NUREG-1556, Volume 21, Revision 1 - External Comments				
Comment No.	**Commenter**	**Location in the Volume**	**Comment**	**Resolution**
1	Kael Ma't Culan	General	General statements about the production of uranium and nuclear accelerators	**Comment not accepted.** The statements provided are not applicable to the guidance information provided in Volume 21, Revision 1.
2	Aaron Ahern	General	General statements about intellectual property rights and copyright protection	**Comment not accepted.** The statements provided are not applicable to the guidance information provided in Volume 21, Revision 1.
3	Marc Berridge, President, 3D Imaging Drug Design and Development	General	Additional precision in the guidance regarding the application of the various requirements mentioned in Volume 21, Revision 1, to various types of applicants would be helpful. Applicants include accelerator operators who are commercial nuclide manufacturers, radiopharmaceutical manufacturers, hospitals, universities, and radiopharmacies, all of whom have different types of resources and expertise and different approaches to applications under the current regulations. It would help to consider the interpretations that apply to each of these groups.	**Comment not accepted.** The purpose of this NUREG is to provide guidance on a regulation that applies to all of the categories of licensees that the commenter specifies. This guidance cannot specify different methods for complying with the regulation based on differences in the types of applicants and their resources, expertise, and approaches. These differences vary too widely to make a more comprehensive and detailed guidance document feasible within a manageable length of this volume. More important, the burden is on the applicant or licensee to have the resources, expertise, and approach

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3				necessary to ensure compliance. Each applicant or licensee is responsible for applying the guidance to its particular operations.
4	Marc Berridge, President, 3D Imaging Drug Design and Development	Page 1-1, Line 10	This line contains a statement that a radiopharmacy license is required to also manufacture and commercially distribute radioactive drugs. This may be interpreted as meaning that the facility must be a radiopharmacy. While current regulations do allow for a manufacturing radiopharmacy which is licensed by the state board of pharmacy as a nuclear pharmacy, current regulations also allow for a manufacturer that is not a radiopharmacy to produce radioactive drugs under appropriate approvals from the U.S. Food and Drug Administration (FDA), and with a wholesale distributor license from the applicable state board of pharmacy. Therefore, to require a manufacturer that is not currently a pharmacy to become a pharmacy would not be expected to contribute to public safety or product quality. This could also actually slightly increase the risk of product contamination and would impose a substantial burden for addition of unneeded equipment and staff to comply.	**Comment accepted.** The paragraph was amended to state that "An applicant using this guidance to apply for a license to produce radioactive materials using an accelerator will also need to submit an application for the possession, use, or distribution of the material produced." For example, commercial radiopharmacy licensees that also plan to manufacture and commercially distribute radioactive drugs from the material made by the accelerator should refer to NUREG–1556, Volume 13, which provides guidance about submitting applications for commercial radiopharmacy licenses. Others may need to refer to NUREG-1556, Volume 12, Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution."

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5	Marc Berridge, President, 3D Imaging Drug Design and Development	Page 8-4, Line 31	While there is information available regarding production and likely quantities of incidentally-activated nuclides in an accelerator facility and these nuclides can be listed as discussed, it would be useful to specifically address the fact that an accelerator can cause production of incidentally-activated nuclides that are not anticipated and though such nuclides would necessarily be present in small quantities, it is possible that nuclides not listed will be present. At the same time, efforts to identify and quantify all incidentally-activated nuclides that may be formed in the structural components of the accelerator and its environment have little practical return in safety and planning for waste handling or facility decommissioning once the major contributors to induced nuclide emissions are identified.	**Comment accepted.** A new 2nd sentence has been added: "The applicant should consider incidentally-activated nuclides that are not anticipated as well as incidentally-activated nuclides that are expected to be produced."
6	State of Washington	Page 8-4, Lines 36-38	Regarding the sentence that, "If certain incidentally-activated radionuclides will be produced in much larger quantities than described in the atomic number 1-83 request and the radionuclides have a half-life greater than 120 days, the applicant should list these separately, rather than increase the possession limit for all radionuclides." Should this sentence be explained as being necessary for determining if a decommissioning funding plan (DFP) is required?	**Response to Question:** No, this is for the purpose of determining possession limits only. Issues related to financial assurance and decommissioning funding plans are addressed in Section 8.5.2 of the NUREG. The applicant is responsible for determining whether the quantities of all radionuclides to be possessed exceed the possession limit at which a DFP is required.

