United States
Environmental Protection
Agency

Support Document for the Third Six-Year Review of Drinking Water Regulations for Acrylamide and Epichlorohydrin

Office of Water (4607M)
EPA 810-R-16-019
December 2016
www.epa.gov/safewater

Table of Contents

Table of Exhibits

Abbreviations and Acronyms

AWWA	American Water Works Association
CFR	Code of Federal Regulations
CWSS	Community Water System Survey
DWI	Drinking Water Inspectorate
EPA	U.S. Environmental Protection Agency
epi-DMA	epichlorohydrin-dimethylamine copolymer
EU	European Union
FDA	Food and Drug Administration
FR	*Federal Register*
MCL	maximum contaminant level
MCLG	maximum contaminant level goal
MDL	method detection limit
mg/kg	milligrams per kilogram
mg/L	milligrams per liter
µg/L	micrograms per liter
MRL	minimum reporting level
MWH	Montgomery Watson Harza
NHMRC	National Health and Medicine Research Council
NPDWR	National Primary Drinking Water Regulation
NSF	NSF International
poly-DADMAC	polydiallyldimethyl ammonium chloride
ppm	parts per million
SDWA	Safe Drinking Water Act
SYR2	Second Six-Year Review
SYR3	Third Six-Year Review
WHO	World Health Organization

1 Introduction

The U.S. Environmental Protection Agency (EPA) has completed its third Six-Year Review (SYR3) of national primary drinking water regulations (NPDWRs). The 1996 Safe Drinking Water Act (SDWA) Amendments require the U.S. Environmental Protection Agency (EPA or the Agency) to periodically review existing NPDWRs. Section 1412(b)(9) of SDWA reads:

> ...[t]he Administrator shall, not less often than every 6 years, review and revise, as appropriate, each national primary drinking water regulation promulgated under this subchapter. Any revision of a national primary drinking water regulation shall be promulgated in accordance with this section, except that each revision shall maintain, or provide for greater, protection of the health of persons.

The primary goal of the Six-Year Review process is to identify NPDWRs for possible regulatory revision. Although the statute does not define when a revision is "appropriate," as a general benchmark, EPA considered a possible revision to be "appropriate" if, at a minimum, it presents a meaningful opportunity to:

- improve the level of public health protection, and/or
- achieve cost savings while maintaining or improving the level of public health protection.

For SYR3, EPA implemented the NPDWR review protocol that it developed for the first Six-Year Review (USEPA, 2003), including minor revisions developed during the second review process (USEPA, 2009b) and the third review process (USEPA, 2016a). Following the review method in the protocol, EPA sought new information that might affect the following NPDWR components:

- **Maximum Contaminant Level Goals** (MCLGs; the health goal) – for some contaminants new health effects assessments completed since the MCLG was promulgated or last revised provide a revised reference dose and/or cancer classification.
- **Maximum Contaminant Levels** (MCLs; the enforceable standard) – for some contaminants, the MCL is equal to the MCLG, and the health effects assessment indicates potential to revise the MCLG. Improvements in analytical feasibility as indicated by the practical quantitation limit may also indicate feasibility to set the MCL closer to the MCLG.
- **Treatment Technique** (sometimes established in lieu of an MCL) – new information on health effects, analytical feasibility, or treatment feasibility may suggest a possibility to revise treatment technique.
- **Other Regulatory Requirements** (Monitoring) – Other regulatory revisions may be appropriate if information suggest that changes in monitoring standards (e.g., frequency) could reduce health risks or costs while maintaining or improving the level of public health protection.

As part of its SYR3, EPA obtained and evaluated new information pertaining to the NPDWRs for acrylamide and epichlorohydrin, which are regulated by treatment techniques. This document provides background information on these contaminants and the current NPDWR in section 2. Section 3 provides a description of the new information that EPA obtained and analyzed during SYR3. EPA's determination is in section 4.

2 Regulatory Background

Acrylamide and epichlorohydrin occur in drinking water as treatment impurities. They are primarily introduced as residuals in polymers and copolymers used for water treatment, although they can also be present in contact surfaces used in storage and distribution systems.

2.1 Polymer Chemistry

Polymers are long-chained molecules made up of units called monomers. If a polymer contains a single type of monomer, it is called a homopolymer; if it contains two or more types of monomers, it is called a copolymer.

