorporate visual or audible emission indicators which function only during production of radiation.
- C. Sources of radio frequency emissions, which are physically separate ~~separated~~ from the source's means of activation ~~of the sources~~ by a distance greater than ~~2 two~~ meters, shall be provided with a visual or an audible emission indicator at ~~indicators at both~~ the source and the point of activation.
- D. Visual emission indicators shall be ~~so~~ located so that use of the indicators ~~observation~~ does not require human exposure to radio frequency radiation in excess of the ~~applicable values in the radio frequency~~ exposure limits.
- E. Safety devices designed to prevent human exposure to excessive radio frequency radiation shall be inspected for proper operation at intervals not to exceed ~~1 one~~ month.
- F. No change
- G. Radio frequency ~~machines~~ sources shall be physically secured against unauthorized use ~~and tampering or being tampered with when not in use.~~

R12-1-1405. Radio Frequency Exposure Limits

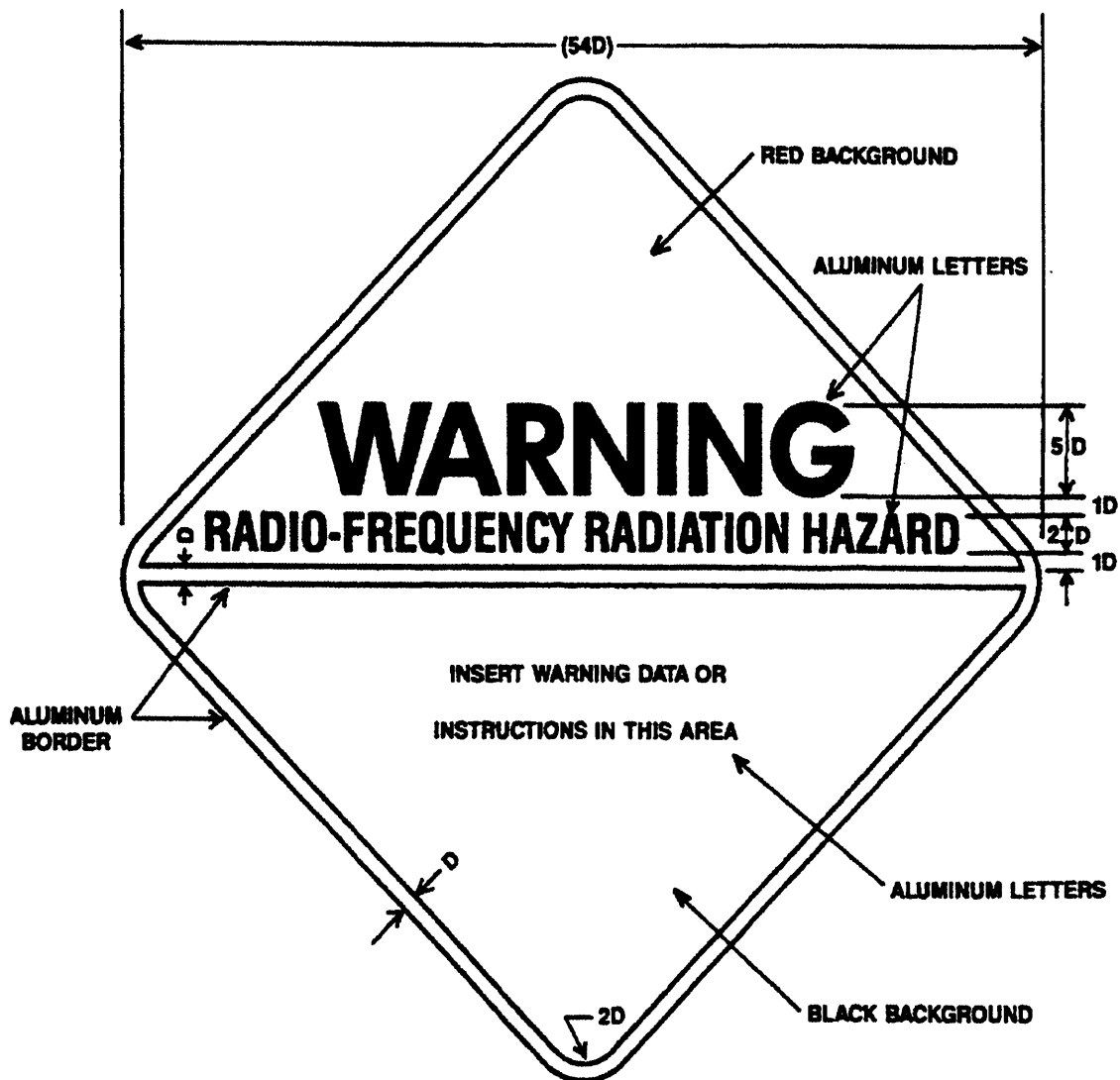
- A. A registrant shall not expose a person to radio frequency radiation in excess of the limits specified in ~~The licensee shall not allow, as a result of operation of radio frequency machines under the licensee's control, human exposure to radio frequency radiation in excess of the maximum permissible radio frequency exposure levels in IEEE C95.1-1991, Institute of Electrical and Electronics Engineers Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3kHz to 300 GHz, 1991 Edition, published~~ Published by the Institute of Electrical and Electronic Engineers, Inc., incorporated ~~herein~~ by reference and on file with the Agency and the Office of Secretary of State, ~~and containing no future editions or amendments.~~ with the following exclusions:
- B.1. ~~At frequencies between 300 kHz and 100 GHz, IEEE C95.1-1991, Institute of Electrical and Electronics Engineers Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3kHz to 300 GHz, 1991 Edition, Published by the Institute of Electrical and Electronic Engineers, Inc., incorporated herein by reference and on file with the Office of Secretary of State,~~ the exposure limits may be exceeded if the exposure conditions can be shown

by laboratory procedures to produce specific absorption rates (SARs) below 0.4 watts per kilogram averaged over the whole body, and spatial peak SAR values below ~~8~~ eight watts per kilogram averaged over ~~1~~ any one gram of tissue.

~~C.2. At frequencies between 300 kHz and 1 GHz, the IEEE C95.1-1991, Institute of Electrical and Electronics Engineers Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3kHz to 300 GHz, 1991 Edition, Published by the Institute of Electrical and Electronic Engineers, Inc., incorporated herein by reference and on file with the Office of Secretary of State, the exposure limits may be exceeded if the radio frequency input power to the radiating device is 7 seven watts or less.~~

R12-2-1406. Radio Frequency Hazard Caution Signs, Symbols, Labeling and Posting

A. ~~Each point of access to controlled Radio frequency controlled areas shall be clearly posted with caution signs of the type designated in Figure 1 at each point of access to such areas.~~



1. Place handling and mounting instructions on reverse side.
2. D = Scaling unit
3. Lettering: Ratio of letter height to thickness of letter lines.
 - Upper triangle: 5 to 1 Large
 - 6 to 1 Medium
 - Lower triangle: 4 to 1 Large
 - 6 to 1 Medium
4. Symbol is square, triangles are right-angle isosceles.

Fig. 1

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- B. ~~Operating procedure restrictions or limitations used to prevent unnecessary or excessive~~ Any limitations or restriction in operating procedures required to prevent unnecessary or excessive exposure to radio frequency radiation shall be posted in a location ~~clearly~~ visible to the operator.
- C. The location of warning ~~Warning~~ signs and labels shall not result in the observer being exposed to ~~be located such that observation does not require~~ unnecessary or excessive exposure to radio frequency radiation.

R12-1-1407. Special Requirements for Microwave Ovens

- A. ~~The power density of microwave radiation emitted by a microwave oven measured at any time subsequent to acquisition by a user shall not exceed 5 milliwatts per square centimeter at any point 5 centimeters from the external surface of the oven.~~
- B. ~~Compliance measurements shall be made with the oven operating at its maximum output, and containing a load of 275 ± 15 milliliters of tap water at 20 ± 5C, within the oven cavity at the center of the load-carrying surface provided by the manufacturer. The water container shall be a low form 600 milliliter beaker having an inside diameter of approximately 8.5 centimeters and made of an electrically nonconductive material such as glass or plastic.~~
- C. ~~Microwave ovens shall be provided with at least two safety interlocks, one of which is not accessible to humans without disassembly of the oven or door. The interlocks shall prevent microwave radiation emission in excess of the requirements of subsection (A). The failure of 1 interlock shall not cause failure of the 2nd.~~
- D. ~~Service performed on microwave ovens shall not result in failure of safety interlocks or the emission limits specified in subsection (A) to be exceeded.~~
- E. ~~Microwave ovens not meeting the standards prescribed in this Section shall be removed from service and not put back into service until the repairs necessary to achieve compliance have been completed.~~
- F. ~~Microwave ovens manufactured after October 6, 1971, shall be maintained in conformance with the requirements 21 CFR 1040.30, 1993 Edition, Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency and the Department and the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.~~

Microwave ovens not meeting the requirements in 21 CFR 1040(30), 2001 Edition, published April 1, 2001, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency and the Department and the Office of Secretary of State, shall register the microwave oven with the Agency. This incorporation by reference contains no future editions or amendments.