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Comment No.	**Commenter**	**Location in the Volume**	**Comment**	**Resolution**
7	State of Wisconsin	Page 8-5, Lines 1-2	Change, "if it is known that specific high-risk, incidentally-activated radionuclides are produced in smaller quantities," to "specific high-risk, incidentally-activated radionuclides that are produced in smaller quantities,".	**Comment accepted.** The sentence has been revised to read: "Similarly, specific high-risk, incidentally-activated radionuclides that are produced in smaller quantities should also be listed separately."
8	State of Washington	Page 8-5, Line 1	How is "high-risk" defined in regards to radionuclides? This could vary depending on whether internal or external exposure is the primary concern, i.e. gamma/x-ray vs. alpha emitters.	**Response to Question:** The level of risk will vary case-by-case based upon the specific accelerator design, its expected uses, its operating environment, the incidentally produced radionuclides expected to be produced with each use, and the user's operating experience. For determining an acceptable level of risk, the NRC expects an applicant to get information from the manufacturer about the operating limits of the accelerator and the expected quantities and energies of materials it will produce incidentally
9	State of Wisconsin	Page 8-5, Lines 8-9	Delete "and the total cumulative quantity for all radionuclides." If the nuclides will be line-itemed on the license, the summed activity is not necessary.	**Comment not accepted.** See response to Comment 10 below.

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10	Organization of Agreement States (OAS)	Page 8-5, Lines 8-9	It is unclear what "the total cumulative quantity for all radionuclides" is referring to. Does this mean the total cumulative quantity for each radionuclide over the anticipated life of the accelerator? Or does this mean the summed activity of each radionuclide? If it is the latter, it doesn't make sense since the guidance says that the nuclides should be line-itemed on the license.	**Comment accepted.** For better clarity, a new sentence has been added referring the reader to Table 8-1, "Sample Format for Providing Information About Requested Radionuclides." This table has also been revised to conform the listing and totaling requirements for byproduct materials with atomic numbers 84 through 96 to the listing and totaling requirements of byproduct materials with atomic numbers 1 through 83. In addition, on p. 8-4, the sentence on lines 33 and 34 has been revised to read: "The applicant should indicate the total cumulative quantity for all radionuclides to be possessed at any one time, and the maximum quantity for any one of the radionuclides within atomic numbers 1-83. The total cumulative possession should be commensurate with the applicant's needs."

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Comment No.	**Commenter**	**Location in the Volume**	**Comment**	**Resolution**
11	State of Washington	Page 8-5, Line 35	Why is this 1 millicurie (mCi) and not 100 millicuries?	**Response to question:** The 1 mCi limit for calibration sources containing beta- and/or gamma-emitting radionuclides is in 10 CFR 32.210(a)
12	State of Washington	Page 8-5, Line 45	"Must" instead of "should"?	**Comment accepted.** The subject sentence has been revised to read: "The applicant must either: 1) provide a range of atomic numbers for the requested radionuclides; or 2) list each requested radionuclide by its element name and its mass number in Item 5 on NRC Form 313, specifying whether the material will be acquired and used in unsealed or sealed form."
13	State of Wisconsin	Page 8-6, Lines 17-21	Delete Lines 17-21. The sentence on lines 17-19 was already stated in Section 3.1. The sentence on lines 19-21 provides the same information as the sentence on lines 14-15.	**Comment not accepted.** The sentence on lines 17-19 is intended as a paraphrased reminder to the applicant to provide the information required in Section 3.1, which must be provided in all license applications for possession of radioactive materials. **Comment accepted.** The sentence on lines 19-21 has been deleted as redundant.