Polymers used in water treatment are characterized by their molecular weight, the predominant sign of their charged sites (anionic, cationic, or nonionic), and their charge density. A simple polymer is nonionic polyacrylamide, the homopolymer formed from acrylamide monomer. More complex polymers may have varying patterns of copolymerization or cross-linked structures.

Acrylamide monomer is used to make anionic and cationic copolymers, as well as nonionic polyacrylamide. Nonionic polyacrylamide may also be hydrolyzed to form an anionic polymer. Epichlorohydrin is used to make various cationic copolymers, notably epichlorohydrin-dimethylamine copolymer (epi-DMA). Epichlorohydrin polymers that contain amine monomers are known as polyamines; however, polyamines in general do not necessarily contain epichlorohydrin.

2.2 Polymer Use in Water Treatment

When polymers are manufactured, a small fraction of the monomer units do not polymerize, and remain in the commercial polymer as an impurity. Thus, there is a potential for exposure to these contaminants as residual monomers in polymers when they are added to water being treated for drinking water use.

The polymers most often used in drinking water treatment are polyacrylamides (anionic, nonionic, and less commonly cationic), epi-DMA (cationic), and polydiallyldimethyl ammonium chloride (poly-DADMAC; cationic). Thus, anionic and nonionic polymers used in drinking water treatment are primarily polyacrylamides, while cationic polymers vary in their composition (Levine et al., 2004; AWWA, 1999). Section 3.4.1 provides more detailed discussion of polymer use in water treatment.

EPA reviewed new information on monomer residuals as part of SYR3 to determine if improvements in the technology or manufacturing process now allow production of the polymer with lower residual monomer content, and to reassess the appropriateness of the maximum allowable dosage of the polymers and copolymers.

2.3 Current Regulatory Framework

EPA proposed drinking water regulations for acrylamide and epichlorohydrin on May 22, 1989 (54 FR 22062, USEPA, 1989) and promulgated final drinking water regulations on January 30, 1991 (56 FR 3526, USEPA, 1991). The NPDWR for epichlorohydrin contains an MCLG of zero based on a cancer classification of B2, probable human carcinogen (56 FR 3526, USEPA, 1991). Similarly, EPA established an MCLG of zero for acrylamide based on a B2 cancer classification (56 FR 3526, USEPA, 1991). In an updated health effects assessment, EPA concluded that acrylamide remains carcinogenic (USEPA, 2010).

EPA regulated these contaminants using a treatment technique requirement – in lieu of an MCL – because of the absence of standardized analytical methods for their measurement in water. The treatment technique requirement for these contaminants limits the allowable monomer levels in polymers and copolymers, as well as the polymer dose in treatment. EPA selected this option because methods are available for measurement of residual monomer in polymer products and these levels are routinely measured by manufacturers. These limits are:

- Acrylamide: 0.05 percent acrylamide in polymers/copolymers and maximum dosage of 1 part per million (ppm) (e.g., 1 milligram per liter or mg/L); and
- Epichlorohydrin: 0.01 percent residual epichlorohydrin concentration in polymers/copolymers and a maximum dosage of 20 ppm.

Under EPA's regulation, each water system is required to certify, in writing, to the Primacy authority (e.g., a state or EPA Region) that the product of the polymer dose and the residual monomer level do not exceed the specifications in the NPDWR. A system may use third-party or manufacturer's certification in lieu of testing for the residual monomer level.

The NSF International (NSF), a third party organization, tests and certifies water treatment chemicals. Chemicals must meet NSF/ANSI Standard 60, *Drinking Water Treatment Chemicals – Health Effects*, which sets out requirements for treatment chemicals based on human health protection (NSF, 2016). The requirements for acrylamide and epichlorohydrin based polymers in Standard 60 are based on EPA's treatment technique requirements. Thus, NSF 60 certification of a polymeric coagulant aid containing acrylamide or epichlorohydrin indicates that users are in compliance of EPA's regulation when a product is used as specified (i.e., for the intended purpose and up to the maximum usage level indicated by NSF).