R12-1-1408. Reporting of Radio Frequency Radiation Incidents

- A. A registrant shall report in writing to the Agency within 15 days a known or suspected personnel exposure to radiation in excess of the limits in R12-1-1405. ~~When it is known or suspected that any individual has been exposed to radio frequency radiation in excess of the limits in R12-1-1405 the licensee shall report the incident to the Agency in writing within 15 days.~~
- B. A registrant shall report to the Agency within 24 hours a known or suspected personnel exposure to radiation in excess of 150% of the limits in R12-1-1405. ~~When it is known or expected that any individual has been exposed to radio frequency radiation in excess of 150% of the limits in R12-1-1405 the licensee shall report the incident to the Agency within 24 hours.~~
- C. A registrant shall report to the Agency immediately a known or suspected personnel exposure in excess of 500% of the limits in R12-1-1405. ~~Immediate notification shall be made to the Agency when radio frequency radiation exposure exceeds 500% of the limits.~~

R12-1-1409. Medical Surveillance for Radio Frequency Occupational Workers

- A. A registrant shall provide a medical examination upon request by the Agency to an individual exposed to radiation reported to the Agency according to R12-1-1408. ~~The Agency may require the licensee to provide medical examinations as necessary to protect the health of any individual exposed to radio frequency radiation produced by equipment under the licensee's control.~~
- B. A registrant shall request an individual under going a medical examination in accordance with subsection (A), to provide a copy of the results to the Agency. ~~The licensee shall request the individual to provide to the Agency a copy of the results of medical examinations ordered pursuant to subsection (A). Such reports shall be held confidential by the Agency, unless all information which could identify the patient has been removed.~~

R12-1-1410. Radio Frequency Compliance Measurements ~~Criteria~~

- A. Measurements made to determine compliance with R12-1-1405 shall be made with instrumentation capable of measuring appropriate for the field strength and frequency of the radiation in question ~~radiations to be evaluated.~~
- B. Instrumentation used for compliance measurements shall be calibrated every 12 months. ~~have been calibrated within the preceding year. The calibration shall be traceable to a national standard maintained by the National Institute of Standards and Technology (NIST). (formerly known as the National Bureau of Standards.)~~

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- C. Compliance measurement of exposure conditions in the near field shall consist of measurements of the electric and magnetic field components. The applicable protection standards for near field measurements shall be the mean squared electric and magnetic field strengths ~~referenced in R12-1-1405 in IEEE C95.1-1991, Institute of Electrical and Electronics Engineers Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3kHz to 300 GHz, 1991 Edition, Published by the Institute of Electrical and Electronic Engineers, Inc., incorporated herein by reference and on file with the Office of Secretary of State.~~
- D. Measurements to determine compliance in far field exposure conditions may be actual measurements of power density in milliwatts per square centimeter, or the calculated equivalent plane wave power density based on measurement of either the electric or magnetic field strength. The applicable protection standards shall be the power density values ~~referenced in R12-1-1405 in IEEE C95.1-1991, Institute of Electrical and Electronics Engineers Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3kHz to 300 GHz, 1991 Edition, Published by the Institute of Electrical and Electronic Engineers, Inc., incorporated herein by reference and on file with the Office of Secretary of State.~~
- E. ~~Measurements made in accordance with this rule shall include: The measurement requirements of this Section shall be met if:~~
1. ~~measurements of both electric and magnetic field strength obtained with an strengths are obtained where the emission frequency is 300 megahertz or less; and~~
 2. ~~measurement of the electric or magnetic field strength is expressed in terms of power density.~~
- F. For mixed or broadband fields at a number of frequencies for which there are different values of protection standards ~~in IEEE C95.1-1991, Institute of Electrical and Electronics Engineers Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3kHz to 300 GHz, 1991 Edition, Published by the Institute of Electrical and Electronic Engineers, Inc., incorporated herein by reference and on file with the Office of Secretary of State,~~ the fraction of the appropriate exposure limit incurred within each frequency interval shall be determined, and the sum of all ~~the such~~ fractions shall not exceed unity (1).
- G. ~~A compliance measurement~~ Compliance measurements shall be made at distances of 5 ~~five~~ centimeters or greater from any object.
- H. ~~A registrant shall make measurements that are~~ Measurements shall be averaged over a 6 ~~minute~~ six-minute period for pulsed and non-pulsed modes of radio frequency emission. Correction shall be made for duty cycle in determining the average field strength.

R12-1-1411. ~~Licensing of Tanning Facilities Repealed~~

- ~~A. No person shall operate a tanning facility unless the person has properly applied for a license on forms provided by the Agency.~~
- ~~B. A facility operating prior to the effective date of this section may continue to operate, provided that the use of the license shall be registered within six months of the effective date.~~

R12-1-1412. ~~Tanning Operations General Safety Requirements for the Operation of Tanning Facilities~~

~~A registrant~~ The licensee shall establish and maintain a program of written policies and procedures for radiation safety sufficient to assure compliance with the requirements in R12-1-1412 through R12-1-1416.

R12-1-1413. ~~Tanning Equipment Standards~~

- A. Only sunlamp products manufactured and certified to comply with 21 CFR 1040.20 Title 21, Code of Federal Regulations, Section 1040.20, 2001 Edition, published April 1, 2001. ~~1993 Edition, Published April 1, 1993,~~ by the Office of Federal Register National Archives and Records Administration, incorporated ~~herein~~ by reference and on file with the Agency and the Office of Secretary of State, and containing no future editions or amendments, "Sunlamp products and ultraviolet lamps intend for use in sunlamp products", shall be used in tanning facilities. Compliance shall be based on the standard in effect at the time of manufacture as shown on the equipment ~~device~~ identification label.
- B. Defective or burned-out lamps, or filters, shall be replaced before further use of the tanning device.
- C. The defective or burned-out lamp, or filter, shall be replaced with a type intended for use in that equipment ~~device~~ as specified on the sunlamp product label ~~on the sunlamp products~~, or, with lamps or filters that are equivalent under the FDA regulations and polices applicable at the time of manufacture. If equivalent lamps are used instead of the Original Equipment Manufacturer (OEM) required lamps, a copy of the equivalency certification, provided by the lamp supplier, shall be maintained on file for review by Agency inspectors.
- D. Each sunlamp product shall have a timer and control system which complies with 21 CFR 1040.10, 2001 Edition, published April 1, 2001, the requirements of Title 21, Code of Federal Regulations, Section 1040.10, ~~1993 Edition, Published April 1, 1993,~~ by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency and the Office of Secretary of State. This incorporation contains no future editions or amendments. The timer and control system shall meet the following requirements:
1. The timer interval shall not exceed the manufacturers maximum recommended exposure time.
 2. Each timer shall be functional and accurate to within +/- 10% of the maximum timer interval of the product.

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3. The timer may not automatically reset and cause radiation emission to resume for a period greater than the unused portion of the timer cycle, when the emission from the sunlamp has been terminated.
 4. The registrant shall ensure that the timer is tested annually for accuracy
 5. New facilities (including existing facilities with change of ownership) shall install remote timer controls prior to the operation of sunlamp products. Existing sunlamp products not equipped with a remote timer control system are required to have remote timer controls (outside of sunlamp product room) installed no later than 6 months after June 1, 2002.
 6. Each sunlamp product shall be equipped with an emergency shutoff mechanism to allow manual termination of the UV exposure by the consumer.
- E. Each sunlamp product shall have physical barriers to protect users from injury caused by touching or breaking lamps. There shall be physical barriers as needed to protect users from injury induced by touching or breaking lamps.
- F. Each tanning facility using stand-up booths sunlamp products shall comply with the following: special requirements.
1. Physical barriers, handrails, floor markings or other means shall be present to indicate the proper exposure distance between the ultraviolet lamps and the user's skin.
 2. A tanning booth shall be constructed in such a way as to construction of the booth shall be such that it will withstand the stress of use and the impact of a falling person.
 3. A tanning booth shall be accessed Access to booths shall be through doors of rigid construction, opening outwardly. Handrails and non-slip floors shall be provided
 4. The interior temperature of a tanning device shall be controlled such that it does not exceed 100 degrees Fahrenheit (38 degrees Centigrade)

R12-1-1414. ~~Operation and Use of Tanning Equipment Operators~~

- A. ~~At There shall be present during operating hours at least one operator knowledgeable in the correct operation of the tanning equipment devices used at the facility shall be present during operating hours and able to inform and assist each user in the proper use of the tanning devices. The operator shall:~~
1. Ensure that only one person is in the tanning room when the tanning equipment is being operated;
 2. Ensure that no one under 18 years of age is allowed to use the tanning equipment without written permission from a parent or guardian.
 3. Limit exposure time to the exposure time to manufacturer's recommendation provided on the equipment label or operator's manual.
 4. Ensure the maximum exposure time in a 24 hour period recommended by the manufacturer is not exceeded.
 5. Maintain a record of each user's total number of tanning visits and tanning times for Agency inspection. The records shall be kept for 3 years from the date of the recording.
- B. ~~Prior to use of a tanning device tanning equipment the operator shall: by any individual the operator shall:~~
1. ~~Provide to the user sanitized protective sunlamp eye wear and directions for its use; its proper use.~~
 2. ~~Demonstrate to the user any the use of physical aids, used as appropriate, to maintain proper exposure distance as recommended by the manufacturer of the tanning equipment; device.~~
 3. Ensure the exposure timer is set so that the user is not exposed to excess radiation; Set the timer.
 4. Instruct the user on the maximum exposure time and proper distance from the radiation source recommended by the manufacturer of the equipment; and
 5. Instruct the user as to the location and proper operation of the emergency shutoff switch
- C. A trained operator shall control a sunlamp's timer.
1. Training of operators shall include:
 - a. The requirements of this Section;
 - b. Facility operating procedures, to include:
 - i. Determination of skin type and associated duration of exposure;
 - ii. Procedures for use of minor and adult user consent forms;
 - iii. Potential for photosensitizing foods, cosmetics, and medications;
 - iv. Requirements for use of protective eye wear by users of the equipment; and
 - v. Proper sanitizing procedures for the facility, equipment, and eye wear.
 - c. Manufacturer's procedures for operation and maintenance of tanning equipment;
 - d. Recognition of injury or overexposure; and
 - e. Emergency procedures used in the case of an injury.
 2. Records of training shall include dates and material covered, and be maintained for 3 years from the date the training was provided, for Agency inspection.
 3. A list of trained operators shall be posted at the facility. The operator shall limit each individual to the manufacturer's maximum recommended exposure time for the tanning device.
- ~~D. The interior temperature of a tanning device shall be controlled such that it does not exceed 38.5C (100.5F).~~
- ~~D.E. Prior to the first use of a tanning facility in each calendar year;~~