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14	State of Wisconsin and OAS	Page 8-6, Lines 36-38	The information in this ***Note*** is not consistent with the guidance on Pages 8-4 and 8-5. The ***Note*** should highlight the detailed information that should be submitted for incidentally produced radionuclides with half-lives >120 days or in significantly larger quantities. Section 8.5.1 should also list examples of radionuclides (Co-57, Co-60, Zn-65, etc.) for each category.	**Comment accepted in part**. The Note has been changed under "Response from Applicant" to clarify that the applicant will need to identify individual incidentally-activated radionuclides with half-lives > 120 days that will be produced in larger quantities, that is, quantities that would exceed 10 percent of the quantity required for financial assurance for decommissioning. Section 8.5.1 does not need to list examples of incidentally-produced radionuclides. Providing such examples of would be of limited benefit for most applicants. Incidentally produced nuclides will differ for any given use based on such variables as the power of the accelerator, the "on" time, and shielding, component, and target materials. An applicant should consult the accelerator manufacturer to determine the radionuclides most likely to be produced by a planned application.

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15	State of Wisconsin and OAS	Page 8-8, Lines 24-26	Delete "Subsection (f) establishes the methods by which any financial assurance instrument, such as a prepayment, surety bond, insurance, or sinking fund, must be provided." This information is described in Figure 8-2 on the same page.	**Comment not accepted.** The figure is for illustrative purposes and to reinforce the narrative. Without the narrative text, the figure could be confusing.
16	State of Wisconsin and OAS	Page 8-9, Lines 1-4	Delete this paragraph. It contains the same information as Page 8-8, Lines 6-10.	**Comment accepted.** The paragraph on lines 1-4 of page 8-9 has been deleted as redundant.
17	State of Washington	Page 8-9, Lines 3-4	"…One of several…" seems vague. Is this referring to the mechanisms covered in NUREG-1757, Volume 3?	**Comment accepted.** In response to Comment 16, this language was deleted.
18	State of Washington	Page 8-9, Line 22	Why is a leaking source not considered the same as a spill?	**Response to Question:** The statements presented in this section are direct quotes from the regulation at 10 CFR 30.35(g)(3), which distinguishes between spills and leaking sources.
19	Marc Berridge, President, 3D Imaging Drug Design and Development	Page 8-11, Lines 35-39	It is unclear what purpose is served by the definition of "consortium" on these lines. While a consortium, as defined in these lines, would not be a fully commercial distributor, a "consortium" is in fact distributing for clinical and commercial purposes. A consortium is required by FDA regulations to operate as a drug manufacturer and to hold approved drug applications for the radiopharmaceuticals it produces. There would seem to be little justification for creating different standards for such a consortium, as opposed to a local commercial distributor that is not owned by its customers.	**Comment not accepted.** Rulemaking would be required to implement this comment, because "consortium" is defined in § 30.4 of NRC regulations. The redefinition sought by the commenter is beyond the scope of this guidance.

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20	Organization of Agreement States (OAS)	Pages 8-12 and 8-13, Table 8-1	Table 8-1 lists the quantities and example nuclides of activation products. Can all accelerators use these values? If not, this should be stated. Are these quantities and nuclides based on the energies of the particles being accelerated and the composition of the target material? Is there a way to determine the quantity and type of activation products based on these inputs? If so, this should be included in this NUREG.	**Responses to Questions:** The table is a sample of typical radionuclides that an applicant would request, and is not intended to be all-inclusive. The table has been modified to clarify that the types and quantities of activation products will vary from the table depending on the design and intended operation of the accelerator. Yes, types and quantities of activation products are based on energy, target material, and shielding material, but there are too many different combinations of variables to make it worthwhile to document all their activation products here. To determine the quantity and type of activation products to be expected from specific planned operating conditions, the applicant should work with the accelerator manufacturer.
21	State of Washington	Page 8-13, Line 8	Delete either “radiation safety officers” or “RSOs”.	**Comment accepted.** The words “radiation safety officer” have been deleted.