2.4 Regulatory Basis

In setting the treatment technique requirement for acrylamide, EPA used a level of 0.05% residual acrylamide monomer and a polymer dose of 1 ppm, based on the maximum acceptable levels in EPA's Drinking Water Additives Advisory Program. This program was operational at the time of the rulemaking, but was later terminated. The residual monomer level was considered to be the lowest level that manufacturers could feasibly achieve at the time the regulation was promulgated, and corresponded to similar requirements in Food and Drug Administration (FDA) regulations governing polyacrylamide as a secondary direct food additive (54 FR 22062, USEPA, 1989). The dose was based on typical doses of polyacrylamide used in drinking water treatment. Polymers may be sold as dry powder, emulsions, solutions, or dispersions with less

than 100% active polymer (AWWA, 2006a, 2006b). The doses specified in the rule are on an active polymer basis.

The 1991 rule similarly limited residual epichlorohydrin and polymer dose, using a level of 0.01% residual epichlorohydrin dosed at 20 ppm. The monomer level and dose were those accepted for epichlorohydrin-based polymers within the framework of the EPA's Drinking Water Additives Advisory Program. As with acrylamide, the monomer level was considered the lowest feasible level for manufacturers, and the dose was based on typical doses of polymers containing epichlorohydrin (54 FR 22062, USEPA, 1989).

To estimate the unobservable level of exposure to the allowable levels of acrylamide and epichlorohydrin, EPA used the worst-case assumption that all residual monomer carries over to the finished water, resulting in finished water concentrations from polymer use of 0.5 micrograms per liter (μg/L) and 2 μg/L, respectively (54 FR 22062, USEPA, 1989). EPA assumed that an additional 10% of acrylamide and epichlorohydrin—that is, up to 0.05 μg/L of acrylamide and 0.2 μg/L of epichlorohydrin—enter drinking water via leaching from these other materials or from raw water.

Thus, taking into account exposure as residual monomer in water treatment chemicals and through leaching from surfaces in contact with water, total human exposure to acrylamide via drinking water will at a maximum be approximately 0.55 μg /l. Similarly, total human exposure to epichlorohydrin via drinking water will at maximum be 0.22 μg /l.

3 Supporting Information for Potential Regulatory Revision to Increase Public Health Protection

3.1 Improvements in Manufacturing – NSF Data on Residual Monomer Content

NSF provided EPA with results of NSF analyses of acrylamide monomer in polyacrylamides and free epichlorohydrin in polyamines.[1] NSF performed the analyses for approval of these products against NSF/ANSI Standard 60. The NSF data provided to EPA included 244 analytical results for acrylamide (in dry and emulsion forms) and 90 analytical results for epichlorohydrin. NSF conducted the analyses between 2013 and 2016. **Exhibit 3-1** provides summary statistics.

Based on data provided by NSF, EPA determined that the residual levels in the products tested and certified are consistently and often substantially less than the residual levels in the current treatment techniques. For analyses of acrylamide, the mean concentration is about one-fifth the residual level in the current treatment technique, and the 90th percentile result is nearly one-half the residual level in the current treatment technique. All analyses for residual epichlorohydrin were non-detects, with a detection limit equal to one-fifth the residual level in the current treatment technique.

Exhibit 3-1. Summary of NSF International Product Testing Results for Acrylamide and Epichlorohydrin, 2013-2016

Contaminant	Number of Analyses and Detections[1]	Detection Limit (mg/kg)	Maximum (mg/kg)	90th Percentile (mg/kg)	Mean[2] (mg/kg)	Median[2] (mg/kg)	Minimum (mg/kg)	Current Treatment Technique (mg/kg)[3]
Acrylamide	244 (163)	10	490	270	105	55	Nondetect	500
Epichlorohydrin	90 (0)	20	NA	NA	NA	NA	NA	100

Source: EPA analysis of data provided by Purkiss, 2016
NA = not applicable – all results are below the detection limit.
1. Detection results shown in parenthesis.
2. Includes nondetection results for acrylamide at the reported detection limit of 10 mg/kg or for epichlorohydrin at the reported detection limit of 20 mg/kg.
3. Treatment technique residual monomer content converted from percent to milligrams per kilogram (mg/kg); 1 mg/kg = $1/10^6$ = 0.000001 = 0.0001%.

These results are similar to EPA's findings during the second Six-Year Review (SYR2), which are in **Exhibit 3-2**. For SYR2, NSF provided results for analyses conducted between 2005 and 2007. All epichlorohydrin analytical results are nondetections and the analytical detection limit is one-fifth the current monomer residual limit. A comparison of the results in Exhibit 3-1 with the results in Exhibit 3-2 shows that the acrylamide mean and 90th percentile values are lower for the data provided during SYR2. The median value is lower for the SYR3 data, however.