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1. The user shall be required to read a copy of the warning in Section R12-1-1415;
2. The user shall sign a statement that the information in subsection (D)(1) has been read and understood.
3. For illiterate or visually handicapped persons, the warning statement shall be read by the operator in the presence of a witness. Both the witness and the operator shall sign the statement.
each user shall be required to read a copy of the warning specified in Section R12-1-1415. The user shall sign a statement that the information has been read and understood. For illiterate or visually handicapped persons, the warning statement shall be read by the operator in the presence of a witness. Both the witness and the operator shall sign the statement.

~~F. A record shall be kept by the operator of each user's total number of tanning visits and tanning times.~~

~~G. Each operator shall be trained and records of training retained in the facility. Training shall include:~~

1. The requirements of this Section;
2. Procedures for correct operation of the facility;
3. Manufacturer's procedures for operation and maintenance of tanning equipment;
4. Recognition of injury or overexposure;
5. Emergency procedures in case of injury.

~~H. A list of operators trained in accordance with R12-1-1414(G) shall be posted at the facility.~~

R12-1-1415. Tanning Facility Warning Signs and Statements for Tanning Facilities

A. A registrant shall conspicuously post the warning sign described in subsection (B) within 1 meter (39.37 inches) of each tanning device. The sign shall be clearly visible, not obstructed by any barrier, equipment or other object, and easily viewed by the user before operating the tanning device. The sign shall read as follows: A warning sign shall be posted in the area where a tanning device is used or where each user must pass before entering a tanning device.

***** <u>DANGER - ULTRAVIOLET RADIATION</u> 1. <u>Follow instructions.</u> 2. <u>Avoid overexposure. As with natural sunlight, exposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin, dryness, wrinkling, and skin cancer.</u> 3. <u>Wear protective eye wear.</u> <u>FAILURE TO USE PROTECTIVE EYE WEAR MAY RESULT IN SEVERE BURNS OR LONG TERM INJURY TO THE EYES.</u> 4. <u>Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult a physician before using a sunlamp if you are using medications or have a history of skin problems or believe you are especially sensitive to sunlight.</u> 5. <u>If you do not tan in the sun, you are unlikely to tan from use of this device.</u> *****

~~B. A sign shall be posted in conspicuous view at or near the reception area with the following text:~~

PERSONS UNDER AGE 18 ARE REQUIRED TO HAVE PARENT OR LEGAL GUARDIAN SIGN AUTHORIZATION TO TAN IN THE PRESENCE OF A TANNING FACILITY OPERATOR

~~B. The sign shall be clearly visible and unobstructed by any barrier or other item.~~

~~C. The lettering on each warning sign shall be at least 10 millimeters high for all words shown in capital letters and at least 5 millimeters high for all lower case letters.~~

~~C. The sign shall read as follows:-~~

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DANGER – ULTRAVIOLET RADIATION

1. Follow instructions.
2. Avoid overexposure. As with natural sunlight, exposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin, dryness, wrinkling, and skin cancer.
3. Wear protective eye wear.

FAILURE TO USE PROTECTIVE EYE WEAR MAY RESULT IN SEVERE BURNS OR LONG TERM INJURY TO THE EYES.

4. Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult a physician before using a sunlamp if you are using medications or have a history of skin problems or believe you are especially sensitive to sunlight.
5. If you do not tan in the sun, you are unlikely to tan from use of this device.

D. The lettering on each warning sign shall be at least ten millimeters high for all words shown in capital letters and at least five millimeters high for all lower case letters.

R12-1-1416. Reporting of ~~Injuries In~~ Tanning Injuries In Tanning Facilities

- A.** A registrant ~~The licensee~~ shall report an incident involving any eye injury, skin burn, fall injury, if the fall occurs within the tanning device or while entering or exiting the device, laceration, or infection believed to be possibly transmitted by use of the tanning device.
- B.** A registrant shall provide a written report of the incident to the Agency within 10 ~~The report shall be forwarded to the Agency within ten~~ working days of its occurrence or the date the registrant became aware of the incident ~~registrant gained knowledge thereof.~~
- C.** No change
 1. The name of the user; ;
 2. Name and location of the tanning facility; ,
 3. A description of ~~nature of~~ the injury and its causes; ;
 4. The name and address of the health care provider treating the user, if any; ; and
 5. Any other information the ~~licensee~~ registrant may consider relevant to the incident.

R12-1-1417. High Intensity Mercury Vapor Discharge (HID) Lamps Photothermolysis

- A.** Unless otherwise approved by the Agency, each facility using HID lamps shall meet the following requirement:
 1. For indoor facilities, HID lamps shall be:
 - a. Self-extinguishing lamps bearing the letter “T” on the label, or
 - b. Non-self-extinguishing lamps, bearing the letter “R” on the label, provided that the lamp is installed within a totally enclosed protective shield which protects the lamp from damage.
 2. For outdoor facilities, HID lamps shall be:
 - a. Self-extinguishing lamps bearing the letter “T” on the label,
 - b. Non-self-extinguishing lamps, provided that the lamp is installed within a totally enclosed protective shield which protects the lamp from damage, or
 - e. Exempted by the Agency as a result of the licensee providing sufficient information to the Agency to enable the Agency to determine that precautions taken to minimize the exposure to ultraviolet radiation with wavelengths less than 320 nanometers are at least as effective as the requirements of subparagraphs (a) and (b) above.
 - d. Street lighting and security lighting fixtures permanently mounted 18 feet (5.5 meters) or higher above ground level are exempted from the requirements of this paragraph.
- B.** A written report of any injury due to overexposure to ultraviolet light from a HID lamp shall be forward to the Agency by the owner of the facility within ten working days of its occurrence or of the date that the licensee gained knowledge thereof. The report shall include:
 1. The names of all individuals known to have been injured;
 2. The name and location of the facility;
 3. The name and address of the health care providers treating the injuries, if any;
 4. The type of lamp involved (“T” or “R”), lamp model designation and manufacturer;
 5. Any other information the licensee may consider relevant to the incident.
- A.** Intense-pulsed light devices used for photothermolysis shall be a Class II surgical device certified as complying with the design, labeling, and manufacturing standards of the Federal Food and Drug Administration (FDA).

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- B. Intense-pulsed light devices for human use shall only be used by a licensed practitioner, or under the direct supervision of a licensed practitioner.
- C. Intense-pulsed light devices used for photothermolysis shall only be sold to licensed practitioners.
- D. Each registrant shall establish a safety training program that provides a thorough understanding of the medical procedures being performed. The program shall be recorded for Agency review, and as a minimum, address the following:
 - 1. Fundamentals of intense-pulsed light device operation;
 - 2. Bioeffects of intense-pulsed light device radiation on the skin and eye, and contraindications for its use;
 - 3. Non-beam hazards of Intense-pulsed light device operation;
 - 4. The responsibilities of management and employee as they relate to control measures; and
 - 5. Regulatory requirements

R12-1-1418. ~~Reserved~~ High Intensity Mercury Vapor Discharge (HID) Lamps

HID lamps not meeting the requirements in 21 CFR 1040(20), 2001 Edition, published April 1, 2001, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency and the Department and the Office of Secretary of State, shall register the microwave oven with the Agency. This incorporation by reference contains no future editions or amendments.