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22	U.S. Department of Health and Human Services, National Institutes of Health	Page 8-14, Lines 39-41 and Page 8-15, Lines 1-9	Section 8.7.1 (Radiation Safety Officer) has a new paragraph beginning at the bottom of Page 8-14 describing the ability of the radiation safety officer (RSO) to appoint an "Alternate RSO." On Page 8-15, lines 5-9 note that, "Designees should have the same management support and decision-making authority as the RSO necessary to accomplish the tasks to which they have been assigned. Please note that only the primary RSO is named on an NRC license. Applicants do not have to identify other responsible individuals if day-to-day tasks will not be delegated." • Does this mean that any "Alternate RSOs" must also have a Delegation of Authority ensuring that decision-making authority has been conveyed? • Although an Alternate RSO designees would not be specifically named on the license, the language of the paragraph suggests that if day-to-day tasks will be delegated, the designees would need to be identified, presumably in license application documentation and a license amendment would need to be submitted anytime there was a change in who is designated or which tasks are delegated. Is this interpretation correct?	**Responses to Questions:** *Question 1:* No, the alternate RSO would not need a delegation of authority. However, management should review the duties given to the alternate RSO and grant delegations of authority as needed. *Question 2:* The name of the alternate RSO is not needed for the license. The text on lines 8-9 of page 8-15 has been revised to delete the sentence, "Applicants do not have to identify other responsible individuals if day-to-day tasks will not be delegated."
23	State of Wisconsin and OAS	Page 8-15, Line 11	Change "it is recommended that the RSO have" to "the RSO should have"	**Comment accepted.**

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24	State of Wisconsin and OAS	Page 8-16, Figure 8-3	This figure was clearly designed for industrial radiography. Several of the icons in the figure do not relate to accelerator facilities, specifically the focus on "devices." In addition, six-month worker audits are not required for accelerator facilities. Revise or delete this figure.	**Comment accepted.** Figure 8-3 has been revised to delete references to equipment and activities not required for accelerator facilities.
25	State of Wisconsin	Page 8-16, Line 4	Change "may need" to "should have."	**Comment not accepted.** "May need" is used for consistency across the NUREG-1556 volumes that discuss the question of a minimum of 40 hours for RSO training. Not all of the NUREG-1556 volumes contain a 40-hour recommendation. The requirement, 10 CFR 30.33(a)(3), listed in Section 8.7.1, "Radiation Safety Officer, states only that, "An application for a specific license will be approved if the applicant is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property."

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26	State of Washington	Page 8-16, Line 10	Change “the” in “obtained the above” to “an” or “any.”	**Comment not accepted.** The sentence is clear as written. The definite article “the” refers specifically to the training described on lines 1 through 8. The indefinite articles “an” and “any” do not specify the type of training required.
27	State of Washington	Page 8-17, Lines 5-7	Change “important” and “should” in the following to “required” and “must”: “It is **important** to notify the NRC and obtain a license amendment before making changes in the designation of the RSO listed on the license. The name and qualifications of the replacement RSO **should** be submitted to the NRC as part of an amendment request.	**Comment accepted.** The need for a license amendment to change the designation of the RSO on the license, and the need to submit the replacement RSO’s name and qualifications, are required under 10 CFR 30.33(a)(3). Accordingly, the Note on p. 8-17 has been revised to read: “Notify the NRC and obtain a license amendment before making changes in the designation of the RSO listed on the license.”
28	State of Washington	Page 8-23, Lines 25-27	Is there a more recent reference than NRC Information Notice 96-28?	**Response to Question:** No. Information Notice 96-28 is the most recent reference.