[1] NSF did not provide any confidential business information such as which manufacturers were included in the analyses. NSF only provided vectors of testing results.

Exhibit 3-2. Summary of NSF International Product Testing Results for Acrylamide and Epichlorohydrin, 2005-2007

Contaminant	Number of Analyses and Detections	Detection Limit (mg/kg)	Maximum (mg/kg)	90th Percentile (mg/kg)	Mean[2] (mg/kg)	Median[2] (mg/kg)	Minimum (mg/kg)	Current Treatment Technique (mg/kg)[3]
Acrylamide	66 (45)	10	420	250	98	60	10	500
Epichlorohydrin	84 (0)	20	NA	NA	NA	NA	NA	100

Source: USEPA, 2009c

NA = not applicable – all results are below the detection limit.

1. Detection results shown in parenthesis.

2. Includes nondetection results for acrylamide at the reported detection limit of 10 mg/kg or for epichlorohydrin at the reported detection limit of 20 mg/kg.

3. Treatment technique residual monomer content converted from percent to mg/kg; 1 mg/kg = $1/10^6$ = 0.000001 = 0.0001%.

The NSF data indicate potential to lower the residual monomer limits for acrylamide and epichlorohydrin. Given consistent nondetection results for epichlorohydrin in both data sets (2005-2007 and 2013-2016), EPA concludes that a value equal to or slightly greater than the detection limit is a feasible option for the residual monomer limit. The feasible option for acrylamide is more difficult to identify. Acrylamide was not detected in one-third of samples taken from 2013-2016 and detected quantities ranged as high as 490 mg/kg, which is close to the current treatment technique limit of 0.05% or 500 mg/kg. Therefore, EPA reviewed drinking water limits or guidelines applied elsewhere.

3.2 Regulations and Guidelines in Other Countries - EU, UK, Canada, WHO

Regulations in other areas of the world are generally more stringent than the current EPA NPDWR for acrylamide and epichlorohydrin in drinking water. **Exhibit 3-3** provides a comparison of recommendations and guidelines used elsewhere to EPA's current regulations.

Canada does not have drinking water guidelines for acrylamide or epichlorohydrin (Health Canada, 2014). Nine of 13 provinces require that drinking water additives be certified to meet health-based standards such as NSF/ANSI Standard 60 (NSF, 2016), which effectively limits the monomer residual content to the same concentration as the U.S. standard. Areas under federal jurisdiction have the same requirements (Health Canada, 2016).

Exhibit 3-3. Comparison of Acrylamide and Epichlorohydrin Drinking Water Guidelines

Country/Region	Regulation or Guideline	Acrylamide	Epichlorohydrin
U.S. EPA	Residual Monomer [a]	0.05%	0.01%
	Maximum Dosage [b]	1 mg/L	20 mg/L
	Water concentration ([a] x [b]) x 1000	0.5 µg/L	2 µg/L
United Kingdom[1]	Residual Monomer	0.02%	0.002%
	Dosage	0.25 mg/L (average) 0.5 mg/L (maximum)	2.5 mg/L (average) 5 mg/L (maximum)
	Concentration in Water	0.1 µg/L (maximum)	0.1 µg/L (maximum)
European Union[2]	Concentration in Water	0.1 µg/L	0.1 µg/L
WHO[3]	Concentration in Water	0.5 µg/L	0.4 µg/L
Australia[4]	Concentration in Water	0.2 µg/L	0.5 µg/L

1. DWI (2010 and 2016). Residual monomer for epichlorohydrin is inferred from concentration limit and dosage limits.
2. EU (2007). The enforceable parameter or limit is the residual monomer concentration in the water based on the maximum release from polymer.
3. WHO (2011). The World Health Organization's guideline for epichlorohydrin is a provisional guideline value because of uncertainties in the health database.
4. NHMRC (2016). The guideline value for epichlorohydrin is below the limit of determination.

The current acrylamide NPDWR is consistent with Canadian drinking water standards and WHO guidelines. The Australian acrylamide standard results in an allowable concentration that is less than half of the maximum allowable concentrations under the NPDWR. The maximum allowable concentrations under the European Union and United Kingdom standards are one-fifth the NPDWR maximum. Thus, there is a lack of international consensus on maximum allowable acrylamide levels in drinking water, but the current NPDWR is in the range of international standards.