R12-1-1421. ~~Laser Safety Requirements, Surveys and Records~~

- A. The requirements contained in this rule ~~These requirements, including special requirements for testing, maintenance, and modification,~~ shall apply to laser products in their intended mode of operation only. During manufacture and research and development activities, when some engineering controls may be inappropriate, the LSO shall specify alternate requirements to obtain equivalent laser safety protection.
 - B. A registrant shall establish and maintain a program of laser radiation safety. ~~The licensee shall appoint a laser safety officer and shall establish and maintain an effective program of laser radiation safety.~~
 - C. Each ~~licensee~~ registrant shall ~~conduct~~ make or cause to be made such laser radiation protection surveys as may be necessary to comply with R12-1-1433 ~~prior to initial use, initially prior to routine operation, upon~~ following system modifications, and ~~routinely~~ at intervals not to exceed 6 ~~six~~ months. Surveys shall include ~~but not be limited to:~~
 - 1. A determination that all laser protective devices are labeled correctly and functioning within the design specifications, and are proper for the type and class of lasers in use; -
 - 2. A determination that all warning devices are functioning within their design specifications; -
 - 3. A determination that each laser controlled area is properly identified, access is controlled, and the area is posted with accurate warning signs in accordance with R12-1-1427; -
 - 4. A re-evaluation of potential hazards from surfaces which may be associated with Class 3 ~~III~~ and Class 4 ~~IV~~ beam paths; and -
 - 5. No change
- D. A registrant ~~The licensee~~ shall retain records of:
 - 1. ~~Surveys~~ Results of all physical surveys made to determine compliance with this Article;
 - 2. ~~Operating~~ Records indicating any restriction in operating procedures necessary to prevent unnecessary or excessive exposure to laser or collateral radiation;
 - 3. ~~Incidents~~ Records relating to any incident for which reporting to the Agency is required ~~in pursuant to~~ R12-1-1436;
 - 4. ~~Medical~~ Results of medical surveillance to determine extent of injury resulting from exposure to laser or collateral radiation;
 - 5. No change

R12-1-1422. ~~General Requirements for All Laser Facilities~~

- A. Each laser product shall have a protective housing which prevents ~~human~~ access during operation to laser and collateral radiation that exceeds the limits ~~for Class 1 lasers of Class I and paragraphs A and B of Table X in R12-1-1426, wherever and whenever such human access is not necessary in order for the product to perform its intended function.~~ Accessible ~~Wherever and whenever humans are able to access to laser radiation levels that exceed the limits of Class 1~~ For the accessible emission limits from Title 21, Code of Federal Regulations, Section 1040.10, 1993 Edition, Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Office of Secretary of State, containing no future editions or amendments, these levels shall not exceed the limits of the lowest laser class necessary to perform the intended function.
- B. ~~To prevent access to radiation above MPE limits each laser devise shall have a safety interlock, which prevents operation of the laser when removing~~ A safety interlock, which shall ensure that radiation is not accessible above MPE limits, shall be provided for any portion of the protective housing which, by design, can be removed or displaced without the use of tools during normal operation or maintenance, ~~and thereby allow access to radiation above MPE limits.~~
 - 1. ~~Adjustment during operation, service~~ Service, testing, or maintenance of a laser containing interlocks shall not cause the interlocks to become inoperative or the radiation to exceed MPE limits outside protective housing except where a laser controlled area as specified in R12-1-1433 is established.

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2. No change
 3. For Class ~~3b~~ ~~IIIb~~ and ~~4~~ ~~IV~~ continuous wave (cw) lasers, the interlocks shall turn off the power supply or interrupt the beam.
 4. No change
 5. Multiple safety interlocks or a means to preclude removal or displacement of the interlocked portion of the protective housing shall be provided if ~~if~~ failure of a single interlock ~~could result in; would allow;~~
 - a. Human access to levels of laser radiation in excess of the radiant power accessible emission limit of Class ~~3a~~ ~~IIIa~~ laser radiation, or
 - b. Laser radiation in excess of the accessible emission limit of Class ~~2~~ ~~II~~ ~~to be~~ emitted directly through the opening created by removal or displacement of that portion of the protective housing; ~~then, either multiple safety interlocks or a means to preclude removal or displacement of the interlocked portion of the protective housing upon such failure shall be provided.~~
- C. A laser with ~~an~~ viewing ports, viewing optics, or display screens included as an integral part of an enclosed laser or laser system shall:
1. Incorporate a suitable means to attenuate the laser and collateral radiation transmitted through the port to less than the MPE and the accessible emission limits for collateral radiation ~~from~~ in 21 CFR 1040(10), 2001 Edition, published April 1, 2001, Title 21, Code of Federal Regulations, Section 1040.10, 1993 Edition, Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency and the Office of Secretary of State. This incorporation by reference contains no future editions or amendments; and, under any conditions of operation of the laser.
 - ~~2.~~ Have specific administrative procedures and use controls such as interlocks or filters determined by the LSO if there is increased hazard to the eye or skin associated with the use of ~~The laser safety officer shall determine the potential for increased hazard that the use of~~ optical systems such as lenses, telescopes, and microscopes ~~may cause to the eye or the skin, and specify administrative procedures and the use of controls such as interlocks or filters.~~
- D. Each Class ~~3~~ ~~III~~ or ~~4~~ ~~IV~~ laser product shall provide visual or audible indication during the emission of accessible laser radiation in excess of the limits of Class ~~1~~ ~~I~~.
1. For class ~~3~~ ~~IIIb~~, except those which allow access only to less than 5 milliwatts peak visible laser radiation, and Class ~~4~~ ~~IV~~ lasers, the indication shall be sufficiently prior to emission of such radiation to allow appropriate action to avoid exposure.
 2. No change
 3. No change
 4. No change
 5. Class 3b and Class 4 lasers for human use shall only be used by a licensed practitioner, or under the direct supervision of a licensed practitioner
- E. In addition to the contents of signs, symbols and labels prescribed in R12-1-1427, R12-1-1428, and R12-1-1429, each ~~licensee~~ registrant shall provide near the signs, symbols and labels within the laser facility operating procedure restrictions and any additional information ~~which is necessary to ensure compliance with this Article and~~ minimize exposure to laser and or collateral radiation ~~within a facility.~~
- F. ~~Any restrictions in operating procedures required to ensure compliance with this Article shall be legibly posted at a position clearly visible to the laser operator.~~

R12-1-1423. Laser Prohibitions

- A. ~~An~~ ~~no~~ individual shall not be permitted to look directly into a laser beam, directly at specular reflections of a laser beam, or align a laser by eye while looking along the axis of a beam when the intensity of the such beams or reflections exceed the MPE limits. ~~exceeds the MPE limits in this Article.~~
- B. A registrant ~~The licensee~~ shall not permit an any individual to enter a laser- controlled area if the when skin exposure is in excess of the MPE limits, ~~is likely unless the licensee~~ registrant provides and requires the use of protective clothing, gloves, and shields.
- C. No change

R12-1-1425. Laser Product Classification

- A. Each laser product or installation shall be classified on the basis of ~~that combination of~~ emission level, emission duration, and wavelength of accessible laser radiation emitted over the full range of resulting operational capability ~~which results,~~ any time during the useful life of the such product or installation, according to in accordance with the requirements of the federal performance standards for light-emitting products contained in 21 CFR 1040.10. 21 CFR 1040(10), 2001 Edition, published April 1, 2001, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency and the Office of Secretary of State. This incorporation contains no future editions or amendments.

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- B. The modification of any laser product or installation, which affects any aspect of performance or intended functions of the ~~such~~ product or installations, shall require reclassification and relabeling ~~according to in accordance with 21 CFR 1040.10 21 CFR 1040(10) 2001 Edition, published April 1, 2001, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency and the Office of Secretary of State. This incorporation contains no future editions or amendments.~~
- C. Any laser system that is incorporated into a laser product ~~that is~~ subject to the requirements of this Article and that is capable, without modification, of producing laser radiation when removed from the ~~such~~ laser product, shall ~~itself~~ be considered a laser product, ~~and shall be separately~~ subject to the applicable requirements of this Article for laser products in its class. Upon removal it shall be classified on the basis of accessible laser radiation emission of laser radiation when so removed.

R12-1-1426. Laser and Collateral Radiation Exposure Limits ~~Maximum Permissible Exposure Limits to Laser and Collateral Radiations~~

- A. ~~A registrant No licensee shall not use, or permit the use of a any laser product products or installation which allows human exposure in excess of the MPE limits. Included are the intrabeam MPE limits for the eye, MPE to the eye for extended source viewing, and the MPE limits for skin exposure. The MPE limits are in ANSI Z136.1-2000 1993, American National Standard for Safe Use of Lasers, 2000 1993 Edition, Published by the Laser Institute of America, Incorporated herein by reference and on file with the Office of Secretary of State, and accessible emission limits in 21 CFR 1040(10), Title 21, 2001 Edition, published April 1, 2001, Code of Federal Regulations, Section 1040.10, 1993 Edition, Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency and the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.~~
- ~~B. Maximum permissible exposure limits to the eye for intrabeam viewing shall not exceed those shown in ANSI Z136.1-1993, American National Standard for Safe Use of Lasers, 1993 Edition, Published by the Laser Institute of America, Incorporated by reference and on file with the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.~~
- ~~C. Maximum permissible exposure to the eye for extended source viewing shall not exceed the limits shown in ANSI Z136.1-2000, American National Standard for Safe Use of Lasers, 2000 Edition, Published by the Laser Institute of America, Incorporated by reference and on file with the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.~~
- ~~D. Skin exposure to laser radiation shall not exceed the MPE limits shown in ANSI Z136.1-1993, American National Standard for Safe Use of Lasers, 1993 Edition, Published by the Laser Institute of America, Incorporated by reference and on file with the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.~~
- ~~B.E. Exposure to collateral radiation shall not exceed the accessible emission limits in 21 CFR 1040(10), 2001 Edition, published April 1, 2001, Title 21, Code of Federal Regulations, Section 1040.10, 1993 Edition, Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency and the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.~~

R12-1-1427. Requirements for Laser Caution Signs, Symbols and Labels

- A. Except as otherwise authorized by the Agency, signs, symbols and labels prescribed by this Section shall use the design and colors specified in ANSI Z136.1- ~~2000 1993~~, American National Standard for Safe Use of Lasers, ~~2000 1993~~ Edition, Published by the Laser Institute of America, Incorporated herein by reference and on file with the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.
- B. No change
- C. No change
- D. All labels placed on lasers or signs posted in ~~to~~ laser facilities shall be positioned so that the reader of the label or sign is not exposed to laser or collateral radiation in excess of the MPE and AEL limits while reading the label or sign, as to make unnecessary, during reading, human exposure to laser or collateral radiation in excess of the MPE and AEL.
- E. No change
- F. Each laser shall have a label permanently and legibly affixed which identifies the classification of the laser according to 21 CFR 1040(10), 2001 Edition, published April 1, 2001 ; in accordance with the requirements in Title 21, Code of Federal Regulations, Part 1040, 1993 Edition, Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency and the Office of Secretary of State, This incorporation contains , containing no future editions or amendments, , the classification of the laser.
- G. At position 2 on the warning logotype affixed to a Class 3 and Class 4 Each Class III and IV laser shall state, at position 2 on the required warning logotype, the maximum output of laser radiation, the pulse duration when appropriate, and the laser medium or emitted wavelength.