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29	State of Washington	Page 8-28, Lines 31 and 34	Change "should" to "must" in the following: "Instrument calibrations **should** be performed by the instrument manufacturer or a person specifically authorized by the NRC or an Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform radiation survey instrument calibrations **should** submit procedures for review."	**Comment not accepted.** The regulations do not specify that a particular party must perform instrument calibrations. **Comment accepted.** Under 10 CFR 20.1501(c), licensees must "ensure that instruments and equipment used for quantitative radiation measurements … are calibrated periodically for the radiation measured." To ensure proper calibration, applicants seeking to perform survey instrument calibrations must submit their calibration procedures for review. In response to both comments, the following language has been inserted into the Discussion section of Item 8.10.2, "Radiation Monitoring Instruments," to replace the sentences on lines 31-34 of page 8-28: "Calibrations requiring the use of radioactive sources should be performed by the instrument manufacturer or persons specifically authorized by the NRC or an Agreement State, unless the applicant specifically requests this authorization.

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29				Radiation survey instruments should be calibrated at least annually (every 12 months), unless another frequency is specified by regulation or license condition. Applicants seeking authorization to perform radiation survey instrument calibrations will need to submit procedures for review."
30	State of Wisconsin and OAS	Page 8-34, Figure 8-6	The 10 CFR 20.1003 definition for "total effective dose equivalent" no longer includes the phrase "deep dose equivalent." Update the text directly above the caption.	**Comment accepted.** The text under Figure 8-6 has been reworded to read: "Total effective dose equivalent (TEDE) = the effective dose equivalent (for external exposures) plus the committed effective dose equivalent (for internal exposures)."
31	U.S. Department of Health and Human Services, National Institutes of Health	Page 8-35, Lines 9-12	Section 8.10.4 (Occupational Dose) has a paragraph on Page 8-35 that discusses individuals who have been determined to have the potential dose exceeding 10% of the limits. Lines 10-11 state that in addition to the licensee being required to monitor those individuals, they must report to the individuals the results of that monitoring, even if the actual dose does not ultimately exceed 10% of the limit. This appears to contradict 10 CFR 19.13(b)(1) which states that reporting is only required if the dose exceeds 1 mSv (100 mrem).	**Comment accepted.** The sentence on lines 9-10 was modified to read "If the prospective evaluation shows that the individual is likely to exceed 10 percent of an applicable limit, monitoring is required -- regardless of the actual dose received." The words "and reporting of the results of monitoring performed" were deleted.

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32	State of Washington	Pages 8-51-8-56, Section 8.11	Why are removable/replaceable activated components from accelerators not mentioned in the waste section (Section 8.11)?	**Response to Question:** The removable/replaceable activated components are not waste until they are removed for storage or disposal. This type of waste is generally covered by this Volume under Item 8.11, "Waste Management." See discussion under the heading, "Transfer to an Authorized Recipient."
33	State of Washington	Page B-1, Item 5	This ***Note:*** would be better if it suggested the types of items that contain these activation products (e.g. concrete, shielding, targets, etc.).	**Comment accepted.** The ***Note*** has been revised on Page 8-7 to read: "For incidentally-activated radionuclides, such as shielding and target material, the applicant may request authorization to possess and use any form of byproduct material with atomic numbers 1 through 83, and indicate the total cumulative quantity for these radionuclides to be possessed at any one time." Also, since ***Notes*** are advisory, all notes were removed from Appendix B.

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34	State of Washington	Page B-11, **Public Dose**	Should the submitted information include estimated doses to the MEI from effluent streams?	**Response to Question:** No. Air effluents are constrained so that a member of the public does not receive an annual dose greater than 10 millirem. (20.1101(d)). Additionally, based on subsequent edits to this NUREG, no response is required for the "Public Dose" section.
35	State of Washington	Page B-11, **Procedures**	Why isn't submission of the procedures for review required?	**Response to Question:** 10 CFR 30.32 requires the submittal for review of procedures in a license application only for a full emergency plan if one is required under 10 CFR 30.32(i). Emergency plans are required only for facilities for which the maximum dose to a person offsite due to a release of radioactive materials would exceed 1 rem effective dose equivalent or 5 rems to the thyroid. A requirement for all applicants to submit for prior review all procedures for safe handling and emergencies would necessitate a rulemaking, which is beyond the scope of this guidance. These procedures and licensees' revisions of them will be reviewed during inspections.