3.3 Food and Drug Administration Regulations

When EPA set the residual monomer level for acrylamide, it took into account the monomer levels specified in FDA regulations governing polyacrylamides as secondary direct food additives. During SYR3, EPA reviewed current FDA regulations on acrylamide and epichlorohydrin to determine whether monomer limits have changed.

FDA regulates polyacrylamides for several applications, including uses as secondary direct food additives (e.g., in resins used for sugar clarification), indirect food additives (e.g., in the manufacture of food container in contact with aqueous and fatty foods), and, in one case, a direct food additive. The cases where FDA regulates residual monomer content are summarized in **Exhibit 3-4.**

Exhibit 3-4. FDA Regulations on Acrylamide and Epichlorohydrin Content in Food Additives

Contaminant	Type of additive	Application	Monomer limit	Code of Federal Regulation (CFR)
Acrylamide (in several polymers)	Secondary direct	Sugar clarification Boiler water additive Fruit/vegetable washing Corn syrup manufacture	0.05% 0.05% 0.2% 0.05%	21 CFR 173.5, 10 21 CFR 173.310 21 CFR 173.315 21 CFR 173.357
	Indirect	Paper for containers Paper food contact surfaces	0.2% 0.2%	21 CFR 176.110 21 CFR 176.170
	Direct	Film former in imprinting of soft shell gelatin capsules	0.2%	21 CFR 172.255
Epichlorohydrin (in epi-DMA copolymer)	Secondary direct	Sugar clarification Corn syrup manufacture	0.001% 0.001%	21 CFR 173.60 21 CFR 173.357

Exhibit 3-4 shows that FDA's regulations on acrylamide content are the same as EPA's current treatment technique requirement, or less stringent than EPA's requirement. This may be because the potential human exposure to acrylamide from food additives is expected to be lower than exposure to acrylamide via drinking water. FDA's requirement for epichlorohydrin in epi-DMA copolymer is more stringent, suggesting that there may be an opportunity for EPA to revise the drinking water monomer residual limit downward.

FDA (2007) also reports acrylamide formation as a reaction between asparagine and reducing sugars. The formation occurs during cooking or thermal processing of foods such as potato products (French fries and potato chips) and cereal products (such as cookies, crackers, and toasted bread), and coffee. The estimated mean daily intake ranged from 21 to 60 μg, which is substantially higher than the daily exposure from drinking water at the maximum allowable concentration of 0.5 μg/L (e.g., daily exposure would be 1 μg for an adult consumption rate of 2 liters per day). FDA recently published *Guidance for Industry Acrylamide in Foods* with recommendations for growers, manufactures, and food service operators to reduce acrylamide-formation precursors as well as acrylamide formation during food processing (FDA, 2016).

3.4 Acrylamide and Epichlorohydrin Occurrence in Drinking Water

There is a potential for exposure to these contaminants as residual monomers in polymers when they are used in water treatment (as direct additive). Finished water may also contain acrylamide and epichlorohydrin because of raw water contamination and because of leaching from components and materials used in drinking water treatment, storage and distribution systems (indirect additives). These components and materials may contain polymers based on acrylamide or epichlorohydrin. EPA's occurrence estimates in finished water are primarily based on the release of residue or impurity from their use as direct additives in drinking water treatment.

3.4.1 Polymer Uses in Water Treatment

The polymers most often used in drinking water treatment are polyacrylamides (anionic, nonionic, and less commonly cationic), epi-DMA, and another cationic polymer - poly-

DADMAC. Thus, anionic and nonionic polymers used in drinking water treatment are primarily polyacrylamides, while cationic polymers vary in their composition (Levine et al., 2004; AWWA, 1999). Polymer type and dose vary by treatment objective and source water quality. The following discussion describes different applications.

Cationic polymers such as epi-DMA are often used in combination with metal ion coagulants at the time of coagulation, operating primarily by charge neutralization. Under some conditions, when the coagulated particles have positive surface charges, anionic polymer may be used instead. As coagulant aids, polymers can permit reductions of 40-80% in the dose of metal ion coagulants, thus reducing sludge volumes. Cationic polymers are also sometimes used by themselves as coagulants for direct filtration, reducing solids volumes in comparison to inorganic coagulants. However, polymers by themselves are ineffective at removing dissolved material (MWH, 2005; Levine et al., 2004).