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- H. Class ~~3~~ **III** and ~~4~~ **IV** lasers, except lasers used in the practice of medicine, shall have a label containing the following wording near each aperture that emits laser radiation or collateral radiation in excess of the MPE limits: in close proximity to each aperture through which is emitted accessible laser or collateral radiation in excess of the MPE limits specified in R12-1-1426, with the following wording as applicable:
1. No change
 2. No change
 3. No change
- I. Each non-interlocked or defeat able ~~defeatably~~ interlocked portion of the protective housing or enclosure which permits human access to laser or collateral radiation which is designed to be displaced or removed during normal operation, maintenance, or servicing, and which thereby would permit human access to laser or collateral radiation, shall have a label containing the following wording be labeled as follows:
1. For laser radiation in excess of the accessible emission limits of Class ~~1~~ **I** or Class ~~2~~ **II** as applicable, but not in excess of the accessible emission limits of Class ~~3~~ **III**, the wording: "DANGER - Laser radiation when open, AVOID DIRECT EXPOSURE TO THE BEAM."
 2. For laser radiation in excess of the accessible emission limits of Class ~~3~~ **III**, the wording: "DANGER - laser radiation when open, AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION."
 3. No change
 - a. No change
 - b. No change
 4. For protective housing or enclosures which have ~~provide~~ a defeat able interlock, the words "and interlock defeated" shall be included in the labels specified above.

R12-1-1429. Posting of Laser Facilities

Each laser facility ~~Facilities~~ shall be posted in accordance a manner consistent with ANSI Z136.1-2000 ~~1993~~, American National Standard for Safe Use of Lasers, 2000 ~~1993~~ Edition, Published by the Laser Institute of America, Incorporated ~~herein~~ by reference and on file with the Agency and the Office of Secretary of State. This incorporation by reference contains, ~~containing~~ no future editions or amendments, or as otherwise approved in writing by the Agency.

R12-1-1433. Laser-controlled Areas

- ~~A. With a Class IIIb or class IV laser, except those class IIIb lasers which allow access only to less than five milliwatts visible peak power, a laser-controlled area shall be established when exposure to the laser radiation in excess of the MPE or AEL in R12-1-1426 is possible. The controlled area associated with a Class IIIb laser shall meet the requirements of subsection B through D for Class IIIb lasers and the requirements of subsection B through H for Class IV lasers.~~
- ~~B. The area shall be the responsibility of the laser safety officer.~~
- ~~C. The area shall be posted as required by R12-1-1427.~~
- ~~D. Access to the laser-controlled area shall be only by permission of the laser safety officer or a trained, designated representative.~~
- ~~E. For Class IV indoor controlled areas, latches, interlocks, or other appropriate means shall be used to prevent unexpected entry into laser-controlled areas.~~
- ~~1. Such measures shall be designed to allow both rapid egress by the laser personnel at all times and admittance to the laser-controlled area in an emergency condition.~~
 - ~~2. For emergency conditions, a control-disconnect switch, panic button, or equivalent shall be available for deactivating the laser.~~
- ~~F. For Class IV indoor controlled areas, during tests requiring continuous operation, the individual in charge of the controlled area shall be permitted to momentarily override the safety interlocks to allow access to other authorized personnel if it is clearly evident that there is no optical radiation hazard at the point of entry and if the necessary protective s are being worn by the entering personnel.~~
- ~~G. For Class IV indoor controlled areas, optical paths such as windows from an indoor facility shall be controlled in such a manner as to reduce the transmitted values of the laser radiation to levels at or below appropriate ocular MPE and AEL in R12-1-1426. When the laser beam must exit the indoor controlled area (as in the case of exterior atmospheric beam paths), the operator shall be responsible for ensuring that the beam path is limited to controlled air space or controlled ground space when the beam irradiance or radiant exposure is above the appropriate MPE and AEL.~~
- ~~H. In cases where removal of panels or protective covers or overriding of interlocks becomes necessary, such as for service, testing, or maintenance and accessible laser, controlled areas shall be established. The laser safety office or a designated representative shall ensure that the necessary laser safety requirements for all potentially exposed individuals shall be established.~~
- A. A laser-controlled area shall be established when it is possible for a person to be exposed to laser radiation from a Class 3b, not to include 3b lasers of less than 5 milliwatts visible peak power, or the radiation from a Class 4 laser in excess of the MPE or AEL in R12-1-1426.

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- B.** A controlled area associated with the Class 3b laser described in subsection (A) shall:
1. Be the responsibility of a LSO;
 2. Be posted in accordance with R12-1-1427; and
 3. Be access controlled by a LSO or a trained, designated representative.
- C.** A controlled area associated with a Class 4 laser shall:
1. Be the responsibility of a LSO;
 2. Be posted in accordance with R12-1-1427;
 3. Be access controlled by a LSO or a trained, designated representative; and
 4. Indoor controlled areas shall:
 - a. Have latches, interlocks, or other appropriate means to prevent unexpected entry into the laser-controlled areas;
 - b. Have a control-disconnect switch, panic button, or equivalent available for deactivating the laser during an emergency;
 - c. Be operated in such a manner that the person in charge of the controlled area can momentarily override the safety interlocks during tests requiring continuous operation to allow access to other personnel if there is no optical radiation hazard at the point of entry and if the entering personnel are wearing the necessary protective devices; and
 - d. Be controlled in such a manner as to reduce the transmitted values of the laser radiation through optical paths such as windows, to levels at or below appropriate ocular MPE and AEL in R12-1-1426. When the laser beam must exit the indoor controlled area (as in the case of exterior atmospheric beam paths), the operator shall be responsible for ensuring that the beam path is limited to controlled air space or controlled ground space when the beam irradiance or radiant exposure is above the appropriate MPE and AEL.
 5. When panels or protective covers are removed or interlocks bypassed for service, testing, or maintenance, accessible laser-controlled areas shall be established. The LSO or a designated representative shall ensure that the necessary laser safety requirements for all potentially exposed individuals are established.

R12-1-1434. Laser Safety Officer Duties

- A.** Each registrant shall appoint a (LSO).
- B.** The Laser Safety officer shall administer the laser radiation protection program and shall:
1. Assure that maintenance and service for Class 3b ~~IIIb~~ and Class 4 ~~IV~~ lasers ~~is shall be~~ performed only by technicians trained to provide the such service by either the manufacturer's service organization or the institution's staff;
 2. Approve written service and maintenance, and operating procedures;
 3. Investigate, document, and report all incidents and accidents as required by R12-1-1436;
 4. No change
 5. No change
 6. No change
 7. No change
 8. No change
 9. Classify or verify the classification of lasers laser and laser systems used under the LSO's jurisdiction;
 10. No change

R12-1-1435. Laser Protective Eye Wear for Use in Laser Facilities

- A.** Protective eye wear, as specified by the LSO laser safety officer, shall be worn:
1. By all individuals having with access to Class 4 Class IV levels of laser radiation.
 2. By all individuals having access to Class 3b laser radiation, and as designated by the LSO. When required by the laser safety officer, by all individuals with access to Class IIIb levels of laser radiation.
- B.** No change
1. Be a label indicating the optical density for the wavelength ~~Be legibly and permanently labeled indicating the optical density at the wavelengths~~ for which each such affords adequate protection;
 2. Be maintained so that in proper condition to assure the protective properties of the protective eye wear are retained;
 3. Be inspected at intervals not to exceed 6 six months to ensure integrity of the protective properties;
 4. Be removed from service when it has been determined that the same level of protective properties is no longer provided to the wearer, should the be determined to be in a condition resulting in decreased protection.
- C.** Records of protective eye wear maintenance, inspections and removal from service shall be retained for 3 five years.

R12-1-1436. Reporting of Laser Incidents

- A.** The licensee shall be responsible for the reporting to the Agency any incident involving known or suspected exposure to laser or collateral radiation, from a source possessed by the licensee, in excess of the MPE limits in R12-1-1426, Tables VII through X.
- A.B.** A registrant shall notify the Agency by telephone ~~The Agency shall be notified within 24 hours by telephone~~ of any incident which has caused or may have caused:

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1. No change
2. No change

B.C. ~~A registrant~~ Each licensee shall notify the Agency by telephone within 5 ~~five~~ working days of any incident which has or may have caused:

1. Second-degree burns of the skin larger than 1 ~~one~~ inch (2.54 centimeter) in greatest diameter; or
2. No change
3. No change

C.D. ~~A registrant~~ Each licensee shall file a written report of a known exposure of an individual to laser radiation or collateral radiation with the Agency ~~make a report in writing~~ within 30 days of its discovery, describing: ~~to the Agency of:~~

1. No change
2. Any incident of which notification is required by subsection (A) or (B) ~~(B) or (C)~~.

D.E. ~~Each report required by subsection (C) (D)~~ shall describe the extent of exposure to each individual, of individuals to laser or collateral radiation, including:

1. An estimate of the ~~Estimates of each~~ individual's exposure;
2. The level ~~Levels~~ of laser or collateral radiation involved;
3. No change
4. The corrective ~~Corrective~~ steps taken or planned to be taken to assure against a recurrence.