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36	Washington	Page C-1, Lines 9-10	Shouldn't training include all individuals who work with or transport radioactive material as well?	**Response to Question:** Yes. The RSO duties and responsibilities are generally listed in this section. Training to personnel should be conducted as specified in the regulations and outlined in Section 8.8. Also, an item was added to Appendix C for the RSO for "ensuring that individuals involved with radioactive materials are properly trained and evaluated".
37	Washington	Page E-2, Line 4	What requirements? To be RSO?	**Response to Question:** Yes. To clarify, this item has been changed to read: "Meets training and experience criteria".
38	Washington	Page E-8, Line 27	Should "**Recordkeeping for Decommissioning"** include "Decommissioning funding plan up-to-date"?	**Response to Question:** No. There is no need to specify that records must be kept for decommissioning funding plan updates. Records of these updates are required to be kept under 10 CFR 30.35(g)(4), which is covered by the regulation cited in the general question, "Decommissioning records include all required data? [30.35(g)]"

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39	Wisconsin and OAS	Page H-2, Example 2	Using phosphorus-32 (P-32) in Example 2 does not seem to be a good example for accelerator facilities.	**Comment accepted.** The examples and the last sentence on page H-1 have been removed.
40	Washington	Page J-1, Line 33	Disagree that P-32 is low energy.	**Comment accepted.** Phosphorus-32 has been removed from the document.
41	Wisconsin and OAS	Page J-3, Table J-2	Several isotopes (e.g., I-131) are on the table twice, and the table is missing a horizontal line separating I-129 and Th-nat.	**Comment accepted.** Errors on Table J-2 have been corrected.
42	U.S. Department of Health and Human Services, National Institutes of Health	Pages J-3 and J-4, Table J-2	Table J-2 (Acceptable Surface Contamination Levels) has a number of changes from the current version in Table M-5. Notably, it removes the catch-all category of alpha emitters and instead lists several individual alpha-emitting nuclides, whose limits are not all the same. There are definitely other alpha emitters (e.g. At-211) that are produced via cyclotrons. Thus, what would the limits be for an alpha emitter not in the revised table?	**Response to Question:** Table J-2 of the revised Volume 21 has been further amended by restoring the catch-all category of alpha emitters from Table M-5 in the original version of Volume 21. The surface contamination levels for alpha emitters were derived by setting them one order of magnitude less than the values for beta-gamma emitters on the bottom row of Table J-2.
43	Washington	Page J-9, Lines 39-40	Change “retention of radioactive material in the body” to “retention of **long-lived** radioactive material in the body”.	**Comment not accepted.** The phrase “long term accumulation and retention of radioactive material in the body” on p. J-9 refers to the biological half-life of the material in the body, not the physical half-life of

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43				the radionuclides themselves. It is not conservative to specify that the radioactive material of interest in the body must only be the long-lived material subject to annual measurement. Periodic bioassays may also need to be performed more frequently than annually for shorter-lived radionuclides.
44	Wisconsin and OAS	Appendix K	Please use the equation editor feature of your word processing program to input the leak test equations.	**Comment accepted.** Leak test equations in Appendix K have been revised for additional clarity.
45	Washington	Page K-4	For wipe test activity, it states 0.005 mCi when it should be µCi	**Comment accepted.** The notation on p. K-4 has been revised to specify microcuries rather than millicuries.
46	Wisconsin and OAS	Appendix L	The contamination limits on Page L-4 are not correct. In 2014, DOT raised the package contamination limits to 240 dpm/cm^2 for beta/gamma/low toxicity alpha and 24 dpm/ cm^2 for all other alpha emitters.	**Comment accepted:** The contamination limits in Appendix L have been conformed to the limits in the most recent U.S. Department of Transportation regulations.