Polymers may also be added after coagulation or flocculation, as flocculation or filter aids. In these applications, they are intended to produce larger, denser flocs that settle faster, or to strengthen the floc so that filtration can more effectively remove particulate and organic matter. These applications rely primarily on particle bridging, where a single polymer chain adsorbs on the surfaces of different particles. Bridging takes place with high molecular weight (i.e., long chain) polymers that are nonionic or have low charge densities (MWH, 2005; Levine et al., 2004).

3.4.2 Frequency of Polymer Use

Estimates of polymer use for drinking water treatment vary. EPA's 2006 Community Water System Survey (CWSS) indicated that polymer use among surface water systems ranged from a low of 16% among systems serving 100 or fewer people to a high of almost 57% among systems serving more than 100,000 people (USEPA, 2009a). Among ground water systems, polymer use did not exceed 3% for any size category (USEPA, 2009a). The American Water Works Association's WATER:\STATS database (cited in Levine, 2004) indicates higher use rates: 66% of surface water treatment plants surveyed used a polymer, predominantly cationic; 13% of ground water treatment plants used a polymer, with anionic polymers most often used. Polymer use among surface water systems is likely to affect more people given the more extensive filtration requirements for surface water systems and the predominance of surface water systems, which provide water to 71% of the U.S. population served by a community water system (EPA, 2016b).

EPA does not have data indicating what percent of the population served by public water systems might be exposed to either acrylamide or epichlorohydrin through drinking water. Based on higher usage frequencies among surface water systems – especially larger systems – that tend to use cationic polymers, polyamines such as epi-DMA are likely to dominate polymer use. The infrequent use of anionic polymers among ground water systems suggests potential acrylamide exposure frequency is low by comparison.

Because quantitation in water is analytically infeasible, EPA does not have estimates of the actual concentrations of residual monomers that people might be exposed to in drinking water. Populations that are potentially exposed to cationic polymers such as epi-DMA are already benefitting from the use of polymers with lower residual monomer levels. Therefore, revising the

allowable residual monomer level of epichlorohydrin to equal or nearly equal its detection level will have no benefits. Revising the allowable residual monomer level of acrylamide might result in health risk reductions if public water systems switch to products with lower residual monomer levels. The NSF 2013-2016 data indicate, however, that almost 90% of products have half the allowable acrylamide residual. Given this information on current manufacturing capabilities and the available information on polymer use patterns – surface water systems that tend to be more likely to use polymers also tend to use cationic polymers such as epi-DMA – EPA does not expect a reduction in the allowable acrylamide residual to substantially reduce the potential for exposure to acrylamide in drinking water.

4 Six Year Review Recommendation

EPA's review of recent NSF analyses of acrylamide and epichlorohydrin impurities in polymers indicates potential to revise the NPDWRs for these contaminants. Specifically, NSF data indicate that it is feasible to reduce the allowable monomer residual levels in water treatment polymers.

The NSF data also indicate that because monomer residuals are already less than EPA's treatment technique requirements, the health benefits associated with the lower impurity levels are already being realized by communities throughout the country. In particular, there will be no benefits associated with epi-DMA use because epichlorohydrin residual levels are already below the detection limit, which is one-fifth of the allowable residual under the NPDWR. The level for a revised acrylamide residual monomer limit is uncertain. Current production capabilities indicate that a technically feasible level could range from the detection limit to the level in the current NPDWR. Almost 90% of the sample results of the products tested had acrylamide concentrations equal to or less than 50% of the current NPDWR monomer limit. Given this information on current manufacturing capabilities and the available information on polymer use patterns – surface water systems that tend to be more likely to use polymers also tend to use cationic polymers such as epi-DMA – EPA does not expect a reduction in the allowable acrylamide residual to substantially reduce the potential for exposure to acrylamide in drinking water. Therefore, EPA concludes that a regulatory revision may not provide a meaningful opportunity to improve public health protection. Furthermore, given resource limitations, competing workload priorities, and administrative costs and burden to states to adopt any regulatory changes associated with the rulemaking, the revisions to these NPDWRs are considered a low priority and no longer candidates for revision at this time.

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