E.F. ~~A registrant~~ The licensee shall not operate, nor permit the operation of, any laser product or system which does not meet all of the applicable requirements of this Article.

R12-1-1437. Additional Requirements for Special Lasers and Applications

~~A registrant operating a laser system with an~~ Installations operating laser systems with unenclosed beam path shall:

1. Conduct an evaluation before operating the laser to determine ~~of the expected beam path and the potential hazards from incidental reflective surfaces which may be encountered before operating the laser.~~ Incidental reflective surfaces shall be excluded from the beam path at all points where the laser radiation exceeds MPE limits.
2. Evaluate the ~~The~~ stability of the laser platform shall be evaluated ~~to determine the constraints that shall be placed upon the beam traverse and the extent of the range of control.~~
3. Not operate or make ready for operation a laser ~~No laser shall be operated or made ready for operation until the area along all points of the beam path where the laser radiation will exceed the MPE is clear of individuals, unless the individuals are wearing appropriate protective devices.~~

R12-1-1439. Medical Lasers Additional Requirements for Medical Laser Applications

A. A Class 3 and Class 4 ~~Each Class III and Class IV~~ medical laser product shall incorporate a ~~the~~ means for measurement of the level of laser radiation intended for human irradiation, with an error in measurement of no greater than + 20%, when calibrated in accordance with the laser product manufacturer's calibration procedure.

B. A Medical laser ~~lasers used for human irradiation~~ shall be calibrated according to ~~in accordance with~~ the manufacturer's specified calibration procedure, at intervals not to exceed those specified by the manufacturer.

C. ~~The licensee shall ensure that a~~ medical lasers shall not be used for human irradiation unless all applicable requirements of this Article are met.

C.D. ~~In a medical facility using multiple medical disciplines~~ institutions where a number of different practitioners may use Class 3b ~~IIIb~~ and Class 4 ~~IV~~ lasers, a Laser Safety Committee ~~laser safety committee~~ shall be formed to govern laser activity, establish use criteria, and approve operating procedures.

1. Membership on the committee shall include at least a representative of the Nursing staff, the LSO ~~Laser Safety Officer~~, a representative of institution management, and a representative of each medical discipline that utilizes the lasers.
2. The committee shall review actions by the LSO ~~Laser Safety Officer~~ in hazard evaluation, and the monitoring and control of laser hazards.
3. Users, and ~~those~~ ancillary personnel who may operate or assist in the operation of the lasers under the direction of the users, shall be approved by the committee.

D.E. ~~A Class 3b and Class 4 Laser shall have a~~ For class IIIb and IV lasers, the switch with a guard mechanism to prevent inadvertent exposure which controls patient exposure ~~shall have a guard mechanism to prevent inadvertent exposure.~~

E. Each registrant shall establish a laser safety training program that provides a thorough understanding of established procedures for the type of laser in use and the medical procedures being performed. The program shall be recorded for Agency review, and as a minimum, address the following:

1. Regulatory requirements and the laser classification system;
2. Fundamentals of laser operation and the significance of specular and diffuse reflections;
3. Bioeffects of laser radiation on the eye and skin;
4. Non-beam hazards of lasers (electrical, chemical, reaction by-products, etc.) and ionizing radiation hazards (x-rays from power sources and target interactions when applicable; and

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5. The responsibilities of management and employee as they relate to control measures.

R12-1-1440. Laser Light Shows and Demonstrations

- A.** ~~Prior to the performance of a laser light show or laser demonstration, a registrant~~ the licensee shall provide to the Agency, documentation that a variance has been obtained in accordance with 21 CFR 1040(10), 2001 Edition, published April 1, 2001, Title 21, Code of Federal Regulations, Section 1040.10, 1993 Edition, Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency and with the Office of Secretary of State, to conduct the show. This incorporation by reference contains no future editions or amendments.
- B.** Class IIIa laser lighting and entertainment products used for commercial purposes shall licensed as laser lights and meet the requirements of subsections (C) through (S).
- ~~**B.C.**A registrant~~ The licensee shall notify the Agency in writing, at least 3 working two days in advance of the proposed laser light show or laser demonstration, and shall include the following information:
1. The location, time, and date of the light show;
 2. No change
 3. Scanning beam patterns, scan velocity, and frequency in occupied areas; and
 4. Physical surveys and calculations made to ensure compliance with this Article.
- ~~**C.D.**A registrant~~ The licensee shall also supply such additional information as may be required by the Agency for the evaluation of the safety of the proposed activity performance.
- ~~**D.E.**Prior to the performance of an outdoor laser light show, a registrant~~ the licensee shall notify the Federal Aviation Administration of the proposed show.
- ~~**E.F.**Laser radiation emissions outside the spectral range 400 to 700 nanometers shall not exceed Class 1 F~~ accessible emission limits.
- ~~**F.G.**Levels of laser and collateral radiation, where the audience is located, and where operators, performers, and employees are located if the radiation is intended to be viewed by them, shall not exceed Class 1 F~~ accessible emission limits.
- ~~**G.H.**All persons, including operators, performers, and employees, in the vicinity of the laser light show or laser demonstration shall not be~~ Operators, performers and employees shall be able to perform their functions without being exposed to laser or collateral radiation exceeding Class 2 H accessible emission limits when the radiation is not intended to be viewed by them.
- ~~**H.I.**Areas where levels of laser radiation exceed the Class 2 H~~ accessible emission limit shall be identified by posting of warning signs and through use of barriers or guards to prevent individuals from entering these areas.
- ~~**I.J.** Scanning devices shall not, as a result of scan failure or any other failure causing a change in either angular velocity or amplitude, permit audience exposure to laser radiation in excess of the accessible emission limits for a Class 1 F~~ laser product.
- ~~**J.K.**No change~~
- ~~**K.L.**At all times a laser light show or laser demonstration shall be~~ Laser light shows shall be at all times under the direct and personal supervision of the laser operator except in cases where the maximum laser power output level is less than 5 milliwatts (all spectral lines), and the laser beam path is located at all times at least 6 six meters above any surface upon which an individual in the audience is permitted to stand, and at any point less than 2.5 meters in lateral separation from any position where an individual in the audience is permitted during the performance.
- ~~**L.M.**Laser radiation levels shall not exceed the accessible emission limits for Class II laser products at any point less than 3~~ three meters above any surface upon which any individual in the audience is permitted to stand and 2.5 meters in lateral separation from any position where an individual in the audience is permitted, unless physical barriers are present which prevent human access to the radiation such levels.
- ~~**M.N.**No change~~
- ~~**N.O.**When laser output power must be limited to less than available power in order to satisfy the requirements of this Article, the laser output power shall be adjusted, measured, and recorded prior to the performance of the laser light show~~ laser demonstration.
- ~~**O.P.**All safety devices and procedures necessary to comply with this Article shall be functionally tested and evaluated after setup, and prior to the performance of~~ to a laser light show or laser demonstration, to ensure compliance.
- ~~**P.Q.**No change~~
- ~~**Q.R.**Laser alignment procedures shall be performed with the laser output power reduced to the lowest practicable level, and protective eye wear shall be worn where necessary to prevent exposure to radiation levels exceeding MPE. Only persons required to perform the alignment shall be present during~~ the alignment such procedures.
- ~~**R.S.**A registrant~~ The licensee shall ensure that no laser light show or laser demonstration is conducted except as specifically authorized in the variance authorized in 21 CFR 1040(10), 2001 Edition, published April 1, 2001, issued in accordance Title 21, Code of Federal Regulations, Section 1040.10, 1993 Edition, Published April 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency and

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with the Office of Secretary of State, and that all applicable requirements of this Article. This incorporation by reference contains co future editions or amendments.

R12-1-1441. Measurements and Calculations to Determine MPE Limits for Lasers

A registrant shall make measurements ~~Measurements~~ to determine MPE limits ~~shall be made~~ in a manner consistent with the procedures contained in ANSI Z136.1-2000 ~~1993~~, American National Standard for Safe Use of Lasers, 2000 Edition, published 1993 Edition, ~~Published~~ by the Laser Institute of America, Incorporated ~~herein~~ by reference and on file with the Agency and with the Office of Secretary of State, or as otherwise approved by the Agency. This incorporation by reference contains co future editions or amendments

R12-1-1443. Laser Compliance Measurement Instruments

A registrant shall ensure the Each radiation output measurement ~~determination requiring a measurement for compliance with this Article shall is performed with an instrument that use instrumentation which~~ is calibrated and designed for use with the laser that is being evaluated for compliance ~~to be tested~~. The date of calibration, accuracy of calibration, wavelength range, and power or energy of calibration shall be specified on a legible, clearly visible label attached to the instrument.

R12-1-1444. Laser Classification Measurements

A. Measurement of accessible emission for classification shall be made:

1. Under ~~the those~~ operational conditions and procedures which maximize the accessible emission levels including start-up stabilized operation, and shutdown of the laser or facility;
2. No change
3. No change
4. ~~With the~~ The measuring instrument detector ~~so~~ positioned in a manner that the maximum possible radiation is measured by and so oriented with respect to the laser as to result in the maximum detection of radiation by the instrument; and
5. With ~~For a laser other than a laser system, with the laser coupled to the that~~ type of laser energy source specified as compatible by the laser fabricator and which produces the maximum emission of accessible laser radiation from it that laser.

B.6. Accessible emission levels used to classify for classification of laser and collateral radiation shall be based upon measurements performed according to 21 CFR 1040(10), 2001 Edition, published April 1, 2001, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Agency and with the Office of Secretary of State. This incorporation by reference contains co future editions or amendments ~~the following measurements:~~

- a. ~~For laser products intended to be used in a locale where the emitted laser radiation is unlikely to be viewed with optical instruments, the radiant power in watts or radiant energy in joules detectable through a circular aperture stop having a diameter of 7 millimeters, except for scanned laser radiation, and within a circular solid angle of acceptance of one milliradian with collimating optics of 5 diopters or less.~~
- b. ~~The irradiance in watts per square centimeter or radiant exposure in joules per square centimeter equivalent to the radiant power or radiant energy detectable through a circular aperture stop having a diameter of 7 millimeters and, for irradiance, within a circular solid angle of acceptance of one milliradian with collimating optic of 5 diopters or less, divided by the area of the aperture stop in square centimeters.~~
- c. ~~The radiance in watts per square centimeter per steradian or integrated radiance in joules per square centimeter per steradian equivalent to the radiant power or radiant energy detectable through a circular aperture stop having a diameter of 7 millimeters with a circular solid angle of acceptance of 10 microsteradian with collimating optics of 5 diopters or less, divided by that solid angle and by the area of the aperture stop in square centimeters.~~
- d. ~~Accessible emission levels of scanned laser radiation shall be based upon the measurement of radiation detectable through a stationary circular aperture stop having a seven millimeter diameter and within the circular solid angle of acceptance with collimating optics applicable under subparagraphs (a), (b) and (c). The direction of the solid angle of acceptance shall change as needed to maximize detectable radiation, with an angular speed of up to five radians per second. A 50 millimeter diameter aperture stop with the same collimating optics and acceptance angle will be used for all other laser products.~~

Appendix A. Radiofrequency Radio Frequency Devices

~~RADIOFREQUENCY DEVICES INCLUDE BUT ARE NOT LIMITED TO:~~

~~DIELECTRIC HEATERS AND SEALERS
INDUSTRIAL MICROWAVE OVENS AND DRYERS
MEDICAL DIATHERMY UNITS
ASHER – ETCHER MACHINES~~

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RADAR
RADIO AND TELEVISION TRANSMITTERS
R.F. ACTIVATED ALARM SYSTEMS
MICROWAVE RELAY LINKS
SPUTTER MACHINES
R.F. WELDING EQUIPMENT
R.F. ACTIVATED LASERS
MEDICAL SURGICAL COAGULATORS
EDGE GLUERS

Radio Frequency Devices include but are not limited to the following:

Medical diathermy units
Dielectric heaters and sealers
Radar
R.F. activated alarm systems
Sputter devices
R.F. activated lasers
Edge gluers
Industrial microwave ovens and dryers
Asher-etcher equipment
R.F. welding equipment
Medical surgical coagulators

Appendix B. ~~Repealed~~ Application Information

A registration will be issued if an application contains the following information as required in R12-1-1401(B)(3). The Agency shall provide an application form to an applicant with a guide, if available, or shall assist the applicant to ensure only correct information is provided in the application.

Name and mailing address of applicant
Person responsible for radiation safety program
Type of facility
Legal structure and ownership
Radiation source information
Shielding information
Equipment operator instructions and restrictions
Classification of professional in charge
Type of request: amendment, new, or renewal
Protection survey results, if applicable
Radiation Safety Officer name, if applicable
Laser class and type, if applicable
Other licensing requirements in Article 14
Use location
Telephone number
Facility subtype
Signature of certifying agent
Equipment identifiers
Scale drawing
Physicist name and training, if applicable
Contact person
Appropriate fee listed in Article 13 schedule

**ARTICLE 17. ~~RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE~~
OPERATIONS AND SUBSURFACE TRACER STUDIES**

R12-1-1702. Required Written Agreement

- A. ~~Prior to beginning operation of a wireline service a~~ No licensee shall have made a written agreement with the well operator, well owner, drilling contractor, or land owner. As a minimum the agreement shall contain the following elements: perform wireline service operations with a sealed source unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor, or land owner that:
1. In the event a sealed source is lodged downhole:
 - a. A reasonable effort at recovery will be made; and
 - b. Indicate who is responsible for making the recovery; In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made; and
 2. An attempt at source recovery will not occur, if in the opinion of the licensee, the recovery effort could rupture the source; No person will be permitted to attempt recovery of the source in any manner which, in the opinion of the licensee, could rupture the source; and
 3. Equipment and personnel will be decontaminated prior to release from the job site, if contaminated with radioactive material from a leaking source; and the job site will be decontaminated before it will be released for unrestricted use; and If the job site, equipment or personnel are contaminated with radioactive material, such equipment or personnel must be decontaminated before release from the site, and the job site must be decontaminated before release for unrestricted use; and
 4. If it is decided to In the event a decision is made to abandon the sealed source downhole, the requirements of R12-1-1751(C) and the appropriate of the rules of the Oil and Gas Conservation Commission or the Department of Water Resources will, as appropriate, shall be met.
- B. A copy of the agreement ~~shall~~ must be maintained at the field station during logging operations. The licensee shall retain a copy of the written agreement for 3 ~~three~~ years after completion of the well logging operation.

R12-1-1703. Limits on Levels of Radiation

Sources of radiation shall be ~~used, stored and transported~~ according to in such a manner that the transportation requirements of Article 15, and used or stored in such a manner that the dose limits in Article 4 of this Chapter are not exceeded. ~~limitation requirements of Article 4 of this Chapter are met.~~

R12-1-1712. Storage Precautions

- A. Each source of radiation, ~~except accelerators,~~ shall be provided with a storage container, or transport container, or both combination thereof. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of the source and exposure to radiation of, or exposure to, the source of radiation.
- B. No change

R12-1-1714. Radiation Survey Instruments

- A. The licensee shall maintain at each field station and temporary job site keep a calibrated and operable radiation survey instrument capable of detecting beta and gamma radiation at each field station and temporary job site to make the radiation surveys as required by this Article and by Article 4 of this Chapter. The
1. ~~To satisfy this requirement, the radiation survey instrument shall be capable of measuring 1.0 microsievert (0.1 millirem) per hour through 500 microsievert (50 millirem) per hour.~~
 2. ~~Survey instruments acquired before the effective date of this rule and capable of measuring 1.0 microsievert through at least 200 microsieverts (20 millirem) per hour may be used to satisfy this requirement until July 14, 1992.~~
- B. No change
- C. No change
1. At intervals not to exceed 6 ~~six~~ months and after each instrument servicing;
 2. No change
 3. For linear scale instruments, at two points located approximately 1/3 and 2/3 of full-scale on each scale or for logarithmic scale instruments, at mid-range of each decade, and at two points of at least 1 ~~one~~ decade;
 4. No change
- D. Calibration records shall be retained for a period of 3 ~~three~~ years from the date of calibration.

R12-1-1715. Leak Testing of Sealed Sources

Each sealed source containing radioactive material shall be tested for leakage according to in accordance with the provisions of R12-1-417. Records of the leak tests shall be retained for a period of 3 ~~three~~ years from the date of the test, and a copy shall accompany the source to Job sites.

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R12-1-1716. Inventory

Each licensee ~~or registrant~~ shall conduct an inventory every ~~6 six~~ months to account for all sources of radiation. Records of inventories shall be retained for ~~3 three~~ years from the date of the inventory and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the inventory.

R12-1-1717. Utilization Records

Each licensee shall maintain ~~current~~ records of use, which shall be retained for ~~3 three~~ years from the date of the recorded event, ~~containing showing~~ the following information for each source of radiation:

1. No change
2. No change
3. No change
4. No change

R12-1-1718. Design, Performance and Certification Criteria for Sealed Sources Used in Downhole Operations

- A. No change
1. No change
 2. No change
 3. No change
- B. No change
1. The prototype source shall be held at a temperature of -40 degrees Celsius (C) for 20 minutes, then at 600 degrees C for ~~1 one~~ hour, and then be subjected to a thermal shock by dropping the temperature from 600 degrees C to 20 degrees C within 15 seconds.
 2. A five kilogram steel hammer, 2.5 centimeters in diameter, shall be dropped from a height of ~~1 one~~ meter onto the prototype source as a test of impact resistance.
 3. The prototype source shall be subjected to vibration at a frequency of from 25 Hz to 500 Hz and at an amplitude of ~~49 m/sec² (5g) five g~~ for 30 minutes.
 4. A ~~1 one~~ gram hammer with a 0.3 centimeter diameter pin attached shall be dropped from a height of ~~1 one~~ meter such that the end of the pin strikes the prototype source.
- C. Certification documents shall be retained for a period of ~~3 three~~ years after source disposal. If the source is abandoned downhole, the certification documents shall be retained ~~indefinitely permanently~~.

R12-1-1719. Labeling

- A. Each source, source holder, or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, ~~containing as a minimum which has, as a minimum~~, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

DANGER (or: CAUTION)
RADIOACTIVE

This labeling shall be on the smallest component transported as a separate piece of equipment.

- B. Each transport container shall have a visible permanently attached durable label ~~to it a durable, legible, and clearly visible label which has,~~ as a minimum, contains the standard radiation caution symbol and the following wording:

DANGER (or: CAUTION)
RADIOACTIVE
NOTIFY CIVIL AUTHORITIES (or name of company)

R12-1-1720. Inspection and Maintenance

- A. ~~At intervals not to exceed 6 months, each~~ Each licensee shall conduct, ~~at intervals not to exceed six months,~~ a program of inspection and maintenance of holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper labeling and physical condition. Records of inspection and maintenance shall be retained for a period of ~~3 three~~ years.
- B. If ~~an any~~ inspection conducted ~~according to subsection (A) pursuant to R12-1-1720(A)~~ reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.
- C. ~~Repair~~ ~~The repair~~, opening, or modification of ~~a any~~ sealed source containing radioactive material shall be performed only by persons specifically authorized to do so by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

R12-1-1721. Training Requirements

- A. ~~A licensee shall not permit an~~ ~~No licensee shall permit any~~ individual to act as a logging supervisor until the individual has attended an Agency approved course and demonstrated an understanding of the course materials, as defined in Article 4 until such individual has:

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- ~~1.~~ Received, in a course A course of study shall be deemed acceptable if recognized by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. As a minimum the course shall contain the subjects listed in subsection (B), instruction in the following subjects and demonstrated an understanding
- B.** The course shall include the following subjects: ~~thereof:~~
- ~~1.a.~~ Fundamentals of radiation safety
 - ~~a.i.~~ Characteristics of radiation
 - ~~b.ii.~~ Units of radiation dose and quantity of radioactivity
 - ~~c.iii.~~ Significance of radiation dose
 - ~~i.(1)~~ Radiation protection standards
 - ~~ii.(2)~~ Biological effects of radiation dose
 - ~~d.iv.~~ Levels of radiation from sources of radiation
 - ~~e.v.~~ Methods of minimizing radiation dose
 - ~~i.(1)~~ Working time
 - ~~ii.(2)~~ Working distances
 - ~~iii.(3)~~ Shielding
 - ~~2.b.~~ Radiation detection instrumentation to be used
 - ~~a.i.~~ Use of radiation survey instruments
 - ~~i.(1)~~ Operation
 - ~~ii.(2)~~ Calibration
 - ~~iii.(3)~~ Limitations
 - ~~b.ii.~~ Survey techniques
 - ~~c.iii.~~ Use of personnel monitoring equipment
 - ~~3.e.~~ Equipment to be used
 - ~~a.i.~~ Handling equipment
 - ~~b.ii.~~ Sources of radiation
 - ~~c.iii.~~ Storage and control of equipment
 - ~~d.iv.~~ Operation and control of equipment
 - ~~4.f.~~ The requirements of pertinent federal and state regulations
 - ~~5.e.~~ The licensee's written operating and emergency procedures
 - ~~6.f.~~ The licensee's recordkeeping procedures
- ~~C.2.~~ In addition to requiring each logging supervisor candidate to attend an Agency approved course, a licensee shall require each candidate to:
- ~~1.~~ Read and receive ~~Read and received~~ instruction in the rules contained in this Article and the applicable Sections of Articles 1, 4, 10 and 15 of this Chapter or their equivalent, conditions of appropriate license ~~or certificate of registration~~, and the licensee's operating and emergency procedures, and demonstrated an understanding of the rules, license conditions, and procedures thereof; and
 - ~~2.3.~~ Demonstrate ~~Demonstrated~~ competence to use sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.
- ~~D.B.A.~~ No licensee shall not permit an ~~any~~ individual to assist in the handling of sources of radiation until the ~~such~~ individual has:
- 1. Read or received instruction in the licensee's operating and emergency procedures and demonstrated an understanding of the procedures thereof; and
 - 2. No change
- ~~E.C.~~ The licensee shall retain employee training records for 3 ~~three~~ years following termination of employment.
- R12-1-1722. Operating and Emergency Procedures**
- Each licensee shall develop ~~The licensee's~~ operating and emergency procedures that shall include instructions in at least the following:
- 1. Procedures used to ensure that no individual is likely to be exposed to radiation in excess of the limits in Article 4 of this Chapter. Including:
 - a. The use of sealed sources in wells without surface casing for protecting fresh water aquifers, if appropriate; and
 - b. Methods employed to minimize exposure from inhalation and ingestion of licensed tracer materials;
 - c. Methods for minimizing exposure of individuals in the event of an accident; Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in Article 4 of this Chapter;
 - 2. The use of remote handling tools for manipulating radioactive sealed sources and tracers
 - ~~3.2.~~ Methods and occasions for conducting radiation surveys;
 - ~~4.3.~~ Methods and occasions for locking and securing sources of radiation;
 - ~~5.4.~~ Personnel monitoring and the use of personnel monitoring equipment;

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- ~~6.5.~~ Transportation to temporary job sites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles, and securing sources of radiation during transportation;
6. ~~Minimizing exposure of individuals in the event of an accident;~~
7. Procedure for notifying proper ~~persons~~ personnel in the event of an accident;
8. No change
9. No change
10. Procedure to be followed in the event a sealed source is:
 - a. Lost or lodged downhole; or
 - b. Ruptured, to include safeguards to prevent job site and personnel contamination, and inhalation; ingestion lost or lodged downhole;
11. No change
12. No change

R12-1-1723. Personnel Monitoring

- A. No change
- B. No change
- C. Personnel monitoring records shall be maintained according to ~~in accordance with~~ R12-1-419(C).

R12-1-1731. Security

During each logging procedure or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized or unnecessary entry into a restricted area, ~~as defined in Article 4 of this Chapter.~~

R12-1-1733. Subsurface Tracer Studies

- A. No change
- B. ~~A No licensee shall not inject~~ cause the injection of radioactive material into potable aquifers without prior written authorization from the Agency.
- C. A licensee shall dispose of tracer study waste contaminated with radioactive material in accordance with R12-1-434.

R12-1-1734. Use of a Sealed Source in a Well Without a Surface Casing and Particle accelerators

- A. A licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers provided the licensee follows a procedure for reducing the probability of the source becoming lodged in the well.
- B. A licensee may not begin well logging operations in a well without a surface casing until the Agency has approved the licensee's procedures for logging in an uncased hole.
- C. No licensee or registrant shall permit above-ground testing of particle accelerators, designed for use in well-logging, which results in the production of radiation, except in areas or facilities controlled or shielded so that the requirements of Article 4 of this Chapter, as applicable, are met.

R12-1-1741. Radiation Surveys

- A. No change
- B. No change
- C. After removal of the sealed source from the logging tool and before departing the job site, the logging tool detector shall be energized, or a survey meter used, to assure that the logging tool is free of contamination. The test for contamination shall be recorded.
- D. No change
- E. Records of surveys conducted according to subsections ~~required pursuant to R12-1-1741(A) through (D)~~ shall include the dates, the identification of individuals making the survey, the identification of survey instruments used, radiation measurements in millirem or microsievert per hour and an exact description of the location of the survey. Records of these surveys shall be retained for 3 ~~three~~ years after completion of the survey.

R12-1-1742. Documents and Records Required at Field Stations

Each licensee utilizing a field station shall have the following documents and records available for the specific devices and sources used at the field station:

1. Appropriate license, ~~certificate of registration,~~ or equivalent document;
2. No change
3. Applicable rules ~~regulations~~;
4. Records of the latest survey instrument calibrations required in pursuant to R12-1-1714;
5. Records of the latest leak tests performed according to test results pursuant to R12-1-1715;
6. Inventories of sealed sources required in pursuant to R12-1-1716;
7. Utilization records required in pursuant to R12-1-1717;
8. Records of inspection and maintenance required in pursuant to R12-1-1720; and

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9. Survey records required ~~in pursuant to~~ R12-1-1741.

R12-1-1743. Documents and Records Required at Temporary Job Sites

Each licensee conducting operations at a temporary job site shall have the following documents and records available at that site:

1. No change
2. Survey records required ~~in pursuant to~~ R12-1-1741 for the period of operation at the site;
3. No change
4. No change

R12-1-1751. Notification of Incidents, Abandonment and Lost Sources

A. Notification of incidents and sources lost in other than downhole logging operations shall be made according to ~~in accordance with appropriate provisions of~~ Article 4 of this Chapter.

B. Whenever a sealed source or device containing radioactive material is lodged in a well hole the licensee shall notify the Agency of the planned procedures for recovery prior to attempting recovery and shall:

1. No change
2. No change

C. No change

1. Advise the well operator of the Agency rules ~~regulations of the Agency~~ regarding abandonment and an appropriate method of abandonment, which shall include:

- a. No change
- b. No change
- c. No change

2. No change

3. File a written report with the Agency within 30 days of the abandonment, containing ~~setting forth~~ the following information:

- a. No change
- b. No change
- c. No change
- d. No change
- e. No change
- f. No change
- g. No change
- h. No change

D. No change

1. No change

2. No change

- a. No change
- b. No change
- c. No change
- d. No change
- e. No change
- f. No change
- g. No change
- h. No change

E. No change